DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS, USING DELPHI TECHNIQUE: PRINCIPLES FOR GOOD PRACTICE

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การพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยในโรคเขตร้อนโดยใช้เทคนิคเดลฟายเพื่อเป็นหลักปฏิบัติที่ดี

นางสาวธริสรา สกุลแถว

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาสาธารณสุขศาสตรดุษฎีบัณฑิต
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ธริสรา สกุลแถว : การพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยในโรคเขตร้อนโดยใช้เทคนิคเดลฟายเพื่อเป็นหลักปฏิบัติที่ดี (DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS, USING DELPHI TECHNIQUE: PRINCIPLES FOR GOOD PRACTICE) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ. ดร. กาญจนา รังษีหิรัญรัตน์, 183 หน้า.

นโยบายของหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อถูกพัฒนาขึ้นเพื่อเป็นแนวทางมาตราฐานในคลังเนื้อเยื่อเพื่อการวิจัย การศึกษาแบ่งออกเป็นสองขั้นตอนที่สำคัญ วัตถุประสงค์แรกสำรวจทัศนคติและความเข้าใจของผู้เข้าร่วมศึกษาการวิจัยทางคลินิกที่เกี่ยวข้องกับไบโอแบงค์หรือคลังเนื้อเยื่อเพื่อการวิจัย โดยจะใช้ผลการศึกษานี้ในการพัฒนาเนื้อหาของหนังสือยินยอมเข้าร่วมการวิจัยทางคลินิกที่เกี่ยวข้องกับไบโอแบงค์ และพัฒนานโยบายเพื่อปรับปรุงคุณภาพและมาตรฐานสำหรับ หน่วยงานในเครือของหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด (MORU) กรุงเทพมหานคร ประเทศไทย โดยเครื่องมือใช้วัดหาทัศนคติ ความเข้าใจของอาสาสมัครในการวิจัยทางคลินิก และการหาฉันทามติข้อตกลงของผู้เชี่ยวชาญในการกำหนดนโยบายสำหรับหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยในอนาคต ขั้นตอนที่หนึ่งใช้วิธีการวิจัยเชิงคุณภาพดำเนินการวิจัยกับผู้เข้าร่วมการศึกษาวิจัยทางคลินิกที่โรงพยาบาลเวชศาสตร์เขตร้อนจำนวน 24 คน โดยอาสาสมัครได้รับแผ่นข้อมูลอธิบายเกี่ยวกับไบโอแบงค์ ดำเนินการสัมภาษณ์ในเชิงลึกพร้อมกับถามข้อมูลพื้นฐานในแบบสอบถามกับอาสาสมัครทีละราย วิเคราะห์ผลโดยใช้ซอฟแวร์ NVIVO เวอร์ชั่น 10 จากผลการศึกษาร้อยละห้าสิบสี่ของอาสาสมัครมีความเข้าใจเกี่ยวกับไบโอแบงค์มากขึ้นหลังจากที่ได้อ่านแผ่นข้อมูลอธิบายเกี่ยวกับไบโอแบงค์ โดยอาสาสมัครทั้งหมดมีความเต็มใจที่จะบริจาคตัวอย่างเลือดให้ไบโอแบงค์ ข้อสรุปในการศึกษาครั้งนี้แสดงให้เห็นว่านักวิจัยควรให้ทั้งข้อมูลที่เป็นลายลักษณ์อักษรและมีการพูดคุยกับอาสาสมัคร ให้เวลาสำหรับอาสาสมัครในการตัดสินใจเข้าโครงการคลังเนื้อเยื่อเพื่อการวิจัย และให้เวลาอาสาสมัครเพื่อทำการเข้าใจถึงวัตถุประสงค์ของการศึกษาไบโอแบงค์ ก่อนที่จะให้อาสาสมัครลงนามในใบยินยอมเข้าร่วมโครงการวิจัย

ขั้นตอนที่สองใช้เทคนิคเดลฟายดำเนินการวิจัย ผู้เข้าร่วมวิจัยครั้งนี้ เป็นบุคลากรที่มีความเชี่ยวชาญในด้านการวิจัยทางคลินิก มีตำแหน่งในการวางแผนนโยบายและทำงานอยู่ในเครือข่ายหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด จำนวน 30 ท่าน โดยใช้ซอฟแวร์ NVIVO เวอร์ชั่น 10 ในการวิเคราะห์ข้อมูลในรอบที่หนึ่ง สถิติเชิงพรรณนาถูกนำมาใช้ในการประเมินระดับของฉันทามติในรอบที่สอง โดยใช้ค่าเฉลี่ยร้อยละ (mean) และค่าเบี่ยงเบน interquartile (IQD) สำหรับรอบสามและรอบสี่ใช้ร้อยละของจำนวนการตอบมาใช้ในกระบวนการวิเคราะห์หาฉันทามติ จากผลการศึกษา ผู้วิจัยได้ร่างนโยบายของหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยในโรคเขตร้อน ไปพร้อมกับการออกแบบหนังสือแบบยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยและเอกสารชี้แจงผู้เข้าร่วมคลังเนื้อเยื่อเพื่อการวิจัย โดยเครื่องมือนี้จะช่วยลดภาระของเจ้าหน้าที่ที่รับผิดชอบในงานวิจัยทั่วไปและคลังเนื้อเยื่อเพื่อการวิจัย ในขณะเดียวกันเป็นการเพิ่มการป้องกันสิทธิของผู้เข้าร่วมการวิจัยทางคลินิก เพื่อเป็นหลักปฏิบัติที่ดีในเครือข่ายของหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด ในประเทศไทย

สาขาวิชา สาธารณสุขศาสตร์ ลายมือชื่อนิสิต .....

ปีการศึกษา 2558 ลายมือชื่อ อ.ที่ปรึกษาหลัก .....

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KEYWORDS: BIOBANKING, CLINICAL TRIAL PARTICIPANT

THARISARA SAKULTHAEW: DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS, USING DELPHI TECHNIQUE: PRINCIPLES FOR GOOD PRACTICE. ADVISOR: ASST. PROF. KANCHANA RUNGSIHIRUNRAT, Ph.D., 183 pp.

The policy of informed consent for biobanking were developed for a standardize guidelines in biobanking. This study is divided into two major phases, the first objective to explore the attitudes and understanding of clinical trial participants to biobanking, subsequently using these results to identify and develop a content of inform consent of biobanking as a policy to improve the quality and standardize for affiliates of Mahidol-Oxford Tropical Medicine Research Unit (MORU); Bangkok in Thailand. The instrument is oriented toward clinical participant attitude, understanding and agreement of experts to determine the policy for future study related to informed consent of biobanking. Phase one using qualitative research methodology, clinical trial participants (N=24) who were already enrolled to clinical research studies at the Hospital for Tropical Diseases were given an information sheet explaining biobanking. An in-depth interview was then conducted along with a demographic questionnaire. The results were analyzed using NVIVO 10 software. From the results, fifty four percent felt they had a clearer understanding of biobanking after reading the brochure. All the respondents were willing to donate a blood sample to a biobank. In conclusions, this study suggests that researchers should provide both written and oral information during enrollment for biobanking studies, giving time for participants to better understand the purpose of biobanking studies prior to signing a consent form.

Phase two, four round Policy Delphi techniques was conducted using participants who are expert in clinical trial, policy maker position and currently working in clinical research, based in network of Mahidol-Oxford Tropical Medicine Research Unit (N=30). The master policy narratives was derived through these consensus results. Thematic content analysis was used to analyze the data by using NVIVO 10 software in round one. Descriptive statistics were used to evaluate levels of agreement, including the mean, the percentage of agreement, and the interquartile deviation (IQD) in round two. The percentage of response rate were used in the analytical process in round three and round four. From the results, policy of informed consent for biobanking in Tropical disease research project were developed along with designing of consent form and patient information sheet for biobanking study. The tools will reduce the burden placed on research staff responsible for the generic projects and biobank, at the same time, maximize the protection of clinical trial participants and for principle for good practice in affiliates of MORU in Thailand.

Field of Study: Public Health Student's Signature .....

Academic Year: 2015 Advisor's Signature .....

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CHAPTER I: INTRODUCTION

1.1 BACKGROUND

A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others [1]. Since the late 1990s biobanks have become a key resource for the medical research community, supporting many types of contemporary research such as genomics and personalized medicine [2].

Biobanks give researchers access to samples and data derived from large numbers of individual people. Furthermore, samples in biobanks and the data derived from those samples can often be used by multiple researchers for multiple purposes. Some diseases are rare, so building up banks of sufficient patient numbers was previously difficult in one center. Others occur in developing settings where resources for biobanking are limited, so collections of samples are of enormous potential value such as genetic conditions associated with single-nucleotide polymorphisms, are best studied using genome-wide association studies and these modern research methodologies can only be supported by access to large, clinically well characterized sample sets. Large collections of samples representing tens or hundreds of thousands of individuals are necessary to conduct these kinds of studies and researchers struggled to acquire sufficient samples prior to the advent of biobanks [3].

However there are potential problems with biobanking. Many people have not heard of the concept of samples sharing and retention for use in different studies to that

which they have given their initial consent to. They may not understand what is involved, so consent for donating a sample to a biobank cannot be assumed but must be informed by explanation, especially in developing as opposed to developed countries [4]. Biobanks have invoked many questions of research and medical ethics. While viewpoints on what constitutes appropriate biobanking ethics diverge, consensus has been reached that relying on biobanks without carefully considered governance principles and policies could negatively impact communities participating in biobank programs [5].

Biobanking often raises concerns both from patients donating samples, regarding their use, the information which may result and confidentiality. In some cases they may have religious, cultural or personal objections to their samples being kept, or may have different views on retaining samples depending on their nature and potential use.

Importantly such attitudes vary according to country and culture and we have little information about the potential factors influencing patient understanding of biobanking in Thailand [6]. Gaining data on the attitudes which affect patients participation in research trials, and the level of their knowledge about biobanking is a key process [7] . Qualitative research is needed to understand patients attitudes and the factors which might influence their decision making process. This is important to allow preparation of information sheets and discussions with patients in gaining proper informed consent in the future [8].

The appropriate structure and content of a document for informed consent by patients participating in biobanking trials is not available in the Mahidol-Oxford Tropical Medicine network, because we used copies of informed consent documents for biobanking (sample sharing) from a different source. In this study the researcher will attempt to develop a policy of informed consent for biobanking for standard use in affiliates of MORU in Thailand.

1.2 RESEARCH GAP

1. From systematic literature review the defined and standardised informed consent process for biobanking is not available, and there are no studies associated with instrument development for informed consent process in Thailand. Therefore, research tools to determine informed consent policy in biobanking need to develop for improve the quality and standardization of content of informed consent documents for biobanking in affiliates of MORU in Thailand.

2. Lack of appropriate local ethic requirement in informed consent of biobanking.

3. The high percentage of rejection of protocols involving the use of biobanks may also result from a lack of guideline of appropriate procedures for gaining informed consent for biobanking.

1.3 RESEARCH OBJECTIVES

Phase I

1. To investigate the attitude of clinical trial participants in from different backgrounds, to gather data about their understanding of the concept of biobanking.

Phase II

1. To develop a policy of informed consent for biobanking studies for confidentiality and security of related data. The master policy narratives will be derived through these consensus results. The tools will reduce the burden placed on research staff responsible for the generic projects and, at the same time, maximize the protection of research participants.

2. To develop an approach that eventually leads to unified consent forms and procedures for different studies which involve biobanking.

3. To provide data which may be used in the future interventional studies (educational) to educate donors about biobanking and increase participation in biobanking studies, and ensure that consent for such studies are properly carried out.

4. To design a model of informed consent for biobanking that will facilitate future biobank-based research while appropriately balancing the conflicting interests and principles involved.

1.4 RESEARCH QUESTIONS

1.What are the attitudes and understanding of clinical trial participants (patients) in the Hospital for Tropical Diseases to biobanking?

2. What are the key questions to measure the opinion of experts for content of an Informed consent document for biobanking?

3. What is the consensus of experts to biobanking policy?

4. What is appropriate content of an informed consent document to standardize guidelines for biobanking studies in Thailand?

1.5 SCOPE OF THE STUDY

This study will be conducted in Hospital of Tropical Medicine, Bangkok, Thailand.

1.6 OPERATIONAL DEFINITIONS

Agreement	A decision or arrangement, often formal and written, between two or more groups or people [9].
Biobank	Tissue samples derived from human bodies are stored, distributed and used for therapeutic, educational, forensic and research purposes as part of routine healthcare in most western countries. Gradually such collections have become known under various names such as biobanks, bioresources, biolibraries, tissue repositories, genetic databases, or DNA banks [2].
Clinical Trial/Study	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

	For example, some demonstration and service programs may include research activities [10].
Compensation of expenses	Refers to travel expenses, costs and the distribution of the payments during the study period.
Disagreement	An argument or a situation in which people do not have the same opinion [9].
Discomfort	Refers to discomfort from blood puncture/ sample collection.
Family income	Refers to the total amount of monthly income earning of the whole household.
Human sample	Refers to blood sample.
Human subject	Refers to clinical trial participants. An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.[10].
Impartial Witness	Refers to a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject legally acceptable representative cannot read, and who

	reads the informed consent form and any other written information supplied to the subject.
Independent Ethics Committee (IEC)	Refers to an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Marital status	Refers to the legal status of each individual in relation to the marriage laws.
Occupation	Refers to the type of current job at the time of interview.
Religious	Refers to the religious respondent at the time of interview which are Buddhist, Islam, Christian, Hindu, Sikh and other.
Tropical disease	Refers to Malaria and Dengue Hemorrhagic fever.

Vulnerable Subjects	Refers to an individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

1.7 CONCEPTUAL FRAMEWORK

There were two important phases of framework including developing a policy of informed consent for biobanking and surveying the attitude and understanding of patients sharing their specimen for biobanking – linked system as shown in figure 1.

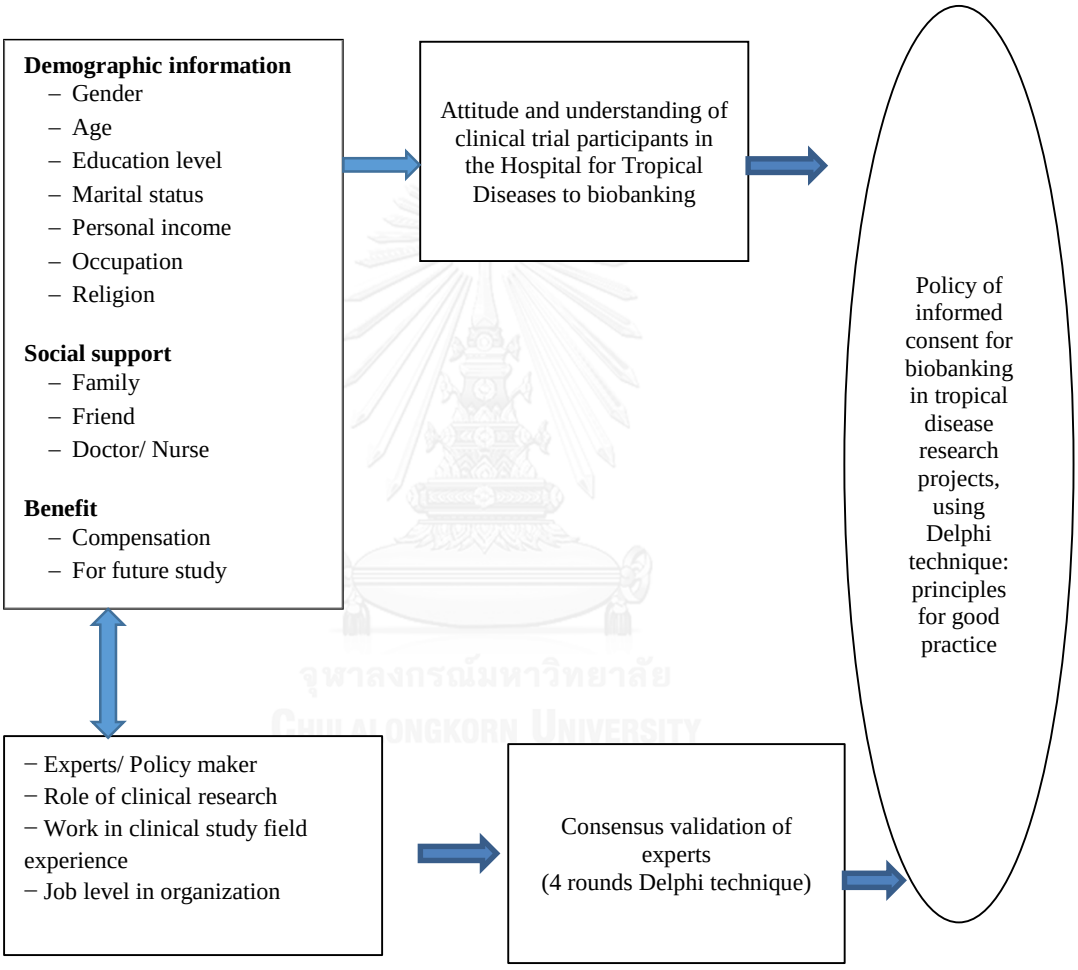


Figure 1 _ Conceptual framework

CHAPTER II: LITERATURE REVIEW

2.1 OVERVIEW:

Corresponding to objective of this study a literature and research review present in this chapter emphasizes five major parts. The related literatures are reviewed as follows:

1. Biobanking
2. Biological specimen
3. Informed consent
4. Delphi technique
5. Related study of informed consent/ policy of biobanking

2.2 BIOBANKING

Human tissue has been stored and used for research on a regular basis for more than 100 years. Tissue samples derived from human bodies are stored, distributed and used for therapeutic, educational, forensic and research purposes as part of routine healthcare in most western countries. Gradually such collections have become known under various names such as biobanks, bioresources, biolibraries, tissue repositories, genetic databases, or DNA banks. In tandem with increased scientific appreciation of their worth, during the 1990s such collections began being framed as ethical challenges. After having been associated with dull routine for almost a century, the interest in biobanks has exploded – triggering several hundred academic articles as well as a number of books and edited volumes [2]. Despite some media reports claiming that

this interest is a reaction to the disclosure of previously clandestine biobanking practices, those with practical experience of biobanking know that tissue storage in general was never secret. The academic debate and legislatory action tend to focus on informed consent, and most of the concerns that donors have remain unaddressed [11]. In recent years, there has been a growing interest in the development of biological samples and biobanks that make it easier for investigators to have access to quality samples and their associated clinical and epidemiological data. Thus, biobanks have become indispensible technological platforms for the development of both basic and clinical research [12].

Biobanks are developed in relation to a research question having its own strategy and specific demands on quality and annotation of the collected samples, resulting in a very heterogeneous concept in Biobanking. Even considering exclusively human sample-related banks for research, there are multiple designs according to the different possible goals. In a brief summary, human-driven biobanks include three mayor types; (A.) Population banks. Their primary goal is to obtain biomarkers of susceptibility and population identity, and their operational substrate is germinal-line DNA from a huge number of healthy donors, representative of a concrete country/region or ethnic cohort. (B.) Disease-oriented banks for epidemiology. Their activity is focused on biomarkers of exposure, using a huge number of samples, usually following a healthy exposed cohort/ case–control design, and studying germinal-line DNA or serum markers and a great amount of specifically designed and collected data. (C.) Disease-oriented general biobanks (i.e. tumour banks). Their goals correspond to biomarkers of disease through prospective and/or retrospective collections of tumor and

no-tumor samples and their derivate (DNA/RNA/proteins), usually associated to clinical data and sometimes associated to clinical trials. Those data are usually not collected for a concrete research project, except in case of clinical trials, but from the healthcare clinical records. The amount of clinical data linked to the sample determinate the availability and biological value of the sample [13].

There is unanimous agreement that for biomedical investigation to reach standards of excellence it needs samples and data of human origin. This research area's purpose is becoming more centered towards approving hypotheses through *in vitro* studies performed on human samples [1]. For instance, in Spain there are numerous regulations on biomedical research, although they mainly concern drug clinical trials. The publication of the Spanish royal decree which regulates the clinical trials for pharmaceutical products and medicinal preparations dates back to 1978 [14]. However, legislation on obtaining, storing and using human samples in research was comparably scant until 2007, when the Spanish Law 14/2007 on biomedical research (LBR) [15] came into force, which partly aimed to cover the previously indicated deficiency. The main regulations in force in Spain, concerning the use of human biological samples and associated data are: the Convention for the Protection of Human Rights and Dignity of the Human Beings with regard to the Application of Biology and Medicine [16].

Martin Arribas, M.C. and J. Arias Diaz [12] defined that the LBR considers an invasive procedure to be any intervention performed for research purposes that involves physical or psychological risk to the subject involved. It is based on the general principle that research must not cause the participant risk or discomfort disproportionate

to the expected potential benefits. Studies which entail invasive procedures on human beings require insurance against possible adverse effects or unforeseen damages that could occur during research, as well as meeting the requirements necessary for any given project. The subjects must be informed about why their samples are being taken and must give consent before they are taken and used, no matter the research purpose, whether it is anonymously stored or codified, or stored in a collection or a biobank. The informed consent process is described in a document consisting of a form and an information sheet. This document should at least include the information on the following:

1. The purpose and objectives of the research project;
2. The procedure and the possible disadvantages associated with giving samples;
3. Identity of the researcher and the person in charge of the collection or biobank;
4. The subject's right to express whether he/she consents to future use of his or her samples, whether he/she consents to other researchers having access to his or her samples and/or related data and, where applicable, access conditions;
5. Guarantee that confidentiality of information will be maintained;
6. The right to withdraw consent at any moment, and right to dispute, rectify, and Cancel his or her data in accordance with current legislation;
7. The right to decide if he/she wishes to receive information about the research results and, where applicable, when, how and by whom he/she shall be informed;
8. The expected benefits from participating in the research (for him/her, his/her family, if there are any, for science and the health system);
9. The measures taken to assure appropriate compensation if the subject were to suffer an adverse effect or unforeseen damage.

If the sample is to be included in a biobank or collection, the subject should also be informed of the following:

1. The biobank or institution where the sample shall be stored;
2. The collection or biobank's purpose and objectives;
3. That the biological material or the research results may generate profits, and that

the subject will not receive any financial compensation.

Before the LBR was approved, ethics was mainly evaluated by clinical research ethics committees. The LBR outlines that the research ethics committee should assess the ethics associated with all research involving human beings, biological samples or personal data. With regard to samples to be used in research, the research ethics committees must ensure that:

1. They have been consent to by the source subject.
2. When using samples collected before the LBR came into force, the best alternative for making the research possible must be sought without violating the source subjects' rights.
3. Using samples from diagnostic archives for research purposes must not compromise the source subjects' rights to health.
4. Appropriate measures must be established to ensure that related information and participant's privacy is maintained confidential.
5. Appropriate measures have been taken to insure possible unforeseen damages.
6. As far as is practical, the project shall be monitored by means of relevant progress

reports and a final report, and the incidences that could entail ethical repercussions during the study are to be assessed.

The UK Biobank aims to include 500,000 people from the UK who are aged 40–69 years. The project will involve baseline questionnaires and physical measures (eg, standard anthropometry and spirometry), and will store blood and urine samples. The strategy is to collect baseline data on a large general population sample, to obtain broad consent from participants for unspecified health research, and to follow up the participants through linked population-level UK medical and other health-related records so that nested case-control studies of a wide range of common adult diseases can be investigated. The UK Biobank is a big idea that, like all bold visions, will continue to attract plaudits and criticism. One of the key national benefits might simply prove to be the enablement of the physical and intellectual infrastructures that are being constructed by the project. This vision has taken much time and resources, together with energy and commitment on the part of the investigators and staff. As a result, the UK now stands at the threshold of an extraordinary cohort opportunity and a sentinel achievement—another step to the discovery and use of the genes and modifiable environmental factors underlying common diseases [17].

The Oxford Centre for Histopathology Research (OCHRe) is an integrated service-driven facility which enables access to equipment and methodologies for research, and importantly the expertise essential for the generation and interpretation of reliable and reproducible results. OCHRe is closely linked to the Oxford Radcliffe Biobank (ORB) which provides a simple and efficient way to collect and store samples according to

regulatory requirements, and ensures fair access to the samples. The ORB and OCHRe are supported by the Oxford Biomedical Research Centre which is a partnership between the Oxford University Hospitals NHS Trust and the University of Oxford [18]

2.3 BIOLOGICAL SPECIMENS

Human biospecimens are subject to a number of different collection, processing, and storage factors that can significantly alter their molecular composition and consistency. Biorepositories store various types of Biospecimen including “serum, urine, solid tissue, whole blood, or another product derived from a human being”. Different specimens are useful for different purposes [19].

Biobank specimens				
specimen	**uses**	**extraction technique**	**storage**	**characteristics**
cheek tissue	DNA profiling	buccal swab		participants can collect themselves; can be collected by mail; so easy to collect that informed consent may be insufficiently addressed
whole blood		venipuncture		requires phlebotomist to collect
Dried blood spot	gives high quality DNA and RNA	Fingerstick	stores easily for years at room temperature	
organ tissue	gives high quality DNA, RNA, Mitochondrial DNA, and source of disease	Biopsy		many uses shared with blood; also suitable for proteomic analysis; may be difficult to obtain
Plasma	limited DNA and RNA content	Blood plasma fractionation		requires phlebotomist to collect
Urine	marker for some diagnostic tests	Urination		non-invasive
Feces	marker for some diagnostic tests	Stool sample		non-invasive
Skin	Mostly used by forensic teams investigating criminal cases			in criminal cases, collected without consent of donor
Hair	Mostly used by forensic teams investigating criminal cases	Hair analysis		in criminal cases, collected without consent of donor

Figure 2_Biobank specimens [20]

In other countries such as the USA, Europe and Japan, similar laws have been enacted to regulate the use of biosamples and set up governance frameworks. For instance in the UK the Human Tissue Authority has the power to license biobanks and audit their performance. In contrast in Thailand there is a lack of a national biobank, no clear legislation to control the use of human samples, and very little data on the attitudes of Thai people to participation in research studies requiring biobanking. It is important to understand the factors influencing Thai patients willingness to give informed consent to research studies, because this may not be easily modeled using research methodology developed in Western populations [21]. In some less developed settings such as Africa [6] rather than approach a patient directly it may be preferable to discuss the ethical

implications of research studies with a community engagement panel before the studies are proposed in order to ‘disseminate’ understanding of their rationale in a community as a whole [8].

2.4 INFORMED CONSENT

The Council for International Organizations of Medical Sciences (CIOMS) stated that informed consent is a process for getting permission before conducting a healthcare intervention on a person [22]. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics. This term was first used in a 1957 medical malpractice case by Paul G. Gebhard [23] .

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. The investigator is responsible for ensuring the adequacy of informed consent from each subject. The person obtaining informed consent should be knowledgeable about the research and capable of answering questions from prospective subjects. Investigators in charge of the study must make themselves available to answer questions at the request of subjects. Any restrictions on the subject’s opportunity to ask questions and receive answers before or during the research undermines the validity of the informed consent.

Informed Consent takes a central position in clinical research. The right of any person to decide on his/her own, whether or not being enrolled in a clinical trial, is closely related to the degree of understanding the trial's key elements, the planned interventions and the related risks and benefits. Understanding the Informed Consent as a process, and not just as signing a simple permission note, is essential in conducting clinical trials in humans. Special attention has to be paid on vulnerable persons and populations, such as minors, illiterate, mentally impaired or unconscious subjects. The key elements of an informed consent are defined and each of those elements should be integrated in the informed consent form. The entire text, as well as the wording used in each paragraph, should state obviously and clearly, that the participation to this study is voluntary and that a rejection of the participation is without any consequences for the potential candidate [24, 25]

Tab. 3: Key elements of an informed consent	
1	Aims and scopes of the trial
2	Modality of the intervention(s)
3	Benefits: expected and possible already known
4	Risks: anticipated and already known
5	Discomfort
6	Any alternative and available treatments
7	Sharing any new information which turns up during the trial
8	Subject's responsibilities
9	Insurance to cover related injuries
10	Compensation of expenses (e.g. travel)
11	Contact details, 24 hours emergency
12	Right to withdraw at any time, without disclosing a reason
13	Circumstances for termination of participation
14	Duration of the trial
15	Number of participants
16	Confidentiality
17	Measures to be taken regarding pregnancies
18	Any conflicts of interest

Figure 3_Key elements of an informed consent

1. Consent to use for research purposes biological materials (including genetic material) from subjects in clinical trials. Consent forms for the research protocol should include a separate section for clinical-trial subjects who are requested to provide their consent for the use of their biological specimens for research. Separate consent may be appropriate in some cases (e.g., if investigators are requesting permission to conduct

basic research which is not a necessary part of the clinical trial), but not in others (e.g., the clinical trial requires the use of subjects' biological materials).

2. Consent use of medical records and biological specimens. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the

research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed. Patients have a right to know that their records or specimens may be used for research. Refusal or reluctance of individuals to agree to participate would not be evidence of impracticability sufficient to warrant waiving informed consent. Records and specimens of individuals who have specifically rejected such uses in the past may be used only in the case of public health emergencies.

3. Secondary use of research records or biological specimens. Investigators may want to use records or biological specimens that another investigator has used or collected for use, in another institution in the same or another country. This raises the issue of whether the records or specimens contain personal identifiers, or can be linked to such identifiers, and by whom. If informed consent or permission was required to authorize the original collection or use of such records or specimens for research purposes, secondary uses are generally constrained by the conditions specified in the

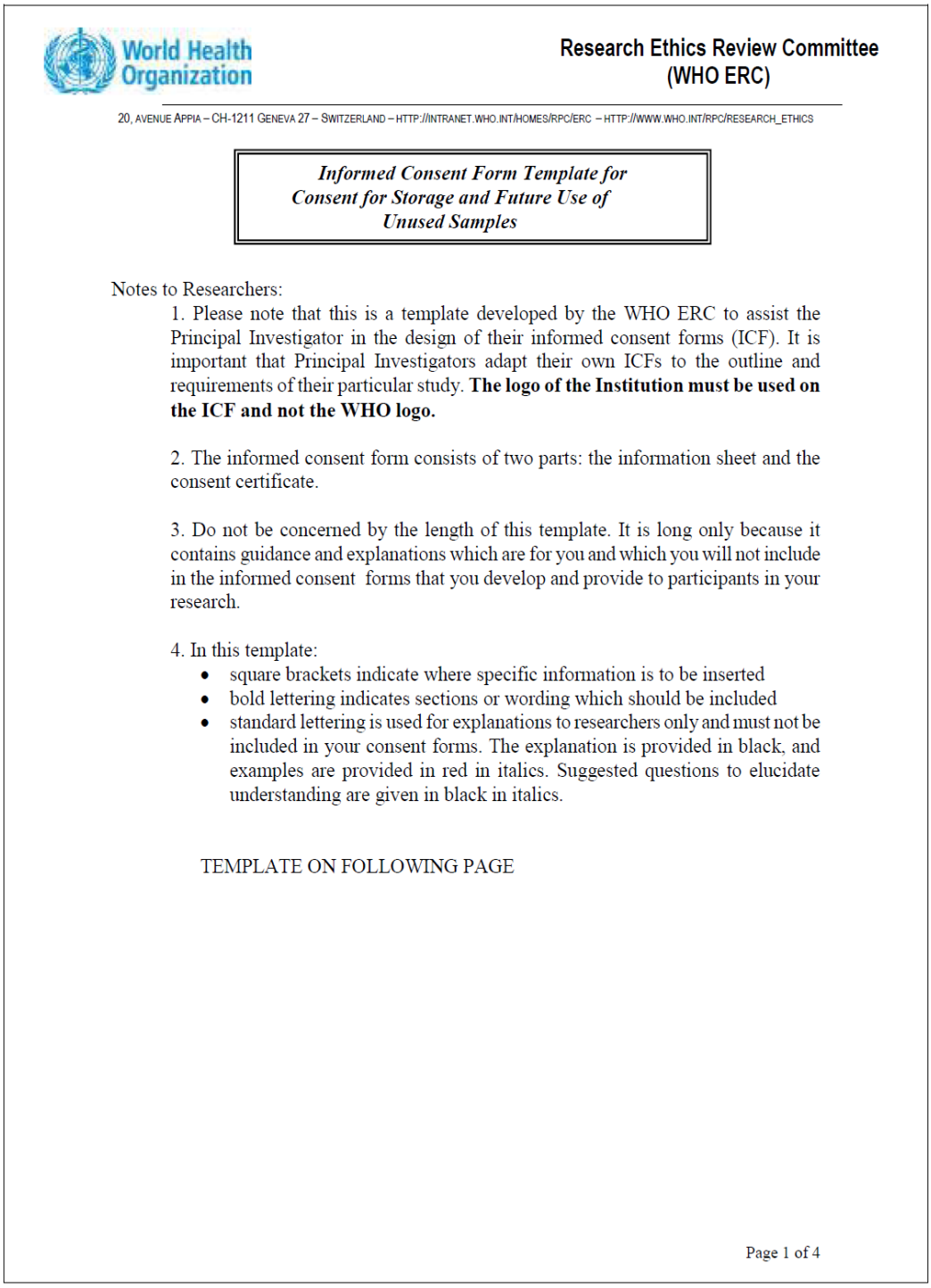
original consent. Consequently, it is essential that the original consent process anticipate, to the extent that this is feasible, any foreseeable plans for future use of the records or specimens for research. Thus, in the original process of seeking informed consent a member of the research team should discuss with, and, when indicated, request the permission of, prospective subjects as to:

i) Whether there will or could be any secondary use and, if so, whether such secondary use will be limited with regard to the type of study that may be performed on such materials;

ii) The conditions under which investigators will be required to contact the research subjects for additional authorization for secondary use;

iii) The investigators' plans, if any, to destroy or to strip of personal identifiers the records or specimens; and

iv) The rights of subjects to request destruction or anonymization of biological specimens or of records or parts of records that they might consider particularly sensitive, such as photographs, videotapes or audiotapes [22].



World Health Organization

Research Ethics Review Committee
(WHO ERC)

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – HTTP://INTRANET.WHO.INT/HOMES/RPC/ERC – HTTP://WWW.WHO.INT/RPC/RESEARCH_ETHICS

Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

Page 1 of 4

Figure 4.1_Informed Consent Form Template

for Consent for Storage and Future Use of Unused samples; page 1/4 [25]

Additional Consent to [Name of Project]

Include the following section if the research protocol calls for storage and future use of samples

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood/tissue/sperm/sputum sample because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw

Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current research study will not be affected in any way. Inform the participant that they may withdraw permission at anytime and provide them with the name, address, and number of the person and sponsoring institution to contact.

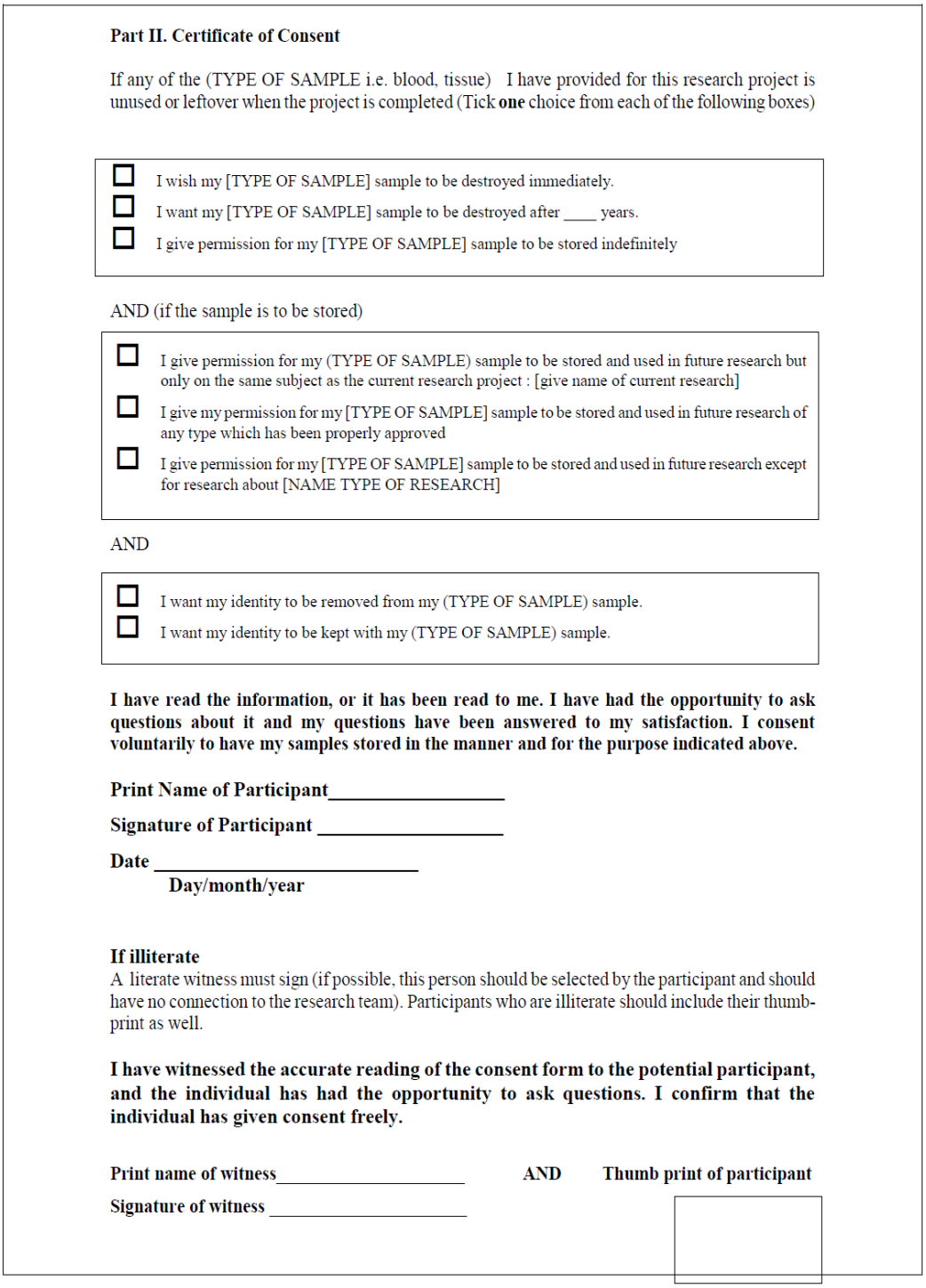
Confidentiality

Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

Figure 4.2_Informed Consent Form Template

for Consent for Storage and Future Use of Unused samples; page 2/4



Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

- ☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.
- ☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

- ☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]
- ☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved
- ☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

- ☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.
- ☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Figure 4.3_Informed Consent Form Template

for Consent for Storage and Future Use of Unused samples; page 3/4

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

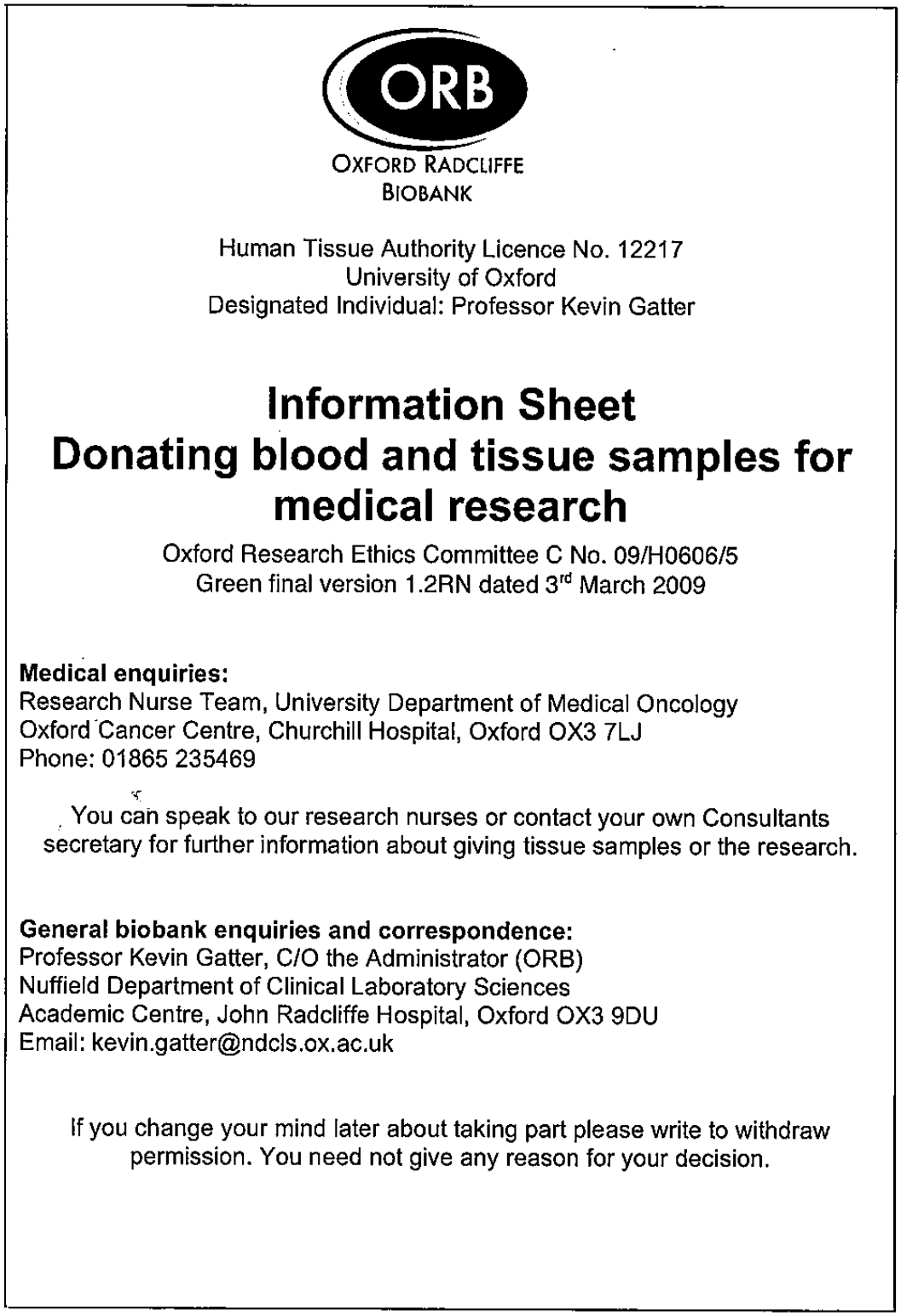
Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

Page 4 of 4

Figure 4.4_Informed Consent Form Template

for Consent for Storage and Future Use of Unused samples; page 4/4



OXFORD RADCLIFFE
BIOBANK

Human Tissue Authority Licence No. 12217
University of Oxford
Designated Individual: Professor Kevin Gatter

Information Sheet
Donating blood and tissue samples for medical research

Oxford Research Ethics Committee C No. 09/H0606/5
Green final version 1.2RN dated 3rd March 2009

Medical enquiries:
Research Nurse Team, University Department of Medical Oncology
Oxford Cancer Centre, Churchill Hospital, Oxford OX3 7LJ
Phone: 01865 235469

You can speak to our research nurses or contact your own Consultants secretary for further information about giving tissue samples or the research.

General biobank enquiries and correspondence:
Professor Kevin Gatter, C/O the Administrator (ORB)
Nuffield Department of Clinical Laboratory Sciences
Academic Centre, John Radcliffe Hospital, Oxford OX3 9DU
Email: kevin.gatter@ndcls.ox.ac.uk

If you change your mind later about taking part please write to withdraw permission. You need not give any reason for your decision.

Figure 5.1_Information sheet Donating blood and tissue samples for medical research

ORB Information Sheet

1. Invitation
We are inviting you to take part in a research study. We want to emphasise this is entirely voluntary. Your decision will not affect your care in any way. Before you decide, it is important to understand why the research is being done and what it would involve. Please take time to read the following information carefully. Thank you for reading this.

2. What is the research project about?
The Oxford Radcliffe Biobank collects blood and other tissue samples for use in medical research. Our work may help develop new and better ways to manage cancer and other diseases in future. An important part of our work is to look at both normal and abnormal (diseased) tissue samples from patients. We can use samples to study changes in proteins and other molecules in cells. We can test how cells grow in the laboratory. These are the best ways to look at the mechanisms which make cells grow and also what makes them sensitive or resistant to treatment. It can also help develop tests for early disease detection.

We also want to study genetic differences between patients' normal and abnormal cells. These genetic tests are different from the genetic screening offered to families at high risk of developing cancer. We want to look at how the body responds to injury or other stress. The results will be pooled to see if any genetic changes predict a particular outcome from the disease or treatment.

3. Why have I been chosen?
Your hospital consultant is interested in medical research and has agreed to invite their patients to take part.

4. What will it involve if I decide to take part?
We will ask you to donate a sample of blood and/or other tissues for research. These will be taken at the same time as your routine medical diagnostic tests or planned treatment. Donating samples should not involve any extra procedure, inconvenience, distress or pain. During your medical care we may ask permission to take further follow up samples. We may also ask the hospital to provide samples from any surplus tissue left over from any routine surgery, biopsy or diagnostic tests that you may have had or may need in the future. Your samples may be taken and used at once but it is more likely that they will be stored for many years.

Figure 5.2_Information sheet Donating blood
and tissue samples for medical research

Donating blood and tissue samples for medical research

It often takes 10 years or more to relate the findings from samples to how diseases behave. Many new techniques are likely to be developed and we would like to apply new methods as they are developed to your samples. We would also like to collaborate with other scientists worldwide. Our research programme has been reviewed and approved by an independent Research Ethics Committee. Your samples will only be used in ethically approved research.

If you decide to take part we will ask you to sign a consent form. If you decide not to take part it will not affect your care in any way. You can change your mind at any time. If you write to withdraw your permission we will destroy any unused samples.

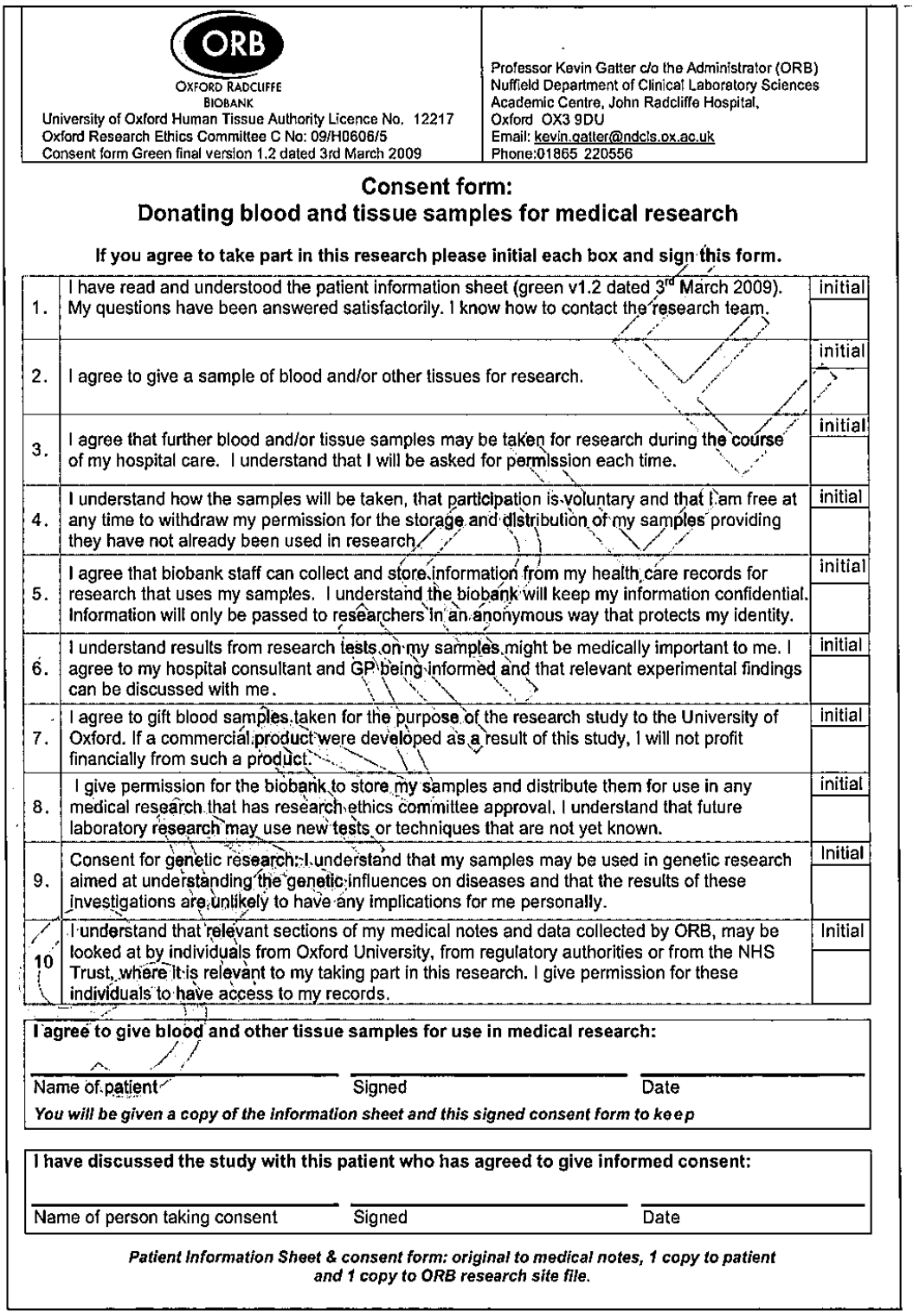
5. What are the advantages and disadvantages of taking part?
Your own medical care will not be affected. We do not routinely report individual results. This research involves testing large numbers of samples from many different people to try to identify factors that influence disease. Our findings may require further testing which may take many years. We may test your samples to see if promising new treatments or investigations might be suitable for you. We will give your hospital consultant and GP any results that might be useful to know. They will explain the information to you. Our research is not done for profit but may involve commercial companies. You will not benefit financially if your samples are used to help develop valuable new treatments or tests.

6. Will my taking part be confidential?
Yes. Biobank staff will need access to your medical records to take information needed for research. We may ask your medical care team for regular follow-up reports. This information will help us understand the meaning of our laboratory findings. We will hold the link or 'code break' between your medical data and research samples in strictest confidence. We will not give researchers information that could identify you. Individual patients are never identified when research results are published.

7. How can I obtain more information about this study?
Please ask any questions before deciding whether to take part. You can speak to the Consultant or specialist nurse responsible for your care. You can also contact us at the addresses on the cover.

Thank you for considering participation in this study.

Figure 5.3_Information sheet Donating blood
and tissue samples for medical research



ORB
OXFORD RADCLIFFE BIOBANK
University of Oxford Human Tissue Authority Licence No. 12217
Oxford Research Ethics Committee C No: 09/H0606/5
Consent form Green final version 1.2 dated 3rd March 2009

Professor Kevin Gatter c/o the Administrator (ORB)
Nuffield Department of Clinical Laboratory Sciences
Academic Centre, John Radcliffe Hospital,
Oxford OX3 9DU
Email: kevin.gatter@ndcls.ox.ac.uk
Phone:01865 220556

Consent form:
Donating blood and tissue samples for medical research

If you agree to take part in this research please initial each box and sign this form.

1.	I have read and understood the patient information sheet (green v1.2 dated 3rd March 2009). My questions have been answered satisfactorily. I know how to contact the research team.	initial
2.	I agree to give a sample of blood and/or other tissues for research.	initial
3.	I agree that further blood and/or tissue samples may be taken for research during the course of my hospital care. I understand that I will be asked for permission each time.	initial
4.	I understand how the samples will be taken, that participation is voluntary and that I am free at any time to withdraw my permission for the storage and distribution of my samples providing they have not already been used in research.	initial
5.	I agree that biobank staff can collect and store information from my health care records for research that uses my samples. I understand the biobank will keep my information confidential. Information will only be passed to researchers in an anonymous way that protects my identity.	initial
6.	I understand results from research tests on my samples might be medically important to me. I agree to my hospital consultant and GP being informed and that relevant experimental findings can be discussed with me.	initial
7.	I agree to gift blood samples taken for the purpose of the research study to the University of Oxford. If a commercial product were developed as a result of this study, I will not profit financially from such a product.	initial
8.	I give permission for the biobank to store my samples and distribute them for use in any medical research that has research ethics committee approval. I understand that future laboratory research may use new tests or techniques that are not yet known.	initial
9.	Consent for genetic research: I understand that my samples may be used in genetic research aimed at understanding the genetic influences on diseases and that the results of these investigations are unlikely to have any implications for me personally.	Initial
10	I understand that relevant sections of my medical notes and data collected by ORB, may be looked at by individuals from Oxford University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	Initial

I agree to give blood and other tissue samples for use in medical research:

Name of patient | Signed | Date

You will be given a copy of the information sheet and this signed consent form to keep

I have discussed the study with this patient who has agreed to give informed consent:

Name of person taking consent | Signed | Date

Patient Information Sheet & consent form: original to medical notes, 1 copy to patient and 1 copy to ORB research site file.

Figure 5.4_Information sheet Donating blood and tissue samples for medical research

2.5 DELPHI TECHNIQUE

The Delphi technique became known some 50 years ago when the RAND Corporation used it for forecasting. Since then, scholars and forecasters have used it periodically for qualitative explorations into complex issues or domains. The overall purpose of the Delphi is to facilitate formal discussion among selected experts in a given domain around a particular topic; it is particularly useful when those experts cannot easily gather in one place. The method encourages the sharing of diverging worldviews over a few "rounds" or iterations in the hope that the views may converge into some direction around the given topic. For this reason, the Delphi Method has often been used in situations or environments that tend to be somewhat ambiguous and where interviews and surveys are neither timely nor appropriate [26]. The purpose of the Delphi Method is to achieve a consensus among the experts on the subject being evaluated.

Delbecq, Van de Ven, and Gustafson state that three groups of people are well qualified to be subjects of a Delphi study [27].

(1) "The top management decision makers who will utilize the outcomes of the Delphi study"

(2) "The professional staff members together with their support team"

(3) "The respondents to the Delphi questionnaire whose judgments are being sought"

Classification of the Delphi technique [28] there are several types of Delphi;

- The Classic Delphi
- The Policy Delphi
- The Decision Delphi
- The Group Delphi

The Policy, Decision and Group Delphi are variations of the Classic Delphi.

Another author sub classifies Delphi as conventional, real-time and policy. The conventional Delphi is the classical forum for the prioritization of facts. It consists of a questionnaire sent out to a group of experts, with a second questionnaire based on the results of the first. Subsequent questionnaires refine and define the facts or proposals, gauging their accuracy or support from the participants. The real-time or modified Delphi is a shorter variant, where the process takes place during the course of a meeting, using mechanisms to summarize responses to the respondents immediately. The policy Delphi is a forum for ideas where the decision maker is interested in having informed group present options and supporting evidence rather than having a group reach a decision [29]

Types of Delphi designs.

Design type	Aim	Target panellists	Administration	Number of rounds	Round 1 design
Classical [13]	To elicit opinion and gain consensus	Experts selected based on aims of research	Traditionally postal	Employs three or more rounds	Open qualitative first round, to allow panellists to record responses
Modified [15]	Aim varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Varies, postal, online etc.	May employ fewer than 3 rounds	Panellists provided with pre-selected items, drawn from various sources, within which they are asked to consider their responses
Decision [14]	To structure decision-making and create the future in reality rather than predicting it	Decision makers, selected according to hierarchical position and level of expertise	Varies	Varies	Can adopt similar process to classical Delphi
Policy [4_ ,	To generate opposing views on policy and potential resolutions.	Policy makers selected to obtain divergent opinions	Can adopt a number of formats including bringing participants together in a group meeting	Varies	Can adopt similar process to classical Delphi
Real onsensus conference [44]	To elicit opinion and gain consensus	Experts selected based on aims of research	Use of computer technology that panellists use in the same room to achieve consensus in real time rather than post	Varies	Can adopt similar process to classical Delphi
e-Delphi	Aim can vary depending on the nature of the research	Expert selection can vary depending on the aim of the research	Administration of Delphi via email or online web survey	Varies	Can adopt similar process to classical Delphi
Technologica.	Aim varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Use of hand-held keypads allowing responses to be recorded and instant feedback provided		Can adopt similar process to classical Delphi
Online	Aim varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Implementation of the technique on any online instrument such as a chat room, or forum.	Varies	Can adopt similar process to classical Delphi
Argument [45]	To develop relevant arguments and expose underlying reasons for different opinions on a specific single issue	Panellists should represent the research issue from different perspectives	Varies	Varies	Can adopt similar process to modified Delphi i.e. first round involves expert interviews
Disaggregative policy [46]	Constructs future scenarios in which panellists are asked about their probable and the preferable future	Expert selection can vary depending on the aim of the research	Varies	Varies	Adoption of modified format using cluster analysis

Figure 6 _Type of Delphi design

Policy Delphi technique (method)

Building consensus is an essential component of any policy-making process. The hallmarks of the policy Delphi method are to bring together stakeholders with opposing views and to systematically attempt to facilitate consensus as well as to identify divergence of opinion [30]. As many health policy issues are complex, the policy Delphi method is an appropriate tool because it can address a multiplicity of issues and provide direction for policy changes [31]. Unfortunately, this method has not been widely used or reported in the literature [31, 32].

The policy Delphi method is a useful tool for systematically building consensus among decision makers, especially when policy alternatives are not well defined and the issues are complex. The policy Delphi method facilitates the development of consensus either for or against policy issues and should not be confused with lobbying. Although there are a variety of policy Delphi modalities (e.g., phone, written surveys) used to interact with participants, face-to-face interviewing may enhance the involvement of and participation by elected officials. The study described in the case example used a modified set of interview item categories due to the high degree of correlation between goal and option items found in an earlier pilot study with a similar population using a similar interview guide [33].

The goals of the policy Delphi method are to describe a variety of alternatives to a policy issue [30] and to provide a constructive forum in which consensus may occur. The policy Delphi method is a multistage process involving the initial measurement of opinions (first stage), followed by data analysis, design of a new questionnaire based on group response to the previous questions, and a second measurement of opinions [34]. Statistical group feedback—information about the

beliefs of other participants during the first-stage interview— is used in the second-stage interview to facilitate consensus on policy beliefs. Panels of experts or key stakeholders are participants in developing the content of the questionnaire and in responding to issue items. This process allows participants to reconsider their opinions in light of the views of other stakeholders and can be repeated until consensus is reached or saturation of opinion occurs.

The policy Delphi method's unique strength is that it incorporates education and consensus building into the multistage process of data collection, thus enabling description of agreement about specific policy options among key players in the policy decision process. Taking part in the Delphi process can be a highly motivating experience

for participants. Although most applications of the policy Delphi method rely on written questionnaires, some use in-person individual or group interviews, phone or e-mail interviews, or computer conferencing procedures [35]. In-person interviews greatly increase participation [34] and investment in the project. The use of face-to face interviewing is especially appropriate with participants who are in leadership positions because their time may be very limited.

Delphi Technique use in policy-making

From the 1970s, the use of the Delphi technique in public policy-making introduced a number of methodological innovations. The Delphi method has also been used as a tool to implement multi-stakeholder approaches for participative policy-making in developing countries. The Policy Delphi used the results of previous rounds

as feedback during subsequent rounds, in order to enable judgments to be reconsidered in the light of opinions collected in those rounds and thus identify areas of emerging consensus and potential differences of interests [36, 37]. As regards policymaking in the areas of science and technology, expert opinion is often taken into consideration to give new added knowledge on complex issues. Formerly, it was common to gather expert opinions in meetings or in-depth interviews. Nowadays, informa-tion-technology-assisted methods are more often used because they allow the sampling of opinions from fairly large numbers of experts, and they also avoid potential dominance by particularly persuasive individuals. The Delphi method is an example of this kind of a technique [38].

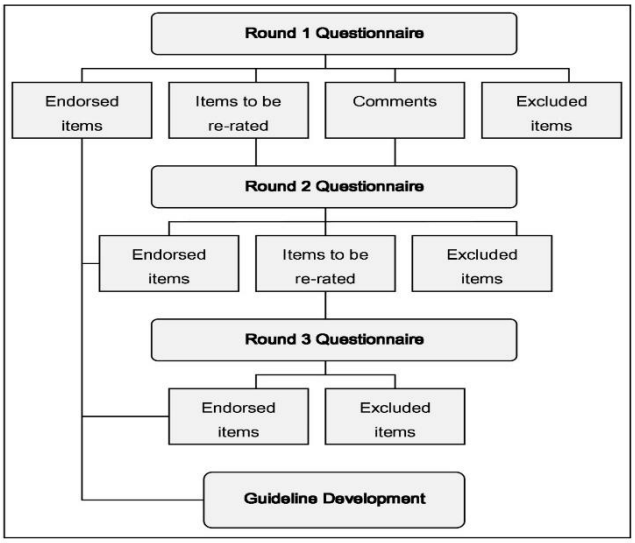


Figure 7 _The Delphi method [39]

Advantages of Delphi Technique:

– Subject anonymity, which can reduce the effects of the study is conducted in writing and does not require face-to-face meetings.

– Dominant individuals which often are concern when using group-based processes used to collect and synthesize information.

– The issue of confidentiality is facilitated by geographic dispersion of the subjects as well as the use of electronic communication such as e-mail to solicit and exchange information.

– Controlled feedback process consists of a well-organized summary of the prior iteration intentionally distributed to the subjects which allows each participant an opportunity to generate additional insights and more thoroughly clarify the information developed by previous iterations.

– Helps generate consensus or identify divergence of opinions among groups hostile to each other.

– Helps keep attention directly on the issue.

– Allows a number of experts to be called upon to provide a broad range of views, on which to base analysis.

– Allows sharing of information and reasoning among participants.

– Inexpensive.

Disadvantages of Delphi Technique:

– Information comes from a selected group of people and may not be representative.

– Tendency to eliminate extreme positions and force a middle-of-the-road consensus.

– More time-consuming than group process methods.

– Need skill in written communication.

– Potential of Low Response Rates: due to the multiple feedback processes inherent and integral to the concept and use of the Delphi process, potential exists for low response rates and striving to maintain robust feedback can be a challenge

– Consumption of Large Blocks of Time: the Delphi technique can also be time-consuming and laborious. Unlike other data collection techniques such as the telephone survey and the face-to-face administration, which can be simultaneously conducted by a group of people and can be completed in a short period of time if the sample size is small, the Delphi technique is iterative and sequential.

– Potential of Molding Opinions: the iteration characteristics of the Delphi technique can potentially enable investigators to mold opinions. An assumption concerning Delphi participants is that they are equivalent in knowledge and experience. However, this assumption might not be justified

– Centralize opinion: the Delphi is a consensus method, it tries to obtain consensus and to centralize opinion and important minority issues may be missed due to nonconformity of general opinion. Loss of objectivity and researcher bias in analyzing findings and generating questions are also possible

– Requires adequate time and participant commitment. [40, 41]

RELATED STUDY OF INFORMED CONSENT/ POLICY OF BIOBANKING

Title	Objective	Design	Method/ Tool	Results
A biobank management model applicable to biomedical research [42].	− To devise a practical and efficient model for the management of biobanks in biomedical research where a medical archivist plays the pivotal role as a data-protection officer.	Qualitative study	Review literature	– A means of protecting the information in biobanks, – The offer ways to provide follow-up information requested about the participants, – The protects the participant's confidentiality – An adequately deals with the ethical issues at stake in biobanking
Banking together. A unified model of informed consent for biobanking [43].	– To propose a model and procedure for drafting, unified consent forms for the storage and use of human biological material and related data for the purpose of research.	Qualitative study	Review literature	– The type of informed consent recommended by the analysis depended on the nature of the study to be carried out. – The remarkable variability in the regulatory requirements for existing informed consent procedures − The consent template was justified on the basis of respecting individual autonomy

Title	Objective	Design	Method/ Tool	Results
A proposal for a model of informed consent for the collection, storage and use of biological materials for research purposes [44].	− To suggest a model of informed consent for the collection, storage and use of biological materials in local biobanks for health research purposes.	Qualitative study	Review literature	Two main rules govern the proposed model of informed consent , as follows: the informed consent for the use of biological materials are – Give donors sufficient information to take informed decisions about possible present and future uses of their biological materials – Consider the specific biological and genetic aims of the research being performed.
Egg Donor Informed Consent Tool (EDICT): development and validation of a new informed consent tool for oocyte donors [45].	− To develop and validate a novel tool to assess the objective and subjective understanding that oocyte donors have of the	Analytic study	Prospective cohort study.	− The Subjective EDICT assesses donors' perceived understanding, and the Objective EDICT measures donors' actual knowledge. − The questions cover the process of oocyte donation, potential risks, and legal and psychologic issues. − The good content validity, a readability level consistent with readability goal of informed consent documents, and good reliability on pilot testing.

Title	Objective	Design	Method/ Tool	Results
Consent for childhood cancer tissue banking in the UK: The effect of the human Tissue Act 2004 [46].	− This review paper explores the effect of the Human Tissue act on consent, in the context of childhood tissue banking. We take as our case study the UK Children's Cancer Study Group tumour bank.	Qualitative study	Review literature	− Analysis suggests that although human-tissue collections are the subject of growing regulation, many legal uncertainties relating to issues of consent remain, especially where samples need to be obtained from children during the course of medical treatment.
Pediatric Biobanks: Approaching Informed Consent for Continuing Research After Children Grow Up [47].	− To examine adults' attitudes about continued research with their pediatric samples/data, particularly when they could not be located to provide consent.	Qualitative study	Telephone interviews were conducted with 1186 patients from 5 academic medical centers by using a hypothetical scenario.	− Most respondents, 799 (67%), would not be concerned about the use of their sample/data after they reached adulthood. Those respondents who were concerned were more likely to be more private about their medical records, less trusting of medical researchers, or African-American. − A total of 543 respondents (46%) believed their consent should be obtained to continue using their sample/data for research. Of these, 407 respondents (75%) would be at least moderately willing to give consent, when asked.

Title	Objective	Design	Method/ Tool	Results
				− 1,186 respondents, 310 (26%) would not want researchers to use their sample/data when they could not be located to ask for consent.
Determination of required content of the informed consent process for human participants in biomedical research conducted in the U.S.: A practical tool to assist clinical investigators [48].	− This article compares the two sets of U.S. regulations and two sets of well respected international guidelines with respect to their requirements for the content of the consent document and consent conference. − A practical decision tree is proposed as a tool to assist Investigators in determining which set(s) of requirements is applicable to a particular study.	Qualitative study	Review literature	− The authors recommend that the organizations that have routinely conduct clinical research studies and employ clinical investigators, such as Universities and hospitals, may informally or formally commit to following international guidelines. Presumably, this would be indicated in a policy handbook and, hopefully, reflected in any institutionally provided template consent form.

Title	Objective	Design	Method/ Tool	Results
Developing a policy for pediatric biobanks: principles for good practice [49].	− To describe principles for good practice related to the inclusion of minors in biobank research, focusing on issues related to benefits and subsidiarity, consent, proportionality and return of results. − To providing principles for good practice for policy makers of biobanks, researchers and anyone involved in dealing with stored tissue samples from children.	Qualitative study	Review literature	− Aggregate results of a study can be sent to participants or published on a website. − The research may generate health information about specific participants. Such information may be the direct result of the research or may be generated as an incidental finding.

CHAPTER III: METHODOLOGY

The study is divided into two major phases, the first objective to explore the attitudes of clinical trial participants to biobanking, subsequently using these results to identify and develop a content of inform consent of biobanking as a policy to improve the quality and standardize for affiliates of Mahidol-Oxford Tropical Medicine Research Unit (MORU); Bangkok in Thailand. The instrument is oriented toward clinical participant understanding and agreement of experts to determine the policy for future study related to informed consent of biobanking.

3.1 RESEARCH DESIGN

The study utilizes qualitative study by using structure in-depth interview in phase I and applying four rounds of Policy Delphi technique for policy development in phase II.

3.2 STUDY TECHNIQUE

Study techniques will describe in each study phase.

PHASE I: ASSESSING THE ATTITUDES AND UNDERSTANDING OF CLINICAL TRIAL PARTICIPANTS IN THAILAND TO BIOBANKING

Biobanking is very new in Thailand and few research projects utilize sample sharing. This phase addresses one specific research question; what are the attitudes and understanding of clinical trial participants in the Hospital for Tropical Disease to biobanking? To measure attitudes toward biobanking, demographic questionnaire and

in-depth interview approach will be used as the key method to gather information for a study.

The data derived from phase one used demographic questionnaire and in-depth interview with clinical trial participants in research studies who have donated a sample (in this study a blood sample) for a specific research study involving the disease / condition they are suffering from or healthy volunteer. The aim is to gather information about attitudes which may affect their decision making in participating in such studies, their understanding of the concept of biobanking for subsequent research studies and to understand the factors which may influence their decision as to whether or not to give permission for their sample/data to be stored in a biobank. Permission will be sought from principal investigators of different studies being conducted at the Hospital Tropical Medicine, Mahidol University to approach the participants in a range of different studies.

Study Process

Prior to the conduct of the study, the researcher was contacted the dean of Hospital of Tropical Disease, principal investigators, the co-investigators and the research nurses to introduce the study. For advertising process in phase one, the researcher was announcement and provided an advertising brochure (A4 size) of the study to clinical trial participants during participate clinical study at B.E ward.

Following agreement to participate in this study, an information sheet and informed consent was given and obtained to the participant who was allowed at least 30 minutes to read this. Following this a demographic questionnaire (to gather personal

information) was filled in, and an in-depth interview was conducted by a qualified researcher (duration typically 40-45 minutes). The interview was conducted in Thai and digitally recorded and transcribed and responses translated into English. The Interview format included a brief introduction of the content and aims of this study to the participant, initial feedback on the information brochure given to enable clarification of any points which they did not understand, and then a series of specific set questions designed to explore their attitudes and understanding of biobanking research and their views on different scenarios involving the potential use of biobanked samples. The consequently result were developed as the tool and use for phase two.

Study population

The sample population for this phase (n=24) were recruited using purposive sampling for study with specific type of knowledge or skill [50], from the population of all clinical study participants enrolled to research studies at the Hospital for Tropical Diseases between October – November 2014. This included patients between 20-60 years old, involved in clinical trials for diseases including malaria and dengue hemorrhagic fever, who were able to write, read and speak the Thai language. They were participating in a clinical research trial which specifically involved collection and storage of a blood sample at enrollment visit, and subsequent follow up visits. Individual patients were invited to participate and recruited according to eligibility criteria having given written consent. The aim was to get a range of patients with different points of view, which required a range of demographics such as age, gender, marital status, religion, education, occupation and income level.

Study area

Hospital for Tropical Diseases, Mahidol University, Bangkok, Thailand.

Sample technique

This qualitative study used purposive (criterion-based) sampling, that is, a sample that has the characteristics relevant to the research question criteria typically define the process as,

1. Qualitative studies often use purposeful or criterion-based sampling, that is, a sample that has the characteristics relevant to the research question [51].

2. Sampling continues until the researcher recognizes no new data were forth coming – a point of data or information redundancy [52].

3. Warren, C.A.B (2002) and Bryman, A. (2012) suggested that the minimum requirements for sample size in qualitative study, the number of interviews needs to be between twenty and thirty [53, 54].

However 24 participants was enrolled to this phase.

Eligibility criteria for study group

Inclusion criteria

- Thai nationality.
- Age 20– 60 years old.
- Able to read, write and speak Thai language.
- Ever participated in clinical research at the Hospital for Tropical Diseases by coming for enrollment visit follow up visits.

- Ever participated in previous clinical research study at the Hospital for Tropical Diseases involving collection of a blood sample.
- Willing to provide written informed consent.
- Able to spend 40 minutes to complete the demographic questionnaire and for in-depth interview.

Exclusion criteria

- Migrant.
- Reject written inform consent process.
- Withdrawn from the study for any reason.
- Incomplete participation the program and incomplete answer on the questionnaire.

Measurement tools

1. Demographic Questionnaire (see Appendix A) was administered to the respondents by apply survey technique.

2. In–depth interview in Thai version (see Appendix C) was administered and used

to interview the clinical trial participants.

Data collection

1. Obtained written informed consent from all study participants prior to the screening process.

2. All consented patients was received 150 THB compensation, regardless of whether they are later withdrawn from the study.

3. Eligible criteria will be access to all participant who welling to participate the study.

4. The participant information sheet was provided to all participants.

5. Demographic questionnaires was administered to participant.

6. The researcher conducted an in-depth interview as follow the manuscript.

7. Tape record the entire interview, and then transcribe the text word for word. The transcribed text then becomes the data that were analyzed.

8. Tape record the interview and note taking at the same time. Later review the tape and notes, occasionally writing down direct quotes that are deemed especially relevant.

9. Tape record and note taking will be destroyed 2 years after study finished.

10. Summary results of individual patient responses was sent to the patient by post to inform them of the results.

Data analysis

Qualitative data:

Computer-assisted qualitative data analysis used NVIVO version 10 software (QSR International; Australia) for data coding, management, and analysis.

Quantitative data:

The completed demographic questionnaires was coded and entered for analysis by the SPSS software version 17 (IBM, Thailand, licensed version at Chulalongkorn University).

Research Instrument

Content validity:

The questionnaire was evaluated prior to use using the index of item objective congruence (IOC) test on 5 trial responses. This process allows experts to rate individual questions on the degree to which they do or do not measure specific objectives listed by the test developer [55]. Thereafter, 5 professional experts reviewed and examined each item of questionnaires for consistency, accuracy and content. The expert judgment used to calculate by index of item objective congruence (IOC) by giving the item a rating of "-1" indicated that the statement clearly did not measuring, "0" indicated that the statement did not clear measure of that category and "1" indicated that the statement clearly measured that category [56]. The IOC score of more than 0.5 was considered to indicate good content validity. The final measure of IOC for the Demographic questionnaire was 1.0 and Interview questionnaire was 0.66.

Formula

$$\text{IOC} = \frac{\sum_{i=1}^{N} R_i}{N}$$

PHASE II. DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS, USING DELPHI TECHNIQUE: PRINCIPLES FOR GOOD PRACTICE

The subsequent follow up study used the results from phase one to develop a first round questionnaire (using a Policy based Delphi format) for phase two, to capture

the necessary data from research investigators and aid policy development. Four round Policy Delphi techniques was conducted using participants who are expert in clinical trial, policy maker position and currently working in clinical research, based in network of Mahidol-Oxford Tropical Medicine Research Unit. The master policy narratives was derived through these consensus results. The tools will reduce the burden placed on research staff responsible for the generic projects and, at the same time, maximize the protection of clinical trial participants.

Study process

1. Instrument development and content validity using data from phase one

    1.1 Developing a tools of inform consent for biobanking for tropical disease

    1.2 Designing architecture and specification of informed consent.

    1.3 Use information on attitudes derives from Phase one to design and write an information sheet explaining biobanking and addressing concerns.

    1.4 Small scale study based in MORU, involving request for biobanking/ storage of a sample.

    1.5 The participant information sheet provided to all participants.

    1.6 30 experts was invited through a member of assurance team to quantify the agreement among the experts professional area.

Measurement tool

These could be sorted into two parts according to content:

1. Demographic Information (See Appendix K).

2. Developing the questionnaire for the Policy Delphi technique by using the results from phase one.

Step I: Instrument development

Round I: An open-ended questionnaire was used to collect opinions from the experts. which was then used to determine different issues in order to develop the contents of the questionnaire for the next round [57]. An email was circulated among experts, inviting them to participate and respond to the questionnaire, in the privacy of the individual's own time and work space (laptop or desktop computer) to avoid bias or coercion. All responses of the expert panel were anonymized prior to collation.

Round II: A questionnaire was developed using the data collected from the first round. Duplicate data was removed. The new questionnaire was then used with the same experts. A 5-point Likert scale was used to identify the areas of disagreement and agreement. In this round, consensus began to form and the actual outcomes can be presented among the experts [41].

Round III: The Policy Delphi method does not aim to reach consensus but it rather explores the various opinions with a view informing process [58]. The experts were asked to evaluate the opinions of the Informed Consent Formed (ICF) and Patient Information Sheet (PIS). The experts received an online questionnaire that included the items and ratings summarized by the researcher in the previous round, and they was asked for their judgments.

Round IV: This is the final round. Generally, when using the Delphi technique the differences of opinion of participants in rounds three and four are minimal [41]. The experts received an online questionnaire again in this round and they were asked for reconsider their judgments. If the data collected in this round is consistent then the process ends and the data can be summarized.

Step II: Implementation

1. Experts including Principal Investigators, Co-Investigator, Project manager/ Study coordinator, Lab technician, Study nurse who achieve the eligibility criteria was invited to participate this study.

2. The first round of questionnaire was distributed to participants. The open-ended questionnaire was used to collect opinions from the participants which used to determine different issues in order to develop the contents of questionnaire for the second round.

3. Revised the questionnaires for the second round. After modification the second rounds questionnaires was distributed to same participant again by ask their rate strongly agreement, agreement, neutral, disagree and strongly disagreement on a Likert scale and they can comment on their responses on each question and ask for return by 10 day.

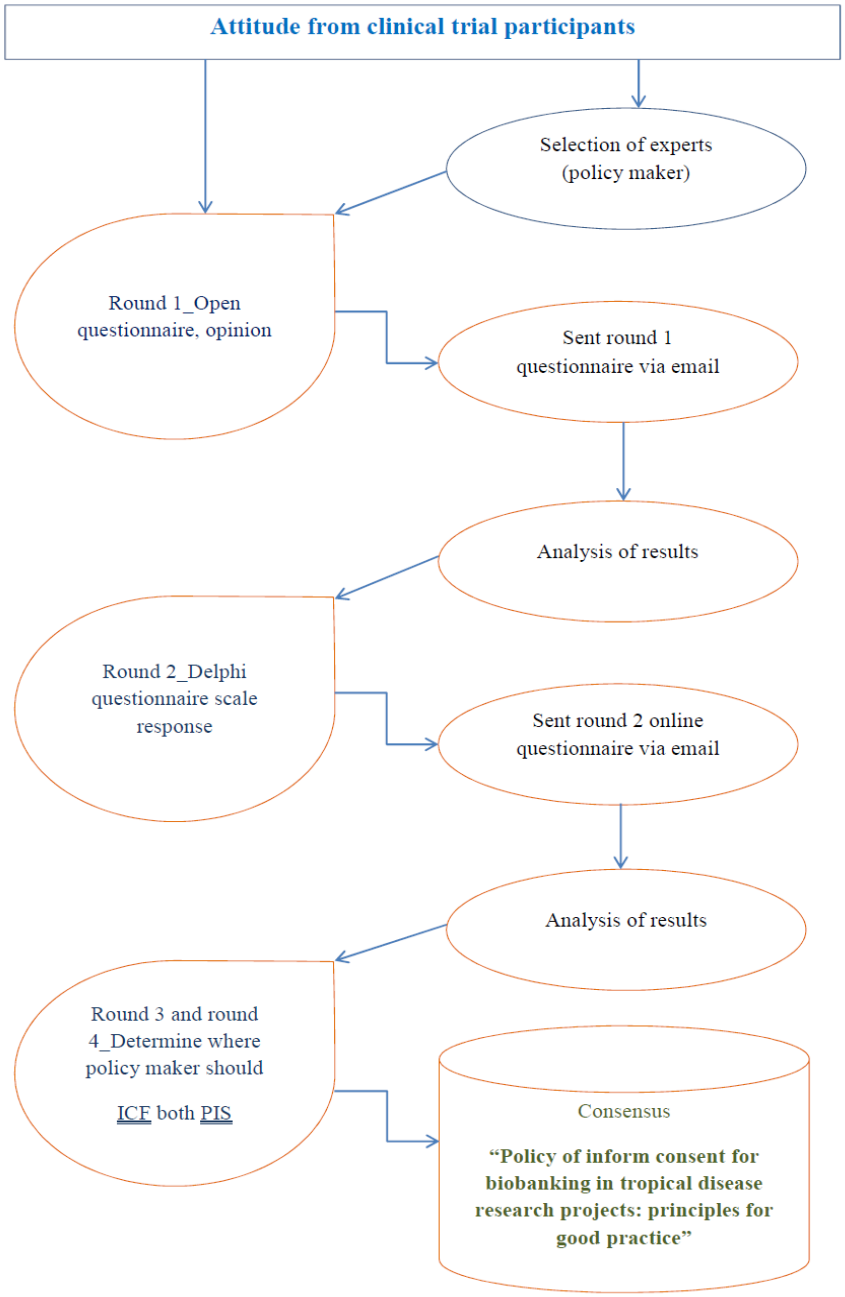
4. The second round of Delphi process was achieved the agreement and sent the questionnaires for develop ICF and PIS for the third round.

5. Summarized the results from round two and revised the questionnaire for round three. The third round questionnaires was distributed to participants. The result of this

round was used to design and develop a template and policy of ICF and PIS for biobanking.

6. This is a final round; round four online questionnaire was revised from round three and sent to experts via email. The consequent result of this round was used to develop a policy and template of ‘informed consent form’ and ‘patient information sheet’ for biobanking in tropical disease affiliate Mahidol-Oxford Tropical Medicine Research unit.

Figure 8_Study implementation



Study population

The population in this study will be the affiliate MORU staff, who base in Mahidol-Oxford Tropical Medicine Research Unit, Shoklo Malaria Research Unit and Lab Melioidosis Mahidol-Oxford Tropical Medicine Research Unit; Sappasitthiprasong hospital. The experience of expert was selected to increase the content validity of the questionnaire [59, 60]. The experts included Principal Investigators, Co-Investigator, Project manager/ Study coordinator, Lab technician, Study nurse who achieve the inclusion criteria. The experts are working in the field of clinical research in order to obtain the most reliable consensus. Members of the panel are chosen if they were willing to participate. The sampling method was purposive and convenient as the participants were chosen for their expert knowledge and availability in the Thailand.

Study area

This study was conducted 3 sites of affiliate MORU as the following;

1. Mahidol-Oxford Tropical Medicine Research Unit; Mahidol University, Bangkok, Thailand.
2. Shoklo Malaria Research Unit (SMRU), Tak, Thailand.
3. Lab Melioidosis Mahidol-Oxford Tropical Medicine Research Unit; Sappasitthiprasong hospital, Ubon Ratchathani, Thailand.

Sample technique

The study participant were purposively selected phase II, the experts was recruitment according to eligibility criteria. Delbecq, Van de Ven, and Gustafson (1975) suggest that ten to fifteen subjects could be sufficient if the background of the Delphi subjects is homogeneous. In contrast, if various reference groups are involved in a Delphi study, more subjects are anticipated to be needed. Witkin (1984) and Altschuld (1991) note that the approximate size of a Delphi panel is generally under 50, but more have been employed. Ludwig (1997) documents that, "the majority of Delphi studies have used between 15 and 20 respondents". In sum, the size of Delphi subjects is variable. If the sample size of a Delphi study is too small, these subjects may not be considered as having provided a representative pooling of judgments regarding the target issue. If the sample size is too large, the drawbacks inherent within the Delphi technique such as potentially low response rates and the obligation of large blocks of time by the respondents and the researcher(s) can be the result [41, 61, 62]. Therefore for this study 30 experts was selected to participate in adapting of policy of biobanking.

Eligibility criteria for study group

Inclusion criteria

- Male or Female member of MORU staff.
- Principal Investigators, Co-Investigator, Project manager/ Study coordinator, Lab technician, Study nurse.
- Has previous clinical research experience of at least 2 years duration.

– Has knowledge of clinical research and relevant regulatory requirements and ICH-GCP guidelines.

– Willing to provide written informed consent.

– Willing to spend time for complete the questionnaire for 4 rounds.

Exclusion criteria

– Reject written inform consent process.

– Withdraw from the study for any reason.

– Incomplete participation in the program or incomplete answers on the questionnaire.

Data collection

1. Eligibility criteria was accessed to all experts who are willing to participate in the study.
2. A participant information sheet was provided to all participants.
3. Obtain inform consent form to study participants prior to the screening process.
4. Questionnaires was sent to respondents via email.

Data analysis

In the Delphi process, data analysis necessitates decision rules being established, to assemble and organize the judgments and insights provided by participants. However, the criteria used to define and determine consensus in a Delphi study are subject to interpretation. One criterion recommends that consensus is achieved by having ‘80 percent of participants’ votes within a prescribed range. The major statistics used in Delphi studies are measures of central tendency (mean, median,

and mode), and level of dispersion (standard deviation, interquartile deviation) in order to present information concerning the collective judgments of respondents. If quantitative scales are required, analysis of Delphi studies usually strongly favors the use of a median score, based on a Likert-type scale, rather than using the mean to measure the participants' responses. This is because the mean most clearly reflects the most popular response, which may be used in subsequent iterations to move towards a consensus response. [41, 59, 61-63]

Step1. Determine importance of scale point on Likert scale

The definition of scale point will determine to 5 scales;

"1 = Strongly agree",

"2 = Agree",

"3 = Neutral",

"4 = Disagree",

"5 = Strongly disagree",

Step 2. Content Validity Index (I-CVI)

I-CVI using ratings of item relevance by content experts, whose value can be computed for each item on a scale. Content validity index (CVI) is the most widely used index in quantitative evaluation. For each item, the I-CVI is computed as the number of experts giving a rating of either 3 or 4 (thus dichotomizing the ordinal scale into relevant and not relevant), divided by the total number of experts. Researchers recommend that a scale with excellent content validity should be composed of I-CVIs

of 0.78 or higher [64]. Lynn (1986) advised a minimum of three experts, but indicated that more than 10 was probably unnecessary advocated using a 4-point scale : 1=not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant [65].

Formula: I-CVI =N_0/N

N_0 = The number of experts giving a rating

N = Number of expert

However, I-CVI =0.83

Step 3. Interpretation of results

The method of determining whether consensus has been reached and modify by reviewing a study that used the Delphi method. The study uses the Delphi method to determine whether a consensus has been reached. In order to measure the experts' consensus score descriptive statistics (percentages and means) were used.

Round I: Thematic content analysis was used to analyze the data. There are several computer-assisted qualitative data analysis software (CAQDAS) packages available that can be used to manage and help in the analysis of qualitative data. Common programs include ATLAS, ti and NVIVO [66]. For this round, the NVIVO software was used. All statements were coded individually, and consensus was reached on the emerging key themes. This coding and identification of themes was used to identify patterns of priorities and to help structure the subsequent development of a research agenda. These themes and their most frequently occurring examples were then used to construct the subsequent questionnaires for rounds two and three [67].

Round II: Descriptive statistics were used to evaluate levels of agreement, including the mean, the percentage of agreement, and the interquartile deviation (IQD). Consensus was established in round two if the mean rating was 3.5, the level of consensus by percentage of agreement among experts who agree or strongly agree was equal to or more than 70%, and IQD was equal to or less than 1.00. Items with an IQD equal to or lower than 1.00 are indicators of consensus [33]. Consensus percentages were calculated for each statement according to the percentage of ratings on either side of the Likert scale with using the following thresholds for level of consensus [58]

1. High consensus = 70% of ratings in one category or 80% in two contiguous categories.
2. Medium consensus = 60% of ratings in one category or 70% in two contiguous categories.
3. Low consensus =50% of ratings in one category or 60% in two contiguous categories.
4. None 60% in two contiguous categories.

Formula

Interquartile deviation (IQD) = Q3 - Q1/ 2

Round III and round IV: The percentage of response rate were used in the analytical process to ensure maximum validity of the results with the Delphi method for improved evidence of consensual decision-making [68]. As the panel had reached the preset levels for consensus, there was no need for another round of the Delphi. The high levels of initial consensus are a positive outcome reflecting appropriate stability in the participants' viewpoints, overcoming a problem inherent in other Delphi projects [69].

Step 4. Feedback loop

The survey feedback from each round records the participants' opinions on the policy. The author was draw a relevant information from each round of feedback to amend the policy, and then submit it to the group again. The cycle repeat until consensus is achieved.

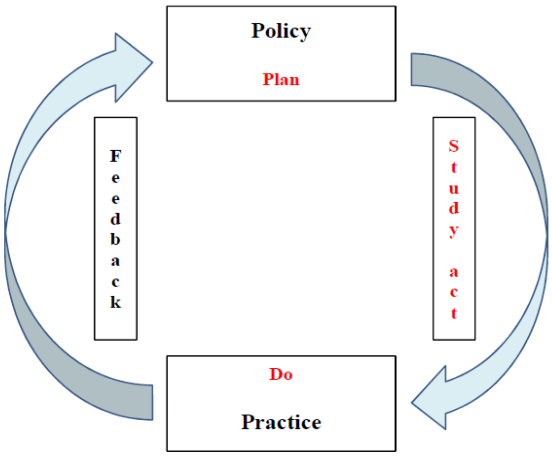


Figure 9_ Feedback loop flow chart

Research instrument

Reliability

A number of authors claim that the Delphi approach enhances reliability. This belief is based on two principles, firstly, the claim that the interactive nature of the approach, combined with the avoidance of group bias and the occurrence of group think scenarios, enhances the reliability of the results. Secondly, as the panel size increases, the reliability of the respondent group also grows, based on sampling a larger group, that will reflect the opinion of the population, providing a tighter confidence interval [70-76].

RESEARCH DURATION

The duration of the study is 7 months starting from 15th October 2014 – 15th January 2015 for phase one, and 16th January 2015 – 15th May 2015 for phase two.

ETHIC CONSIDERATION

Ethical permission to perform this study will be applied for from the Central Ethics Committee (equivalent to an Institutional Review Board or IRB) at the Chulalongkorn university, Faculty of Tropical Medicine (FTM); Mahidol University and OxTREC; Oxford University. The sample questionnaire will checked and verified for content, reliability and validity by my supervisor and members of the Ethics Committee/ IRB.

RIGHTS OF THE RESPONDENTS AND CONFIDENTIALITY

The subjects can withdrawal from study anytime. All personal data will be kept confidential and stored documents kept secure.

GRANT

This study is funded by Mahidol-Oxford Tropical Medicine Research Unit of Bangkok, Thailand.

Refining and readiness test of the system.

Before conducting a large scale study, the author seek a comment and adjustment from experts.

Staffing for implementation

To complete in-depth interview and correct questionnaires for participant, this study required a qualified staff member to interview participants.

CHAPTER IV: RESULTS

The results are presented for 2 phases by the steps of the research study. The first phase was investigated the attitude of clinical research participants (patients) in from different backgrounds and gather data about their understanding of the concept of biobanking. The second phase, the first focused on developed a policy of informed consent for biobanking studies for confidentiality and security of related data, the second was developed an approach that eventually leads to unified consent forms and procedures for different studies which involve biobanking, the third was provide data which may be used in the future interventional studies (educational) to educate donors about biobanking and increase participation in biobanking studies, and ensure that consent for such studies are properly carried out and the fourth was design a model of informed consent for biobanking that will facilitate future biobank-based research while appropriately balancing the conflicting interests and principles involved.

RESULTS PHASE I:

ASSESSING THE ATTITUDES AND UNDERSTANDING OF CLINICAL TRIAL PARTICIPANTS IN THAILAND TO BIOBANKING

The demographic results of the study participants are summarized in Table 1. There were an equal number of male and female participants, with a preponderance of young - middle aged (18/24=75% between the ages of 31-50). There was a mix of income, occupation and education with some bimodal distribution of the level of

education in the female participants with 7/12 (58%) having a Bachelor's degree or above. The participants were overwhelmingly of Buddhist religion (22/24 = 91.6%).

Table 1 Summary Demographics of Participants:

Characteristics N=24		
Gender	Male 12(50%)	Female 12 (50%)
Age		
20-30 years	2 (17%)	2 (17%)
31-40 years	7 (58%)	2 (17%)
41-50 years	2 (17%)	7 (58%)
51-60 year	1 (8%)	1 (8%)
Education		
Primary school	1 (8%)	1 (8%)
High school	5 (42%)	3 (25%)
Diploma/ vocational education	2 (17%)	1 (8%)
Bachelor degree	3 (25%)	3 (25%)
Above bachelor degree	1 (8%)	4 (34%)
Income		
5,000-10,000 THB	1 (8%)	2 (17%)
10,001-20,000 THB	8 (67%)	7 (58%)
20,0001-30,000 THB	2 (17%)	0 (0%)
Above 30,000 THB	1 (8%)	3 (25%)
Occupation		
Public servant/ employee in public sector	4 (33%)	6 (50%)
Temporary worker	4 (33%)	4 (33%)
Employee in private sector	4 (33%)	2 (17%)
Marital status		
Single	6 (50%)	4 (34%)
Married	6 (50%)	6 (50%)
Divorce/ separate	0 (0%)	1 (8%)
Widowed	0 (0%)	1 (8%)
Religion		
Buddhism	11 (92%)	11 (92%)
Christian	0 (0%)	1 (8%)
No religion	1 (8%)	0 (0%)

Attitudes toward clinical trials participation

In terms of their involvement in the original clinical trial which led to them being asked to participate in the biobanking questionnaire, the responses were very positive, with all participants either 'feeling good' about participating in clinical studies (22/24=92%) or 'neutral' (2/24 = 8%) . They gave a number of reasons for these positive attitudes (Figure 1). No respondents felt "Negative" about clinical research.

Example quotes explaining the attitudes of participant included

Positive:

Male, age (41-50 years) "I feel good to know about my health and proud to be a part of research"

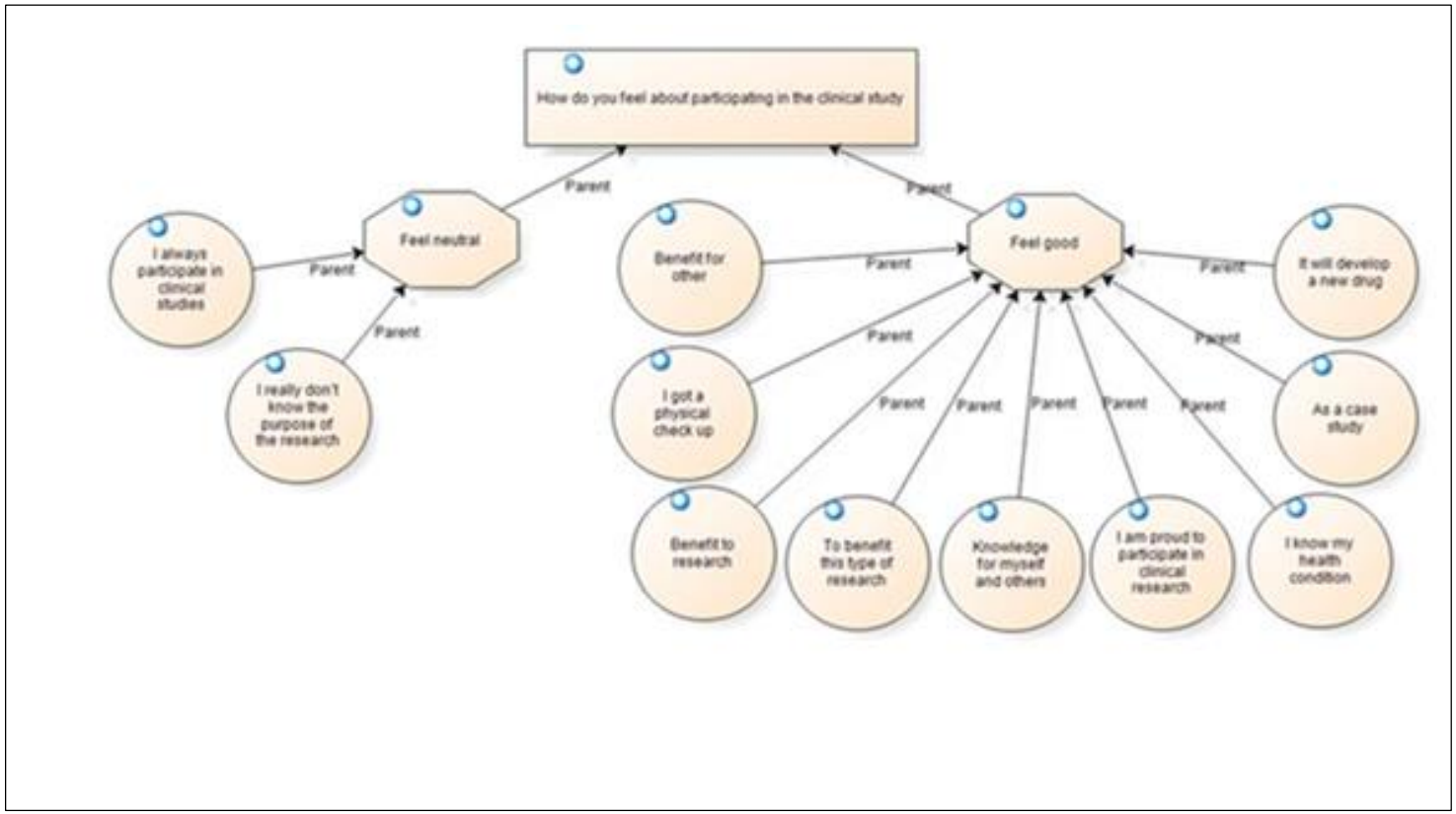
Female, aged (51-60 years) "I feel good and proud to be participating in clinical research, it means I am strong and am able to help research for others (who have this disease) after using the drug treatment that I am involved in"

Neutral:

Male, aged (51-60 years) "I fell neutral because I really don't know the purpose of the research"

Female, age (41-50 years) "I feel neutral because I often participate in clinical studie

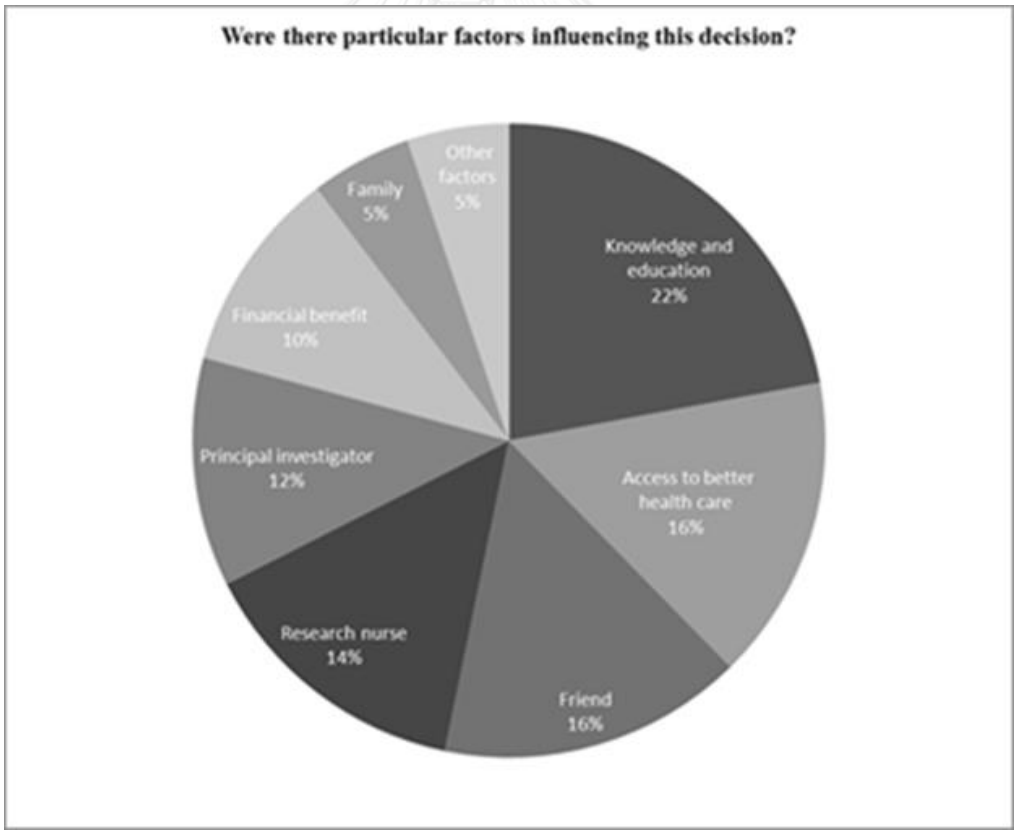
Figure 10_Summary of responses to the question “How do you feel about participating in a clinical study?”



Factors influencing the decision to participate in clinical trials

Interviewees listed a number of factors as impacting on their decision to participate in the original clinical study (summarized in Figure 2) including wanting to have more knowledge and education about their own condition (22%) from the study. Access to better health care (16%) and the advice of friends (16%) were other factors influencing their decision to participate or because the opportunity to participate in the study arose whilst they were a patient, and they wanted to know or learn more about a particular clinical study.

Figure 11_Pie chart illustrating factors listed as influencing decision to participate in clinical trials



Level of Understanding of Participation in Clinical Trials

Half of participants (50%) felt they understand the aim of clinical study based on the information given by researcher before signing the consent form, but 50% stated that this was only a 'partial' understanding.

Example responses included

Male, aged (31-40 years) "I partially understand, it looks like a drug test. There were technical terms during the explanation process. But I am shy to ask questions about them"

Female, aged (41-50 years) "I partially understand. I felt I only had a limited time to read the study documents (PIS) so on some points I did not quite understand"

Male, aged (41-50 years) "I understand. The content of brochure was clear and the Principle investigator provided clear information"

Female, aged (20-30 years) "I understand, because they have study documents to read and I can ask the study staff to explain more"

Understanding of the concept of Biobanking and the Influence of the Information Sheet

Similar to the original clinical trial, the level of understanding of a biobanking study following access to the patient information sheet was about half of all participant (13/24=54%). Those who felt they only partial understood the concept of Biobanking after reading the information brochure (11/24= 46%) requested more details about how their sample might be used in future studies, and others said that they would prefer more "lay" language or non-technical term to be used in leaflet to help increase their understanding of the process.

Comments as to why they did not feel they fully understood included:

Female, aged (41-50 years) “I partially understand, this is new knowledge and the pamphlet needed to add more information”

Female, aged (41-50 years) “I partially understanding. I know you have to store tissue sample but I don’t know what kind of tissue. Need to add more detail to the document”

Male, aged (31-40 years) “I understand it involves stored tissue samples for research, but need time to understand fully”

Female, aged (41-50 years) “Partially understand. Tissue samples such as blood, stored in biobank and then shared with other researchers”

Factors influencing the decision to participating in biobanking a blood sample

All patients mentioned their desire to help with future studies through biobanking as this may help their children or relatives in the future (24/24=100%). There was also agreement amongst all participants for an altruistic ‘Humanitarian’ motivation, contributing to future medical research which might help other people (24/24=100%). In particular they felt that potential future research projects involving genetic testing might benefit themselves or their family. Others mentioned the possibility of monetary benefit, with 8/24 (34%) stating that compensation would influence the decision to donate a blood sample

Male, aged (20-30 years) “Yes, I may gain more knowledge of my health from other studies and it might be related to my genetics”

Male, aged (31-40 years) “Yes, maybe genetic research could imply the risk factors of disease”

Female, aged (41-50 years) “Yes, I don’t know what happen in the future and if it matches my family, it will be useful”

Attitudes toward Biobanking studies - Advantages and disadvantages

All (100 %) of interviewees were willing to share their blood sample or donate it to Biobank for future use. Example quotes detailing participants views as to the potential benefit of biobanking included

Male, aged (31-40 years) “I would like to share my blood sample or donate it to a Biobank if they have a good system and confidential process”

Female, aged (41-50 years) “Yes, I would like to share my sample, but it depends on the criteria and process of the study”

Female, aged (31-40 years) “My blood will useful for studying rare diseases”

Female, aged (20-30 years) “It for developing research for prevention and treatment of disease”

Female, aged (41-50 years) “It for social benefit and it would be benefit drug producing process”

Participants gave a number of different perspectives on the potential benefits and problems of biobanking research (Figure 3). All participants felt it would benefit future research and treatments, and some felt there was an advantage in keeping samples for future research projects because it is saved research costs, reduced time for blood collection and had broader social benefits. Others had personal reasons such as knowledge of their own blood result (and potentially future genetic information derived from it) for themselves or their children / family.

Others (9/24=27%) mentioned potential disadvantages such as blood samples expiring or being used up, lack of ethics of some researchers, confidentiality of personal data, and need to ensure the quality of storage processes. There were specific comments regarding some way to ensure the quality of future research, protect against personal interests being derived from the biobank, ensure consent was granted for each subsequent study, and the problems of donating duplicate samples.

Male, aged (31-40 years) "If my blood is stored for diagnosis I would like to know the results"

Female aged (41-50 years) "It saves research cost but I am concerned for the researchers potential lack of ethics and the quality of the process to store a sample"

Most of participants were positive about the convenience of being asked to use their blood sample in another study by research team (22/24=92%) because it had a wider benefit to society and medical research, and it saved time. None were against this and 2/24 (8%) felt neutral; for instance

Male, aged (51-60 years) "It depend on the other research type that will use my sample"

Female, aged (31-40 years) "It depends on the researcher and type of research"

All participants agreed that a decision to share their sample depended on the sample type – All of interviewees prefer blood (100%) because it easy to collect, but a majority would be willing to donate a sample from tissue (organ) (18/24=75%) or DNA (13/24=54%), if they were involved in a study which allowed collection of these types of sample.

Male, aged (51-60 years) “I agreed, I prefer to donate a blood sample. Organ/tissue samples is inconvenient and I would be afraid of harm to my body. DNA collection would depend on process and where to collect it”

Female, aged (41-50 years) “I agreed. Blood sample can be interpreted to several results and easy to collect. For an organ/tissue sample, it would depend on the process. DNA is fine if it is from my blood”

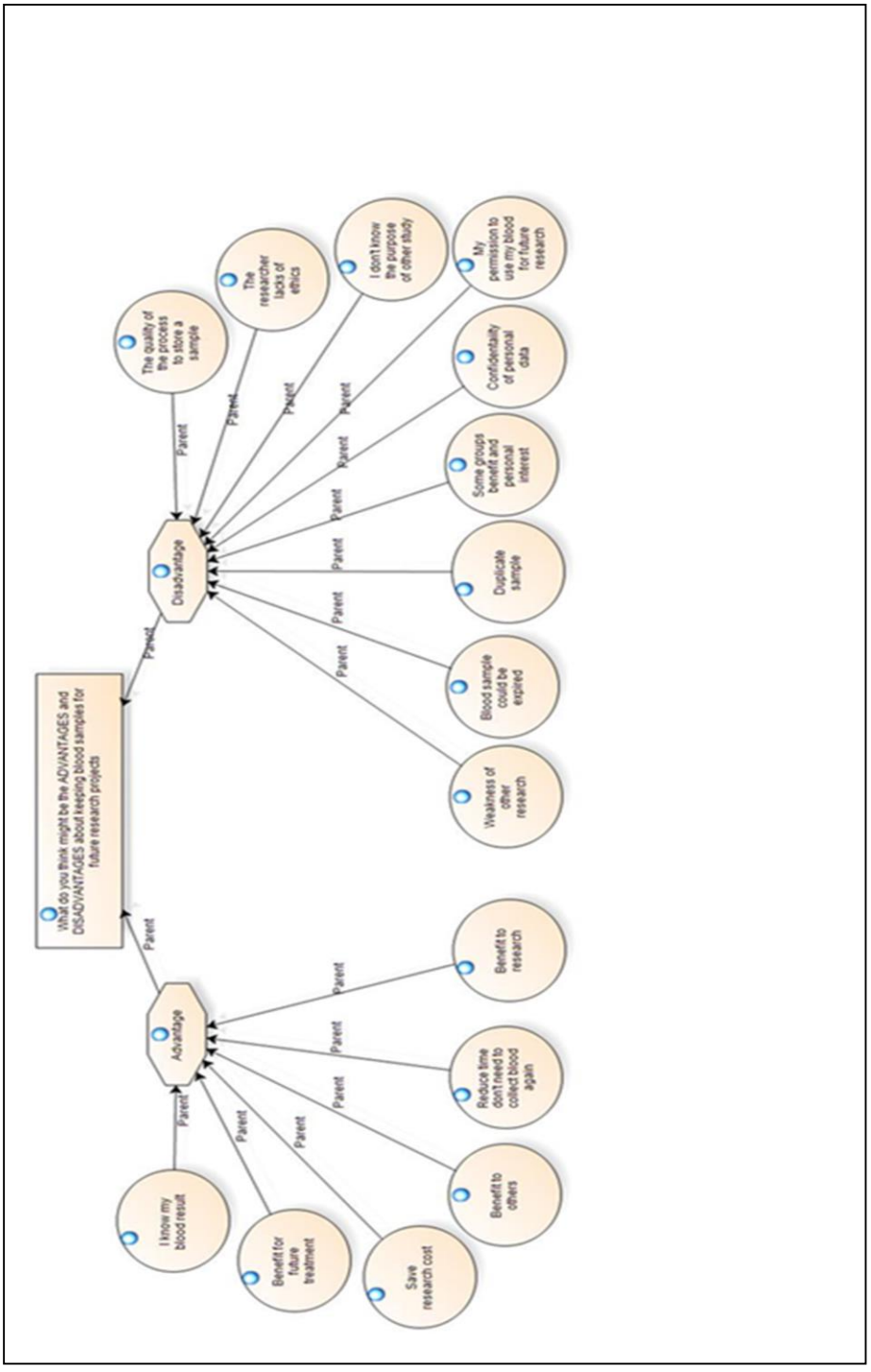


Figure 12_Participants views on the advantages and disadvantages of biobanking studies

Expectations of Monetary Benefit for Donating a Sample

Half of participants expect some direct benefit in return for sharing their blood sample with other researchers or studies. 67% of interviewees who expected to benefit defined this as either a present or monetary payment, or benefits such as getting a free blood sample result, physical exam or treatment. However others meant only that they would like access to the results of further studies (for instance genetic information in the future) and 6/24 (25%) expected no benefit whatsoever, these patients regarded the donation as purely for social benefit. There was some variation in this depending on income – in patients earning less than 20,000 THB/month 10/18 (55%) wanted payment, whereas in those earning >20,000 THB/month this was only 2/6 (33%).

Example responses included

Female, aged (41-50 years) "I would like to get free treatment and physical examination from the doctor in exchange

Female, aged (20-30 years) Yes, I would like to get a present or money from other subsequent studies

Reconsent for Subsequent Studies utilizing biobanked samples

A majority of participants 13/24=54% felt that each time their blood sample could be used in other research, they should be asked to consent to its use separately for each prospective study (Figure 4):

Male, aged (31-40 years) "I want to know whether other research may do harm to me or not, and why it is important to use my blood sample in another study"

Female, aged (31-40 years) “I want to know each time my blood sample could be used in other research, they should ask me to agree because I want to know the details and information of the other research prior to signing consent to participate this study”

Male, aged (41-50 years) “The criteria of reconsent based on a commercial study - I need to reconsent but for non-commercial study the researcher can be done without my permission”

Female, aged (20-30 years) “No, but I need the document to notify me of the purpose of other study”

Male, aged (31-40 years) “No, because I was making a decision to participate in the study when I signed the first informed consent form”

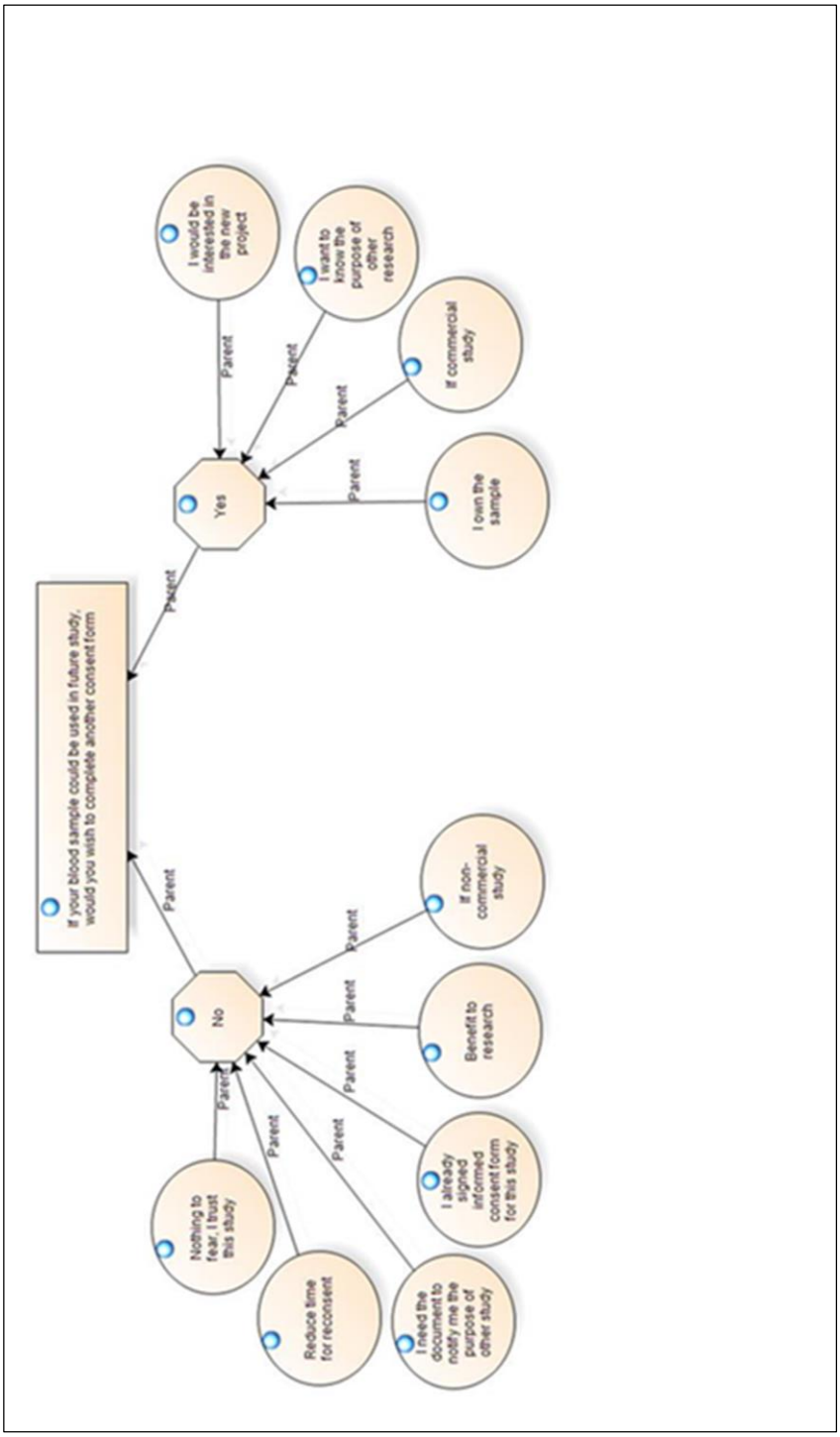


Figure 13_ The issue of Reconsent for Subsequent studies using a Biobanked sample

Feedback on the use of samples in subsequent studies

Most participants (19/24=79%) wanted to be kept informed of the results of subsequent studies using their blood sample. The ways in which they preferred being informed included by letter (8/24= 33%), email (7/24= 29%), or text message (4/24= 17%). Example responses included

Male, aged (31-40 years) "Yes, via email. I want to know the results of my blood sample, I might have some disease that I did not know about before"

Female, aged (41-50 years) "I want to be kept informed of the results of studies using my blood sample, because I want to know whether my blood results are useful for the research or not. I would like to get the results via letter because it has evidence as a document"

Biobank Governance

The participants were asked to suggest different possibilities as to who should be responsible for governing the use of a biobank containing multiple stored specimens from various patients in different studies. They were allowed to suggest more than one response, so they could suggest a number of different organisations who might have control. Responses included establishing a specific Biobank committee 22/24=92%, 18/24=75% felt the researcher should be responsible and 17/24=77% thought a Government organization should be involved.

Male, aged (31-40 years) "I think researchers, principal investigators and specific governing committees should be responsible for my sample because they have good management"

Female, aged (41-50 years) “I think a specific governing committee should be responsible for my sample, as I understand they are researchers and this would prevent conflict of interest”

Views on prospective storage time of samples

The issue of how long a specimen could be stored and used in subsequent studies led to a variety of responses (Figure 5) although most felt it could be kept indefinitely, even after the patients death (15/24= 62%).

Male, aged (31-40 years) “I don’t know the details of how long blood sample can be stored but if for research and treatment I prefer them to store my blood sample forever”

Female, aged (31-40 years) “I think a blood sample could be stored and used forever because it would be useful for others”

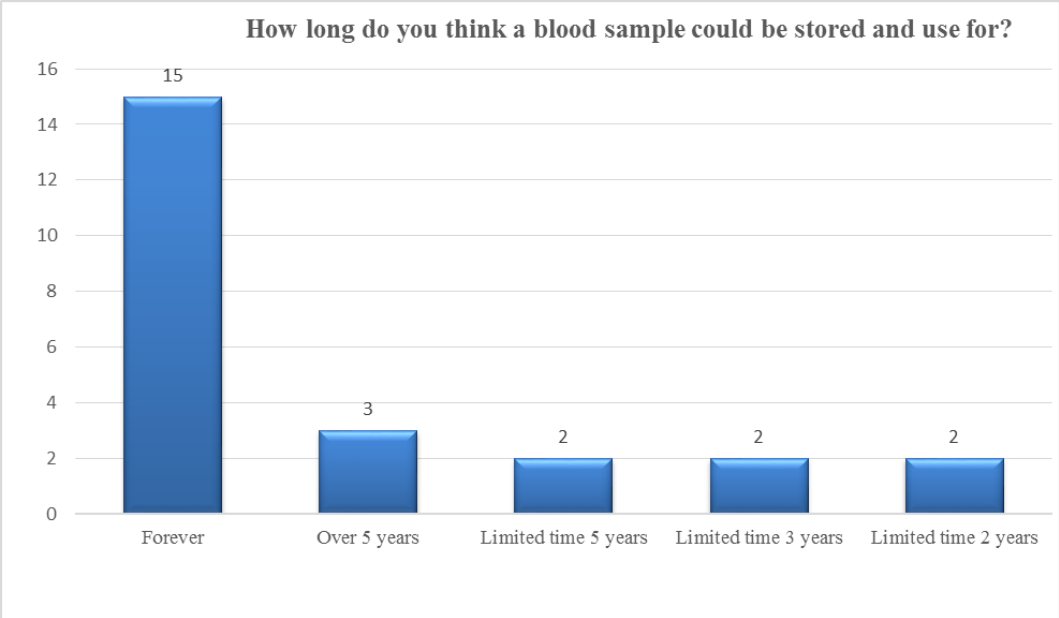
However a minority preferred to have their sample destroyed after their death (3/24=12%):

Male, aged (41-50 years) “I want to destroy my blood sample after I die because if researcher want to get more blood sample from me to other research I cannot give it anymore”

Male, aged (51-60 years) “I want to destroy my blood sample after I die because I am concerned about the confidential of my personal data”

Female, aged (41-50 years) “I want to destroy my blood sample after I die, because I cannot make decision whether to use in other study or not”

Figure 14_Variation in the time for which participants felt a sample could be kept



Use of Biobanked samples in collaboration with Researchers in other countries outside Thailand

Most participants (21/24=88%) were positive about the potential use of blood samples in collaborative international research, if for instance they were made available to researchers in another country.

Male, aged (31-40 years) “If Thai people can do it for other country. I meant we are qualify for biobank management. Team leader”

Female, aged (41-50 years) “In another country they may have a better technology than us”

Use of Biobanked samples in collaboration with Commercial Organizations

However, this did not extend to the unlimited use of samples for other organisations. Where this would involve a financial implication, for instance if samples were made available to researchers in Industry (like drug / pharmaceutical or commercial R&D companies) the majority of participants felt ‘neutral’ (7/24=27%) or ‘uncomfortable’ (15/24=58%) with making a profit out of research, in part by using their to the commercial use of ‘gifted’ blood samples.

Male, aged (20-30 years) “I would feel uncomfortable because it is a financial interest”

Female, aged (51-60 years) “I would feel uncomfortable because I want to volunteer for non-commercial study only”

RESULTS PHASE II:

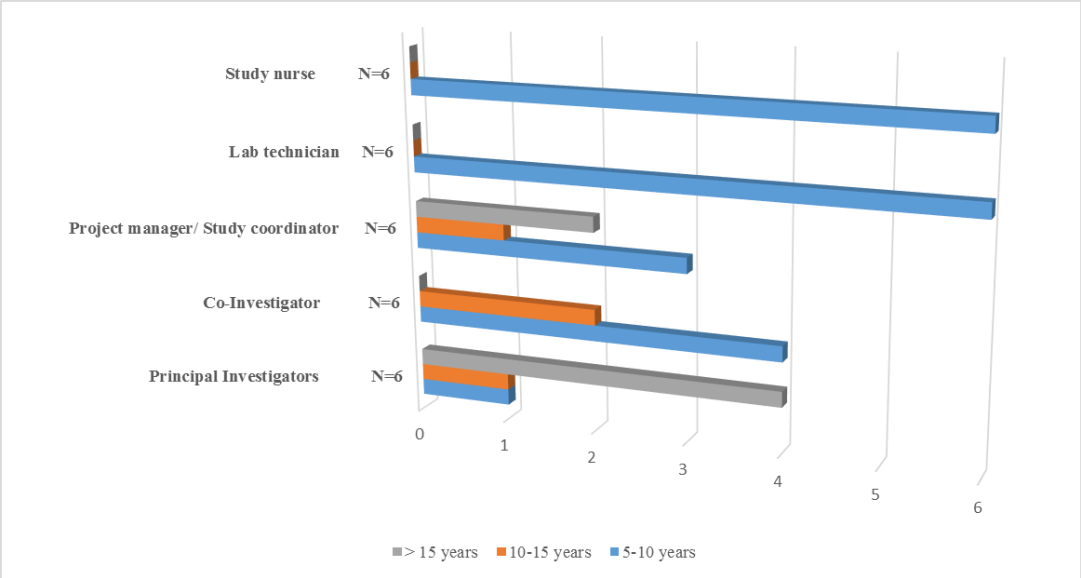
DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS, USING DELPHI TECHNIQUE TO DETERMINE CONSENSUS AMONG EXPERTS: PRINCIPAL FOR GOOD PRACTICE

This step applied a four-round Policy Delphi technique to determine consensus among experts: Principal Investigators, Co-Investigators, Project managers/ study coordinators, Lab technicians, and Study nurses.

Response rates/ participants

Thirty potential panel experts, consisting of six principal investigators, six co-investigators, six project managers/study coordinators, six lab technicians, and six study nurses, were invited to participate in the study. High response rates of 100% (30/30), 93% (28/30) and 80% (26/28) were achieved for rounds one, two and three, respectively. Panelists who did not respond to either round one or round two were not eligible to participate in round three, as they would have been contributing to the final outcome without having made any prior contribution to the process. Each round of the Delphi technique took approximately ten days to complete.

Experts' demographics



Round I: The thirteen items of the open-ended questionnaire were used to collect opinions from the experts which will be used to determine different issues in order to develop the contents of questionnaire for the next round [56]. An email was circulated to experts inviting them to participate and respond to the researcher, in the privacy of the individual's laptop or PC desktop computer to avoid bias or coercion. All responses within the expert panel was anonymized prior to collation and circulation to collect opinions from the participants which used to determine different issues in order to develop the contents of questionnaire for the second round. Table 2 below shows the results of round I.

Table 2_The results of round I

Open-ended questionnaire	**Response from Experts N=30**	
1. What is your opinion of the usefulness of biobanking clinical samples (such as blood) for use in future research?	Biobanking clinical samples is useful in clinical research	27 (90%)
	Biobanks can store 'left-over' samples that remain from specific clinical research trial for potential future use	24 (80%)
2. What is your understanding of the use and aims of biobanking? – do you have any comments as to the following statement as a proposed definition of biobanking? "A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others"	Agree with this sentence, it can reduce cost and time for sample collection	26 (86.6%)
	Agree with this sentence, it can reduce subsequent duplicate sampling	22 (73.3%)
	Agree with this sentence, it allow use of valuable sample by more than one research/ oganization in similar fields of research	20 (66.6%)
3. What is the best way to explain the biobanking process to clinical research participants/patients in order to gain informed consent for their participation in biobanking trials – information sheets, preconsent interview, any others?	Patient information sheet	28 (93.3%)
	Pre-consent interview	22 (73.3%)
	Question and answer with interviewer	19 (63.3%)
	Depends on the patient / participant's education level	16 (53.3%)
	Information brochure/ handout	15 (50%)

	Video	14 (46.6%)
	Link to website	11 (36.6%)
	Focus group discussion	8 (26.6%)
4. What are your concerns as an investigator/researcher about being involved in biobanking studies? (e.g. use of samples by other investigators or pharma, control of samples, responsibility for consent processes for a study which would not be your own etc).	Confidential of patient information	30 (100%)
	Sample potentially available for use by industry / pharmaceutical company	27 (90%)
	Performing a consent process for sample use in future studies over which you have no direct control	24 (80%)
	Appropriate govance structure	23 (76.6%)
	Archiving & quality assurance processes for sample storage	15 (50%)
	Samples freely available for use by other investigators, potentially competitors	13 (43.3%)
	Potential lack of ethics of other researchers	12 (40%)
5. How do you feel about consenting patients/participants for a biobanking study,	Feel fine, if other research provide more information for subsequent study	21 (70%)

which may subsequently involve other research rather than just your own study?	Feel fine, if all information is transparent	15 (50%)
6. What factors would make it easier for you to ask patients/trial participants to donate samples to a biobank, even if this is not the aim of your own study?	Understanding the concept of Biobanking	29 (96.6%)
	Altruistic benefits to future research	23 (76.6%)
	Scientific validity of future studies accessing samples is approved by a biobank governance committee	18 (60%)
	Patient Confidentiality should be assured	16 (53.3%)
	Future studies have specific IRB approval	9 (30%)
7. What factors do you feel might influence a patients decision to consent to donating a sample – e.g. religious beliefs, altruistic reasons, family interest, financial reward, confidentiality, governance of the biobank?	Financial reward	30 (100%)
	Issues of Confidentiality	30 (100%)
	Altruistic reasons - Benefit to wider society	23 (76.6%)
	The patients decision will be influenced by the doctor / PI involved	22 (73.3%)
	Whether consenting to biobanking will involve the patient in future commitements (reconsent, legal ramifications)	20 (66.6%)
	Proposed Governance of the biobank	16 (53.3%)

	Family benefit	15 (50%)
	Religious belief	14 (46.6%)
	Direct benefit to the patient (Consultation with doctor, knowledge about disease for prevention in patient or family)	11 (36.6%)
8. What specific uses of a sample do you feel should be mentioned on a general consent form? e.g. use of data, ensuring confidentiality, extraction of DNA, sharing with other researchers, use abroad or by pharma.	Ensuring confidentiality	30 (100%)
	Time period for which sample will be kept	30 (100%)
	Sharing with other researchers	30 (100%)
	Extraction DNA	28 (93.3%)
	Potential use abroad in collaborative research	26 (86.6%)
	Use by pharma / industry in collaborative research	25 (83.3%)
	Use of the data	24 (80%)
	Ability to withdraw consent and destroy sample later	24 (80%)
9. Do you think patients should be entitled to compensation/payment for donating samples to a biobank? - if yes what form might this take? - Monetary payment, help with transport costs, access to free medical	Yes, money for transportation cost	28 (93.3%)
	Yes, direct monetary payment	22 (73.3%)
	Yes, physical checkup, vaccinations check	12 (40%)

checkup as part of the workup for your study?	Yes, food	5 (16.6%)
	No, they should not be compensated as this might influence their decision to consent	3 (10%)
10. Regarding consent, under what circumstances do you think patients should be contacted to consent separately for each subsequent new study that a sample could be used for?	Depends on type of study (eg. Genetic study on disease carriage)	27 (90%)
	Commercial studies	27 (90%)
	A study might generate genetic data that could impact the patient or relatives	26 (86.6%)
	Where a study produces new data on a patient which could influence their health or treatment	10 (33.3%)
	Depends on patient preference	7 (23.3%)
	Depends on the requirements of Ethic committee/IRB for each subsequent study	6 (20%)
	No need because the original consent should include discussion scope of use for the samples	5 (16.6%)
	No, may involve travel, contacting some patients difficult	4 (13.3%)
	If patient unconscious during enrollment to the study and consent is given by their relative/guardian/parent	2 (6.6%)

11. How long do you feel it is appropriate for a sample to be kept – is it acceptable to keep and use a sample after a patient death?	Keep the sample ≤ 10 years	15 (50%)
	Keep the sample forever	8 (26.6%)
	Keep the sample ≤ 5 years	5 (16.6%)
	Keep the sample ≤ 2 years	2 (6.6%)
12. Do you think participants should be informed the results of subsequent studies using the biobanked sample, and if so how could this be done? e.g. email, letter, text	Contact patient via Letter	18 (60%)
	Email	5 (16.6%)
	Not necessary - generic consent given, unnecessary administrative burden	3 (10%)
	Text	2 (6.2%)
	Interactive website for the biobank	2 (6.6%)
13. Do you think if a researcher would like to share samples with researchers abroad, or commercial organisations such as the pharma industry, they should notify participants?	Yes	24 (80%)
	No	6 (20%)

Opinion of policy maker toward Biobanking

The question was asked about the opinion of expert toward Biobanking**,** all of them (100%) through Biobanking clinical samples are useful in clinical research and Biobanks can store ‘left-over’ samples that remain from specific clinical research trial

for potential future use. It can reduce time and cost for sample collect for similar study. Allows use of valuable samples by more than one research/ organization in similar fields of research and reduce subsequent duplicate sampling and studying rare diseases

Word of Biobanking

All are agreed the word of Biobanking as "A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others" but some expert recommend to pat ethical point of view in Biobanking word.

Way to explain Biobanking process

They have several opinions about the best way to explain the biobanking process to clinical research participants/ patients in order to gain informed consent for their participation in biobanking trials by provide Information brochure/ handout, pre-consent interview, patient information sheet, video, link to website, focus group discussion, question and answer with interviewer and it depend on patient/ participant education level.

What concerned for subsequent study of Biobanking

The expert concerns as an investigator/researcher about being involved in biobanking studies are Appropriate Governance structure, Samples freely available for use by other investigators, potentially competitors, Sample potentially available for use by industry / pharmaceutical company, Performing a consent process for sample use in future studies over which you have no direct control, Confidential of patient information,

Archiving & quality assurance processes for sample storage, Potential lack of ethics of other researchers.

Consent patient/ participant for subsequent study of Biobanking

Expert was feel about consenting patients/participants for a biobanking study, which may subsequently involve other research rather than just your own study by Understanding the concept of Biobanking, Patient Confidentiality should be assured, Future studies have specific IRB approval, Scientific validity of future studies accessing samples is approved by a biobank governance committee and Altruistic benefits to future research.

The factors would make it easier for you to ask patients/trial participants to donate samples to a biobank, even if this is not the aim of your own study

The religious belief, Altruistic reasons - Benefit to wider society, Family benefit, Financial reward, Issues of Confidentiality, Proposed Governance of the biobank, The patients decision will be influenced by the doctor / PI involved, Whether consenting to biobanking will involve the patient in future commitments (reconsent, legal ramifications), Direct benefit to the patient (Consultation with doctor, knowledge about disease for prevention in patient or family).

The specific uses of a sample should be mentioned on the general consent form

The use of data, ensuring confidentiality, extraction of DNA, sharing with other researchers, Potential use abroad in collaborative research, Use by pharma / industry in collaborative research, Ability to withdraw consent and destroy sample later, Time period for which sample will be kept.

Reward

Some expert opinion think patients should be entitled to compensation/payment for donating samples to a biobank by direct monetary payment, money for transportation cost, food in rural area, physical checkup, vaccinations check and some think they should not be compensated as this might influence their decision to consent.

Re-consent

The best represents your opinion regarding the need for patients should be contacted to consent separately for each subsequent new study that a sample could be used depend on the requirements of Ethic committee/IRB for each subsequent study, Depends on patient preference, Depends on type of study (e.g. Genetic study on disease carriage, commercial study), A study might generate genetic data that could impact the patient or relatives, If patient unconscious during enrollment to the study and consent is given by their relative/guardian/parent and no need because it may involve travel, contacting some patients difficult and no need because the original consent should include discussion scope of use for the samples and Where a study produces new data on a patient which could influence their health or treatment. Regarding consent, under what circumstances do you think patients should be contacted to consent separately for each subsequent new study that a sample could be used for depend on subsequent study type and Not necessary - generic consent given, unnecessary administrative burden for each subsequent new study that a sample could be used for letter, email, text and interactive website for the biobank.

Duration for sample in Biobank

It is acceptable to keep and use a sample after a patient death ≤ 10 years and Forever (even after death of patient).

Sample sharing

A researcher would like to share samples with researchers abroad, or commercial organizations such as the Pharmaceutical industry by depend on the sample and study type.

Round II: For the second round, twenty-eight questionnaires were returned by the participants after rating the statements (93% response rate). All five groups of health professionals were represented in this round.

Table 3.1_Opinion of the usefulness of biobanking.

Please tick the box that represent your opinion of the usefullness of biobanking clinical samples (such as blood orDNA) for use in future research	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Biobanking clinical samples is useful in clinical research	17	11	0	0	0	100 % (High)	0.5	4.61	Yes
Biobanks can store 'left-over' samples that remain from specific clinical research trial for potential future use	14	14	0	0	0	100 % (High)	0.5	4.50	Yes
A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others	12	15	1	0	0	96.4 % (High)	0.5	4.39	Yes
Reduce cost & time for sample collection	14	12	2	0	0	92.9% (High)	0.5	4.43	Yes
Allows use of valuable samples by more than one research/ organization in similar fields of research	15	10	3	0	0	89.3 % (High)	0.5	4.43	Yes
Reduce subsequent duplicate sampling	10	12	5	1	0	78.6 % (Medium)	0.5	4.11	Yes
Studying rare diseases	13	11	4	0	0	85.7 % (High)	0.5	4.32	Yes

The results in Table 3.1 show that all items reach consensus. The experts think biobanking is useful in clinical research. Biobanks can store 'left over' samples from specific clinical research trials for potential future use; they can store biological samples and associated data for medical/scientific research and diagnostic purposes, and organize them in a systematic way for use by others; they can reduce costs and time for sample collection; they allow the use of valuable samples by more than one researcher/organization in similar fields of research; they reduce duplicate sampling; and they can be used for studying rare diseases.

Table 3.2_The best way to explain the biobanking process to clinical research participant.

Please tick the box that best way to explain the biobanking process to clinical research participants/patients in order to gain informed consent for their participation in biobanking trials – information sheets, preconsent interview, any others?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Information brochure/ handout	10	12	4	2	0	78.6 % (Medium)	0.5	4.07	Yes
Pre-consent interview	11	15	1	1	0	92.9 % (High)	0.5	4.29	Yes
Patient information sheet	11	14	2	1	0	89.3 % (High)	0.5	4.25	Yes
Video	9	15	4	0	0	85.7 % (High)	0.5	4.18	Yes
Link to website	4	11	11	1	1	53.6 % (None)	0.5	3.57	No
Focus group discussion	6	13	7	2	0	67.8 % (Low)	0.5	3.82	No
Question and answer with interviewer	11	12	5	0	0	82.2 % (High)	0.5	4.21	Yes
Depends on the patient / participant's education level	10	11	6	0	1	75 % (Medium)	0.875	4.04	Yes

The results in Table 3.2 show that the best way to explain the biobanking process to clinical research participants is through pre-consent interviews and questions and answers with an interviewer. This means that a verbal explanation is considered effective to explain the process, and clinical participants can ask questions during that time. Patient information sheets and information brochures/handouts are documents for clinical participants to read and learn from; they can spend some time to understand the information provided about the process of biobanking. A video can also explain the process of biobanking; clinical participants can watch and learn about the process from the movie. The experts also believe that the way to explain the process of biobanking depends on the education level of the clinical research participants. Links to websites and focus group discussions are not thought to be very effective. This may reflect the experts' concerns that not everyone in Thailand has internet access, particularly in rural areas.

Table 3.3_The best concern as an investigator/ researcher about being involved in biobanking study.

Please tick the box that best represents your concerns as an investigator/researcher about being involved in biobanking studies? (eg use of samples by other investigators or pharma, control of samples, responsibility for consent processes for a study which would not be your own etc)	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Appropriate Governance structure	11	13	3	1	0	85.7 % (High)	0.5	4.21	Yes
Samples freely available for use by other investigators, potentially competitors	2	14	7	4	1	57.1 % (None)	0.5	3.43	No
Sample potentially available for use by industry / pharmaceutical company	5	10	5	6	2	53.6 % (None)	1	3.36	No
Performing a consent process for sample use in future studies over which you have no direct control	6	12	8	2	0	64.3 % (Low)	0.5	3.79	No
Confidential of patient information	16	12	0	0	0	100 % (High)	0.5	4.57	Yes
Archiving & quality assurance processes for sample storage	12	14	2	0	0	92.9 % (High)	0.5	4.36	Yes
Potential lack of ethics of other researchers	11	12	2	2	1	82.2% (High)	0.5	4.07	Yes

The results in Table 3.3 show that all experts are concerned about the confidentiality of patient information. Confidentiality is clearly a key issue of concern. Archiving and quality assurance processes for sample storage, and appropriate governance structures are also considered important. Poor governance structures may result in poor biobank management. Respondents are also concerned about a potential lack of ethics of other researchers who gain access to the biobank, which may compromise the confidentiality or anonymity of the data.

Table 3.4_Factors would make it easier for expert to ask clinical participant to donate sample to biobank.

Please tick the box that best represents what factors would make it easier for you to ask patients/trial participants to donate samples to a biobank, even if this is not the aim of your own study?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Understanding the concept of Biobanking	12	14	2	0	0	92.9 % (High)	0.5	4.36	Yes
Patient Confidentiality should be assured	17	11	0	0	0	100 % (High)	0.5	4.61	Yes
Future studies have specific IRB approval	11	13	4	0	0	85.7 % (High)	0.5	4.25	Yes
Scientific validity of future studies accessing samples is approved by a biobank governance committee	13	14	1	0	0	96.4 % (High)	0.5	4.43	Yes
Altruistic benefits to future research	10	15	3	0	0	89.3 % (High)	0.5	4.25	Yes

The results in Table 3.4 show the factors that would make it easier for experts to ask (trial) participants to donate samples to a biobank even if this is not their own study. All experts agree that patient confidentiality should be assured, because they have experience in clinical research and they know about clinical participants' concerns about confidentiality. They also agree that the scientific validity of future studies accessing samples should be approved by a biobank governance committee who will manage the biobank in compliance with good clinical practice. Further, experts expect that if clinical participants understand the concept of biobanking, they will be more likely to donate their sample to the biobank. It is also expected that any future studies should have specific IRB approval separate from the original study. Finally, experts believe that altruistic benefits to future research and to other people can positively influence clinical participants to donate their sample.

Table 3.5_ Factors might influence a patient decision to consent donating a sample.

Please tick the box that best represents what factors you feel might influence a patients decision to consent to donating a sample – e.g. religious beliefs, altruistic reasons, family interest, financial reward, confidentiality, governance of the biobank?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Religious belief	3	12	10	3	0	53.6 % (None)	0.5	3.54	No
Altruistic reasons - Benefit to wider society	8	15	5	0	0	82.2 % (High)	0.5	4.11	Yes
Family benefit	6	11	10	1	0	60.7 % (Low)	0.5	3.79	No
Financial reward	3	16	8	1	0	67.8 % (Low)	0.5	3.75	No
Issues of Confidentiality	10	11	6	1	0	75.0 % (Medium)	0.875	4.07	Yes
Proposed Governance of the biobank	5	11	10	2	0	57.2 % (None)	0.5	3.68	No
The patients decision will be influenced by the doctor / PI involved	4	16	6	2	0	71.4 % (Medium)	0.5	3.79	Yes
Whether consenting to biobanking will involve the patient in future commitements (reconsent, legal ramifications)	3	20	5	0	0	82.1 % (High)	0	3.93	Yes
Direct benefit to the patient (Consultation with doctor, knowledge about disease for prevention in patient or family)	9	16	2	1	0	89.2 % (High)	0.5	4.18	Yes

The results in Table 3.5 show the factors that might influence clinical participants' decision to consent to donating a sample. Experts think the most important of these are: altruistic reasons (the benefits to wider society); issues of confidentiality; whether consenting to biobanking will involve the patient in future commitments (re-consent, legal ramifications); and direct benefits to the patient (consultation with a doctor, knowledge about the disease for prevention in the patient or his/her family).

Table 3.6_ What use the sample should be specific mention on a consent form?

Please tick the box that best represents what uses of a sample you feel should be specifically mentioned on a consent form, rather than just explained in an information	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Use of the data	8	18	2	0	0	92.9 % (High)	0.5	4.21	Yes
Ensuring confidentiality	17	10	1	0	0	96.4 % (High)	0.5	4.57	Yes
Extraction of DNA	6	14	8	0	0	71.4 % (Medium)	0.5	3.93	Yes
Sharing with other researchers	9	18	1	0	0	96.4 % (High)	0.5	4.25	Yes
Potential use abroad in collaborative research	7	17	3	1	0	85.7 % (High)	0.375	4.07	Yes
Use by pharma / industry in collaborative research	10	10	5	2	1	71.4 % (Medium)	1	3.93	Yes
Ability to withdraw consent and destroy sample later	12	12	3	1	0	85.8 % (High)	0.5	4.25	Yes
Time period for which sample will be kept	10	11	5	2	0	75% (Medium)	0.875	4.04	Yes

The results in Table 3.6 show the consensus among experts about what uses of a sample or data should be specifically mentioned in a consent form rather than just explained to participating patients. Experts identify the following: ensuring confidentiality; information about sharing samples and data with other researchers; the ability to withdraw consent and destroy the sample at a later time; the use of the data; the potential use abroad in collaborative research; the time period during which the sample will be kept; the extraction of DNA; and the use by a pharmaceutical company or industry in collaborative research.

Table 3.7_What patient entitled to compensation/ payment for donating?

Please tick the box that best represents whether you think patients should be entitled to compensation/payment for donating samples to a biobank, and if so what form	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Yes, direct monetary payment	5	13	7	3	0	64.3 % (Low)	0.5	3.71	No
Yes, money for transportation cost	10	15	3	0	0	89.3 % (High)	0.5	4.25	Yes
Yes, food	4	7	12	5	0	49.3 % (None)	0.5	3.36	No
Yes, physical check up, vaccinations check	9	10	7	2	0	68.7 % (Low)	1	3.93	No

The results in Table 3.7 indicate that the experts agree that patients should be entitled to compensation/payment for donation of a sample to a biobank. This compensation could take the form of reimbursement of transportation costs.

Table 3.8_Opinion regarding the need for patients should be contacted to consent separately for each subsequent new study that sample could be used

Please tick the box that best represents your opinion regarding the need for patients should be contacted to consent separately for each subsequent new study that a sample could be used for?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
No need because the original consent should include discussion scope of use for the samples	5	13	3	7	0	64.3 % (Low)	0.875	3.57	No
No, may involve travel, contacting some patients difficult	4	9	9	6	0	56.4 % (None)	0.5	3.39	No
Depends on the requirements of Ethic committee/IRB for each subsequent study	5	18	5	0	0	82.2 % (High)	0	4	Yes
If patient unconscious during enrollment to the study and consent is given by their relative/guardian/parent	3	16	3	6	0	67.8 % (Low)	0.5	3.57	No
Depends on patient preference	5	13	7	3	0	64.3 % (Low)	0.5	3.71	No
Depends on type of study (eg. Genetic study on disease carriage, commercial study)	3	18	4	3	0	75.0 % (Medium)	0.375	3.75	Yes
A study might generate genetic data that could impact the patient or relatives	5	12	7	4	0	60.8 % (Low)	0.5	3.64	No
Commercial studies	6	13	4	5	0	67.8 % (Low)	0.5	3.71	No
Where a study produces new data on a patient which could influence their health or treatment	7	14	5	2	0	75.0 % (Medium)	0.75	3.93	Yes

The results in Table 3.8 show experts' opinions regarding the need for patients to be contacted to consent separately for each subsequent new study in which a sample is used. The consensus is that this depends on the requirements of the Ethics Committee/IRB involved in each subsequent study; on the type of study (e.g. a genetic

study on disease carriage, or a commercial study); and on whether a study produces new data on a patient which could influence their health or treatment.

Table 3.9_ The best way to contact patients for re-consent.

What do you feel is the best way to contact patients for re-consent?	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
Contact patient via Letter	3	15	7	3	0	82.1 % (High)	0	3.82	Yes
Email	4	10	11	2	1	75.0 % (Medium)	0.375	3.75	Yes
Text	4	10	10	3	1	50.0 % (None)	0.5	3.46	No
Interactive website for the biobank	1	7	14	6	0	28.6% (None)	0.5	3.11	No

The results in Table 3.9 show the ways in which clinical participants should be contacted for re-consent. The best ways are via letter or email.

Table 3.10_ How long for sample to be kept

Please tick the box that represents how long you feel it is appropriate for a sample to be kept	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	% of Consencus/ Level of consensus	IQD	Mean	Concensus
≤2 years	3	1	11	13	0	14.3 % (None)	0.5	2.79	Yes
≤5 years	3	11	10	4	0	50.0 % (None)	0.5	3.46	Yes
≤ 10 years	4	14	9	1	0	75.0 % (Medium)	0.375	3.86	No
Forever (eg even after death of patient)	4	8	7	8	1	42.9 %(None)	1	3.21	No

The results in Table 3.10 show how long experts feel it is appropriate for samples to be kept in a biobank. Most agree that samples should not be kept for longer than 10 years.

Round III

The third and final round followed the decision to extend the study, with the aim of identifying the priorities of designing consent forms and patient information sheets for informed consent for biobanking. An online survey was sent to the same participants of the previous rounds. 80% (26/28) responded within ten days. On this round 3 items of patient can withdraw sample in any stage, DNA can be extraction and sample will not use with commercial organization permission from the patient were consensus.

Table 4_Designing consent forms and patient informed consent form for biobanking study (round III)

Designing consent forms and patient information sheets for informed consent form for biobanking study (round III)			
	Must be on Informed consent form	Should be on both Informed consent form and Patient information sheet	Can be just on Patient information sheet
Patient confidentiality assured by anonymous	5 (19.2%)	17 (65.4%)	4 (15.4%)
Nature and amount of sample (eg blood, swab, DNA, left over sample)	4 (15.4%)	17 (65.4%)	5 (19.2%)
Site of sample storage	4 (15.4%)	13 (50%)	9(34.6%)
Overall responsibility for sample	7 (27.0%)	13 (50%)	6 (23.0%)
Patient will be re-consent for subsequent studies or patient can give blanket consent	6 (23.1%)	18 (69.2)	2 (7.7%)
No monetary reward for donating a sample	5 (19.2%)	16 (61.53)	5 (19.2%)
Patient will be informed of result of subsequent studies by letter or email	3 (11.5%)	15 (57.7)	8 (30.8%)
Sample will be stored for as least 10 years or forever it consents	5 (19.2%)	18 (69.2%)	3 (11.5%)
Patient can change their mind for withdraw sample in any stage	4 (15.4%)	21 (80.8%)	1 (3.8%)
DNA can be extracted from sample and used for future studied	3 (11.5%)	19 (73.1%)	4 (15.4%)
Sample will not be used with commercial organization (eg Pharma) without specific used	2 (7.7%)	19 (73.1%)	5 (19.2%)

The results in Table 4 show that the percentage of agreement among expert in round Three, the items of withdrawal from study, DNA extraction and sample will not be used with commercial company without permission from the patient were consensus and should clearly and inform both informed consent form and patient information sheet. For another item were not consensus due to the percentage was below 70%.

Round IV

The final round, to identifying the priorities of designing consent forms and patient information sheets for informed consent for biobanking. An online survey was sent to the same participants of the previous rounds. 81% (21/26) responded within ten days. However, there was no scope for reconsideration, as there was already broad consensus on a large number of statements.

Table 5_Designing consent forms and patient informed consent form for biobanking study (round IV)

Designing consent forms and patient information sheets for informed consent form for biobanking study (round IV)			
	Must be on Informed consent form	Should be on both Informed consent form and Patient information sheet	Can be just on Patient information sheet
Patient confidentiality assured by anonymous	0 (0.0%)	20 (95.2%)	1 (4.8%)
Nature and amount of sample (eg blood, swab, DNA, left over sample)	0 (0.0%)	21 (100.0%)	0 (0.0%)
Site of sample storage	0 (0.0%)	20 (95.2%)	1 (4.8%)
Overall responsibility for sample	0 (0.0%)	21 (100.0%)	0 (0.0%)
Patient will be re-consent for subsequent studies or patient can give blanket consent	0 (0.0%)	21 (100.0%)	0 (0.0%)
No monetary reward for donating a sample	0 (0.0%)	20 (95.2%)	1 (4.8%)
Patient will be informed of result of subsequent studies by letter or email	0 (0.0%)	21 (100.0%)	0 (0.0%)
Sample will be stored for as least 10 years or forever it consents	1 (4.8%)	20 (95.2%)	0 (0.0%)

The results in Table 5 show that the percentage of agreement among expert in final round (round four), all information as patient confidential, amount of sample, site of sample storage, overall responsibility of sample, re-consent, no monetary reward for donating a sample, result information, duration of storage, withdrawal from study, DNA extraction and sample will not be used with commercial company without permission from the patient should clearly and inform both informed consent form and patient information sheet.

Policy of informed consent for biobanking in tropical disease research projects: principles for good practice

This policy using the results from phase I and phase II.

Word of Biobanking

A biobank is defined as “a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others” [1].

The advantages and benefits of biobanking

Biobanks store samples that can be useful in clinical research. They can store ‘left-over’ samples that remain from specific clinical research trials for potential future use. They can reduce the time and costs involved in collecting samples for similar studies. They allow valuable samples to be used by more than one researcher or organization in similar fields of research, they reduce subsequent duplicate sampling, and they can facilitate the study of rare diseases.

Disadvantage of biobanking

Disadvantages such as blood samples expiring or being used up, lack of ethics of some researchers, confidentiality of personal data, and need to ensure the quality of storage processes. There were specific comments regarding some way to ensure the quality of future research, protect against personal interests being derived from the biobank, ensure consent was granted for each subsequent study, and the problems of donating duplicate samples.

The best ways to explain the process of biobanking

A pre-consent interview with questions and answers between the medical professional and the clinical participant is the best way to explain the process of biobanking. Patient information sheets, information brochures/handouts and videos can also be used. The education level of the clinical participants is one factor that influences the choice of the best way to explain the process of biobanking. Participants may be unfamiliar with some medical terminology, including the word biobanking itself, and some words may be difficult to explain in layman's terms.

Confidentiality

The most important aspect of informed consent for biobanking is confidentiality, because it influences the patient's decision to donate a sample. All information will be confidential and secure. Each sample is labelled with a code and anonymized. The biobank database links the sample code to a particular Patient but this information is not made available to researchers. However the researcher should ensure that all clinical participants' data are anonymized and treated confidentially.

Sample for biobank

For the sample for biobank, the researcher should be followed by the requirement of local ethic committee and should not collect blood sample over from the original protocol. Only left over blood sample from original study can be stored in biobank and use for future research.

Factors influencing the decision to donate

Altruistic reasons and perceived benefits to the wider society are the main factors influencing patients' decisions to donate a clinical sample. In addition, confidentiality and consent regarding future commitments (re-consent, and legal ramifications) are important. Direct benefits to the patient, such as consultation with a doctor, or increased knowledge about the disease, also influence clinical participants who may want to donate a sample.

Specific information in the consent form

Consent forms should include all relevant information regarding the use of clinical samples. This information should be explicitly mentioned in the consent form rather than just explained to the patient. Consent forms should include information on:

- Ensuring confidentiality;
- Whether the sample will be shared with other researchers;
- Clinical participants' right to withdraw consent and have their sample destroyed at

any time;

- The researcher's commitment to notify the clinical participant about what kind of

data from their sample is used in research;

- The researcher's commitment to notify the clinical participant if their sample is used abroad in collaborative research by, for example, pharmaceutical companies;
- The time period during which the sample will be kept;

- In case the sample is used in clinical research related to DNA, the researcher should

notify the clinical participant.

Re-consent

The re-consent process depends on the requirements of the relevant Ethics Committee/IRB for each subsequent study, on the type of study (e.g. a genetic study on disease carriage, or a commercial study), and on whether a study produces new data on a patient which could influence their health or treatment.

The best way to contact patients for re-consent

Ideally, the researcher should contact a clinical participant for re-consent by letter or email because it can be use it as evidence as a document.

Benefits for patients of donating a clinical sample

There are direct benefits to patients in return for sharing their sample with other researchers or studies. These benefits may include a present or monetary payment, or getting a free blood sample result, physical exam or treatment. Some patients may only like to access the results or findings of further studies, for instance, genetic information. Clinical patients should be entitled to compensation for any transportation costs incurred in the process of donating a sample to a biobank.

Use of Biobanked samples in collaboration with Commercial Organizations

The information about sharing samples and data with other researchers or use by a pharmaceutical company or industry in collaborative research should be notify to clinical participants with ask permission from them. For the sample use in commercial organization, with making a profit out of research, the clinical participant should be gift or profit from their sample.

Designing a 'Patient Information Sheet' for tropical clinical research in Tropical disease affiliate Mahidol-Oxford Tropical medicine Research Unit

Mahidol-Oxford Tropical medicine Research Unit

Patient Information Sheet

Donating blood sample for clinical research in Tropical disease

affiliate Mahidol-Oxford Tropical medicine Research Unit

We are inviting you to take part in a biobank research study. Before you decide whether to participate or not it is important for you to understand why the research is being done and what it will involve. You decision will not affect your care in anyway. Please take time to read the following information carefully and to decide whether or not you wish to be involved. Thanking for reading it.

1. What is biobanking?

The word of Biobanking as "A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others"

2. What is the purpose of this study?

Mahidol-Oxford Tropical Medicine research unit (or affiliate) collects blood sample for use in the future for clinical research in tropical disease.

3. Why I have been chosen

You have been chosen because you are involving for clinical research in Tropical disease. As this studies will be performed using sample that have already been taken during the process of your part of clinical research.

4. Do I have to take part?

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason.

5. What will happen if I take part

If you agree, we will ask you to donate your samples of blood collected during research study will be kept at the Mahidol-Oxford Tropical Medicine Research unit Biobank by management and processing by MORU biobank center. This center will provide the service related to collecting, storage, use and distribution of biobanking blood sample inside the affiliate of "Mahido; Oxford Tropical medicine Research Unit". Your sample will be stored in ≤ 10 years and will use in subsequent or future study in tropical disease. Your sample will only be used in ethically approved research with send the notification letter to you every time we use your blood sample.

6. Will my taking part be kept confidential?

Yes, your blood sample, data and information about you will be treated confidentially. We will use the code for your blood sample. We will not give your information to researchers in subsequence and future study that could identify you.

7. What if I change my mind about taking part?

If you decide to withdraw from the study your standard of care will not be affected. You are free to withdraw from the studies at any time and without giving a reason. If you withdraw, you can ask for your blood samples to be destroyed or made irreversible anonymous.

8. How will the information I provide be used?

We plan to publish the results in a health journal so others can read about and learn from the results of the study. Every time that your blood sample data will launch, we will send the result to you via letter.

9. Further Information

If you require more information about this study please call one of the telephone numbers provided to speak to a clinical member of the research team or, alternatively look at Mahidol-Oxford Tropical medicine Research Unit website http://www.tropmedres.ac/home

Thank you for reading this

Please keep this information sheet for your records.

If you agree to enter the study, please sign the enclosed consent form and we will return a copy to you.

Designing an 'Informed Consent Form' for tropical clinical research in Tropical disease affiliate Mahidol-Oxford Tropical medicine Research Unit

Mahidol-Oxford Tropical medicine Research Unit

Informed Consent

Donating blood sample for clinical research in Tropical disease

affiliate Mahidol-Oxford Tropical medicine Research Unit

1	I have read and understood the Patient Information sheet (version number).	☐ Yes Initial_____	☐ No Initial_____
2	I have received, and having had the opportunity to ask question and my question have been answer satisfactorily.	☐ Yes Initial_____	☐ No Initial_____
3	I know how to contact the research team.	☐ Yes Initial_____	☐ No Initial_____
4	I agree to donating my blood sample for this research, subsequent study and future research that affiliate to Mahidol-Oxford Tropical Medicine Research Unit in Tropical disease	☐ Yes Initial_____	☐ No Initial_____
5	I agree that my blood sample will be collected, stored, used and distribution, management and processing by Mahidol-Oxford Tropical Medicine Research Unit Biobank center.	☐ Yes Initial_____	☐ No Initial_____
6	I understand the MORU Biobank center will keep my information confidential. Information will only passed to researchers in an anonymous way that protect my identity.	☐ Yes Initial_____	☐ No Initial_____
7	I agree that my blood sample may be used by researchers for scientific publication, education purpose and for exploring new treatment related to my currently disease.	☐ Yes Initial_____	☐ No Initial_____
8	I agree that if my blood sample will use in commercial organization, I should get notification from researcher and ask me to permit and will get the profit financial from such a product.	☐ Yes Initial_____	☐ No Initial_____
9	I understand result from my blood sample in subsequent study and future research will send to me via letter that contact address provided by me.	☐ Yes Initial_____	☐ No Initial_____
10	I agree that for re-consent process is depend on the requirements of Ethic committee / IRB for each subsequent study and it depend on type of study (eg. Genetic study on disease carriage, commercial study) and where a study procedure new data on my blood sample which could influence my health or treatment.	☐ Yes Initial_____	☐ No Initial_____

I agree to donate blood sample for use in clinical research for Tropical disease affiliate Mahidol-Oxford Tropical medicine Research Unit:

_____ ____ _____

Name and Surname of donor/ clinical participant Initial Signature

_____ _____

Date Time

You will be given a copy of the information sheet and this signed consent form to keep

I have discussed the study with this donor/ clinical participant who has agreed to give informed consent:

_____ ____ _____

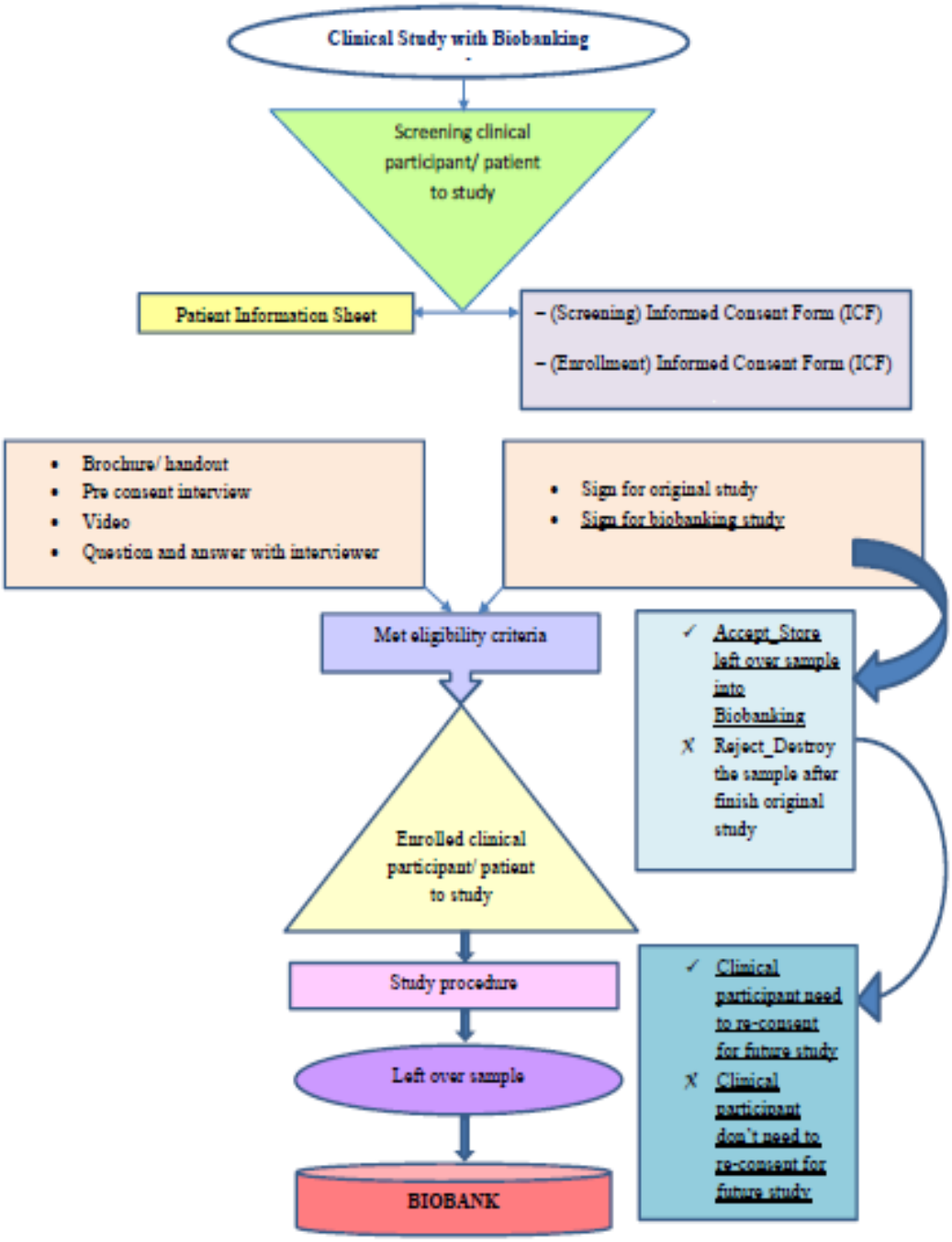
Name and Surname of person taking consent Initial Signature

_____ _____

Date Time

Patient Information sheet and Informed consent form: original to research notes, 1 copy to donor/ clinical participant and 1 copy to Mahidol-Oxford Tropical Medicine research unit biobank center

Figure 15_ Ideal for policy of informed consent for biobanking in Tropical disease projects: principles for good practice



CHAPTER V: DISCUSSION

This chapter presents discussion of the findings, limitation, conclusion, implication and future research for study phase I and phase II.

Discussion phase I

This study explored the attitudes of Thai patients and clinical trial participants towards the unfamiliar concept of biobanking. It showed that most of clinical participants had a generally positive attitude, and were willing to donate samples to a biobank given some caveats on consent, feedback and the nature of future use. This result was consistent with previous study. For instance, one study of parents attitudes on the retention and use of residual newborn screening blood samples indicated that they would be willing to permit use of their children's DBS for future research studies [77]. This finding is also similar to previous study in 2013 [78]. They found that the respondent approached, 521 (88%) agreed to participate in study use of Newborn Dried Blood Spots for Research and they preferred being asked for their consent each time their children's blood spots would be used. They preferred that the children's identity not be linked to the blood spots and that the research will be conducted by university researchers, though these issues had less impact on attitudes than consent. However in 2014, Virgilia T. et al conducted attitudes and willingness to donate biological samples for research among potential donors in the Italian Twin Register and found that more than 80% of respondents expressed willingness to donate their sample [79].

These results suggest the need to survey Thai researchers in the field to gather similar information from potential users of biobank samples similar as Whitley, E.A. et al [80]. They will be used to improve the quality and relevance of information given to

patients, and design a standard informed consent form for research projects in Thailand involving biobanking. They also have implications for planning biobanking projects in Thailand. Such facilities are expensive in terms of staffing, specimen storage (in freezers or liquid nitrogen), administration, computerized audit systems and quality control mechanisms. There would need to be a transparent structure agreed by patient representatives and researchers with clear governance, protection of patient confidentiality and some guarantee that individual patients had access to results and opportunity to re-consent for future studies. Thai patients are willing to participate in biobanking if given the opportunity, but these results argue that a single unified national biobank may be the easiest way to start large scale biobanking trials in Thailand.

The results demonstrate some interesting points, some of them specific to Thailand as a country in which such attitudes have not been explored before. For instance, despite the overwhelmingly Buddhist demographic, the majority of patients would allow retention of a blood sample after death. This result is consistency to Virgilia T. et al 2014 [79] stated that 21.2% of respondents consider donation as a religious/moral duty toward the others ("religious/moral obligation"). However, in this recent study also found that all of the participants were in favors of participating in clinical trials research, and of these (22/24) persons were positive towards biobanking studies on resultant samples. This raises the issue that the participants in this study are open to selection bias, in that their willingness to participate in clinical research might influence both their availability for biobanking trials and a positive general predisposition to being involved in research.

Sample type affected the nature of responses. Because the original clinical trials leading to them being interviewed for this study were based on taking a blood sample,

the respondents were at ease with this, and all would be positive about donating blood samples to a biobank. However they were less familiar with studies which could involve taking DNA or tissue samples. Some level of misunderstanding of the nature of biobanking was implicit in these responses. For instance all participants agreed that sharing blood samples was relatively easy, but only 50% would willingly share DNA, but this is easy to extract from a whole blood sample so such processes should be made clear to participants. This results is similar to the qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria [81] found that participants accepted biobanking once they understand it. Tissue donation was viewed differently from blood, but responses implied that some participants did not realize that they would only be asked for a tissue sample if they were involved in a clinical trial involving tissue collection (such as sampling of surgical resections of cancer tissues). It is very unlikely that a biobanking trial would be approved to allow sampling of tissues from healthy trial participants without a specific hypothesis driven research aim, as this is an invasive procedure which would only be justified by clinical, diagnostic or treatment need. Here biobanking studies are an adjuvant, not the aim of the study. The limitation of this study was conducted at a single hospital, which may not be representative of every institution.

Conclusion phase I

Most respondents have a clearer understanding and positive attitude towards the concept of Biobanking. This study suggests that researchers should provide both written and oral information during enrollment for biobanking studies, giving time for participants to better understand the purpose of biobanking studies prior to signing a

consent form. They have implications for the planning and establishment of Biobanking facilities in Thailand.

Discussion phase II

This study sought to explore the opinions and consensus of researchers with the aim to inform the development process of a policy of informed consent for biobanking. A three-round Policy Delphi technique was used in this study as a 'decision-facilitating' tool. The Policy Delphi does not aim to reach consensus, but rather it explores the various opinions on different policy options with a view to informing the decision-making process [58, 82]. This study sought to explore and determine an appropriate policy of informed consent for biobanking of tropical diseases based on the one hand on the opinions and consensus among experts including Principal Investigators, Co-Investigators, Project managers/Study coordinators, Lab technicians, and Study nurses (Phase II), and on the other hand on the attitudes of clinical participants themselves (Phase I). The inclusion of the latter is in line with Colledge F. & Persson K., 2014 [83], who state that the content of guidelines and recommendations can be helpful for a better justified perspective of biobanking stakeholders and ethical committee members.

A particular strength of this study is that it represents the opinions of policy makers with expertise and qualifications in the area of tropical disease research. They have received specific education on Good Clinical Practice. The Delphi procedure uses two iterations of a questionnaire in rounds I and II, and a different questionnaire in round III to design an informed consent form and patient information sheet. In each round participants submit their responses to the researcher via email. An open-ended

questionnaire was used in round, and sent to the experts via email, while in rounds II and III a link to an online survey (SurveyMonkey), similar to Gill FJ et al 2014 [84].

Grisham T. 2008 [85] state that, natural of this technique is a qualitative approach, not a quantitative approach, which a weakness of Delphi method. It may also not yield exact repeatable results. For instance, if a group of experts were asked to respond to the same questions as the Delphi panel addressed in my work on round two, three and round four, their answers would not be exactly the same.

This study has identified the top priorities in the development of a policy for informed consent regarding tropical disease biobanking: confidentiality, and the advantages/benefits of biobanking. All experts are concerned about the confidentiality of clinical participants involved in biobanking studies. This echoes the results of phase one, in which most participants expressed concern for the confidentiality of their data, and this finding is also consistent with Staunton C. and Moodley K., 2013 [86] and Caenazzo L. et al 2013 [87] who identified data protection and consent as key issues. The consent document protects the participant from potential harm and promotes his/her autonomy and dignity. As for the advantages or benefits of biobanking, both participants in phase one and phase two think that biobanking clinical samples are useful in clinical research and biobanks can store ‘left-over’ samples that remain from specific clinical research trials for potential future use. Biobanks can reduce time and costs for sample collection for similar future studies. In addition, they can reduce subsequent duplicate sampling and facilitate the studying of rare diseases. To our knowledge, this is the first time the Delphi method has been successfully used to inform a policy of informed consent relating to tropical diseases. This is an important first step towards documenting a framework of best practice.

Conclusion phase II

A policy of informed consent for tropical disease biobanking can contribute to the standardization of processes and information for obtaining informed consent from participants or donors. However, this also raises ethical questions, which are not analogous to those encountered in the use of tissue samples from adults or to the issues associated with clinical trials. Moreover, these ethical issues have policy implications. In this study I have presented some issues that should be considered when starting up a biobank or when using existing collections of biological samples for research. Issues include the need for re-consent. When a biobanking policy is developed, the type of biobank in question is also relevant. Different requirements should be taken into account when there is no frequent contact between participant and researcher, or when there is no possibility for genetic counselling. On the one hand, issues such as return of results or re-contact are impossible when samples are completely anonymized, which could be the case in large-scale epidemiological genetic research. On the other hand, withholding relevant medical information or not informing a child about research done on his or her DNA may be unacceptable when there are frequent contacts between researchers and participants or when the research is done in a clinical context.

LIMITATION

1. Biobanking is very new word in Thailand, and participants will need time to understand the concept.

2. The iterations of the Delphi technique require considerable time and effort from.

3. The limitation of this study was conducted at a single hospital, which may not be representative of every institution.

EXPECTED BENEFIT AND APPLICATION

1. The results of this study will help increase knowledge of attitudes to biobanking amongst both clinical research subjects and researchers in Thailand.

2. The study will provide a knowledge base for designing a policy, consent and information sheets for subsequent biobanking programs, to improve the quality of 'informed consent' in such studies.

3. The findings should reduce cost and time for consent procedures in subsequent studies.

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APPENDIX

APPENDIX A

DEMOGRAPHIC INFORMATION (PHASE I)

คำชี้แจง

แบบสอบถามนี้ ผู้วิจัยมีความประสงค์ใคร่ขอความร่วมมือจากท่านในการตอบแบบสอบถามให้ครบทุกข้อตามความเป็นจริง โดยกาเครื่องหมาย ☑ ลงในช่องสี่เหลี่ยม และไม่ต้องลงชื่อในแบบสอบถาม

ข้อมูลส่วนบุคคล

1. เพศ
   - ☐ ชาย
   - ☐ หญิง
2. อายุ
   - ☐ อายุ 20-30 ปี
   - ☐ อายุ 31-40 ปี
   - ☐ อายุ 41-50 ปี
   - ☐ อายุ 51-60 ปี
3. ระดับการศึกษาชั้นสูงสุด
   - ☐ ไม่ได้รับการศึกษา
   - ☐ ประถมศึกษา
   - ☐ มัธยมศึกษา
   - ☐ อนุปริญญาหรืออาชีวศึกษา
   - ☐ ปริญญาตรี
   - ☐ สูงกว่าปริญญาตรี

4. สถานภาพสมรส

☐ โสด

☐ สมรส

☐ หม้าย

☐ หย่า หรือ แยกกันอยู่

5. รายได้ส่วนตัวต่อเดือน

☐ 5,000 บาทหรือต่ำกว่า

☐ 5,001-10,000 บาท

☐ 10,001-20,000 บาท

☐ 20,001-30,000 บาท

☐ 30,000 บาทขึ้นไป

6. อาชีพ

☐ นักเรียน นักศึกษา

☐ ข้าราชการ พนักงานรัฐวิสาหกิจ

☐ พนักงานบริษัทเอกชน

☐ ธุรกิจส่วนตัว อาชีพอิสระ

☐ อื่นๆ กรุณาระบุ……..

7. ศาสนา

☐ พุทธ

☐ คริสต์

☐ อิสลาม

☐ ฮินดู

☐ ซิกข์

☐ อื่นๆ กรุณาระบุ……..

APPENDIX B

BROCHURE OF BIOBANKING (PHASE I)

ไบโอแบงค์)Biobanking) หรือ คลังเนื้อเยื่อเพื่อการวิจัย คืออะไร?

ในขบวนการรักษาโรค หรือการวิจัยในมนุษย์ จะมีชีววัตถุหรือ ตัวอย่างชีวภาพ ได้แก่ เลือด หรือ เนื้อเยื่อ ของผู้ป่วย หรือ ของคนปกติ เหลืออยู่ภายหลังการตรวจเพื่อการรักษาหรือภายหลังเสร็จสิ้นกระบวนการการวิเคราะห์วิจัย ชีววัตถุหรือตัวอย่างชีวภาพเหล่านี้ เป็นทรัพยากรที่มีค่าและสามารถนำไปเก็บไว้เพื่อตรวจวินิจฉัย หรือเพื่อศึกษาวิจัยต่อองค์ความรู้อื่น ๆ ได้ หากมีการบริหารจัดการอย่างเป็นระบบ ปัจจุบันในต่างประเทศมีระบบการบริหารและจัดการเก็บรักษาชีววัตถุให้คงสภาพพร้อมที่จะนำไปใช้ได้เป็นระยะเวลายาวนาน การบริหารจัดการดังกล่าว คือกระบวนการคุณภาพ ที่จะ ต้องมีแนวทางการดำเนินการ ที่ชัดเจนได้มาตรฐานสากล

แนวทางการดำเนินการมาตรฐาน ของคลังเนื้อเยื่อเพื่อการวิจัย

- เริ่มต้นตั้งแต่ระบุชัดเจนในโครงร่างงานวิจัย ต้องมี หนังสืออนุมัติจากคณะกรรมการ คลังเนื้อเยื่อ และเอกสารรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน เพื่อพิจารณา ว่าจะมีการเก็บเหตุผลและความจำเป็นในการเก็บ การมอบมอบเนื้อเยื่อชนิดใด จำนวนและปริมาณ เท่าใด ให้กับใคร เพื่อไปทำอะไร และจะให้ข้อมูลประกอบกับ เนื้อเยื่อที่มอบเพียงใด ตลอดจน ระยะเวลาในการขอเก็บ และต้องระบุ ระเบียบการจัดเก็บเพื่อการสืบค้นในการนำไปใช้ในการส่งมอบแก่ผู้วิจัยจะต้องมีหลักฐาน ประกอบ

- กระบวนการให้ข้อมูลแก่ผู้ป่วย หรือ อาสาสมัคร ที่จะเข้าร่วมโครงการวิจัย เพื่อขอรับบริจาคเนื้อเยื่อจนถึงเนื้อเยื่อมาถึงคลังฯ จะต้องมีการตรวจโดยแพทย์ หรือ พยาธิแพทย์ และจะแบ่งส่วนที่เหลือมาเก็บเพื่อมิให้รบกวนต่อกระบวนการวินิจฉัยโรค

- ต้องมีหนังสือการแสดงเจตนายินยอมในการบริจาคเนื้อเยื่อ ผู้บริจาคมีสิทธิเลือกว่าจะอนุญาตให้เก็บส่งตัวอย่างที่เหลือหรือไม่ โดยที่ต้องการให้ความเคารพในสิทธิส่วนบุคคลของผู้บริจาคเนื้อเยื่อให้แก่คลัง เริ่มจากการเชิญชวนให้บริจาคเนื้อเยื่อ ไปจนถึงมาตรการ รักษาความลับของข้อมูลส่วนบุคคล นี้ เอกสารชี้แจงผู้บริจาคเนื้อเยื่อจะต้องมีข้อมูลเพียงพอที่ จะทำให้ผู้ที่ได้รับการเชิญชวน สามารถตัดสินใจได้ และเน้นย้ำว่า การตัดสินใจไม่ว่าจะบริจาคเนื้อเยื่อหรือไม่จะไม่มีผลกระทบต่อสิทธิและการบริการใดๆอันพึงได้รับรวมถึงการรักษาพยาบาลตามสิทธิด้วย

- การจัดเก็บและนำส่งต้องมาตรการรักษาความลับด้วยการทำรหัส จะต้องมีการเก็บข้อมูลส่วนบุคคลและข้อมูลทางคลินิกร่วมด้วย โดยผู้ที่สามารถเข้าถึงชั้นความลับระดับต่างๆ และขั้นตอนของการนำไปใช้จะต้องมีมาตราฐานและระบุไว้ชัดเจน

- กระบวนการ นำเนื้อเยื่อออกจากร่างกายของผู้บริจาค จนถึงเนื้อเยื่อมาถึงคลัง จะต้องมีการตรวจโดยแพทย์ หรือพยาธิแพทย์ และจะแบ่งส่วนที่เหลือมาเก็บเพื่อมิให้รบกวนต่อกระบวนการวินิจฉัยโรค การรักษาคุณภาพของตัวอย่างชีวภาพ ต้องระบุชัดเจน เช่น เก็บอย่างไร อุณหภูมิเท่าไร ใช้สารเคมีพิเศษอะไร เก็บนานเท่าใด

คลังเนื้อเยื่อเพื่อการวิจัยกับประเทศไทย

- ปัจจุบันนี้ในประเทศไทยยังไม่มีระบบการจัดการและบริหารที่ดี
- ผู้ที่มีความรู้และประสบการณ์มีจำกัด
- ยังไม่มีหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยที่ดีพอ
- ในกรณีที่ ต้องการเนื้อเยื่อจากผู้ที่เป็นโรคที่พบไม่บ่อยผู้วิจัยต้องกลับไปขอความยินยอมจากเจ้าของเนื้อเยื่อทีละราย ทุกครั้งก่อนนำเนื้อเยื่อมาทำวิจัย

ประโยชน์ของการมีหนังสือยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยอย่างเหมาะสม

- เพื่อปกป้องความลับของข้อมูลส่วนบุคคลก่อนส่งมอบให้แก่ผู้วิจัย
- ผู้วิจัยจะได้รับเนื้อเยื่อตรงตามเกณฑ์การคัดเข้าสำหรับการวิจัยโดยไม่ทราบว่าเป็นเนื้อเยื่อของผู้ใด จึงสามารถดำเนินการวิจัยได้อย่างถูกต้องตามหลักเกณฑ์ทางจริยธรรมการวิจัยในคน
- ประหยัดเวลาในการขอรับการรับรองจากคณะกรรมการจริยธรรม การวิจัยในคน เพราะการวิจัยประเภทนี้จัดอยู่ในประเภท ที่มีความเสี่ยงต่ำ
- การรักษา ความลับของข้อมูลส่วนบุคคลเพื่อมิให้เกิดผลกระทบต่อเจ้าของเนื้อเยื่อ โดยการทำรหัส สำหรับการคัดแยก จัด เก็บ และสืบค้น

ตรวจเอกสารโดย อาจารย์แพทย์หญิง พจนีย์ จิตตะมาลา
คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล

ที่มา Biospecimen Banking for Research: Ethical and Pragmatic Considerations
http://www.thaitect.org/th/popup_knowledge.php?knowledge_id=[88] 13

APPENDIX C

แบบสอบถามเชิงลึกเกี่ยวกับทัศนคติ (PHASE I) Thai version

1. คุณรู้สึกอย่างไรเกี่ยวกับการมีส่วนร่วมในการเข้าร่วมศึกษาวิจัยทางคลินิก

.....

.....

2. ปัจจัยอะไรที่มีอิทธิพลต่อการตัดสินใจในการเข้าร่วมศึกษาวิจัยทางคลินิกครั้งนี้หรือครั้งที่ผ่านมา

หัวหน้าโครงการวิจัย.....

พยาบาลวิจัย.....

คนในครอบครัว.....

เพื่อต้องการได้รับสิทธิพิเศษในการรับการรักษาปกติ.....

เพื่อน.....

เพื่อความรู้/ เพื่อการศึกษา.....

ผลประโยชน์ทางการเงิน.....

ปัจจัยอื่นๆ.....

3. คุณคิดว่าคุณเข้าใจจุดประสงค์ของการศึกษานี้ดีเมื่อคุณได้ฟังคำชี้แจงจากผู้วิจัยและก่อนลงลายมือชื่อในหนังสือยินยอมเข้าร่วมการวิจัย

.....

.....

4. คุณเข้าใจเกี่ยวกับคำว่าคลังเนื้อเยื่อเพื่อการวิจัยหลังจากได้อ่านข้อมูลจากจุลสาร (โบโชว์) ว่าคืออะไร

.....

.....

5. สิ่งใดที่คุณคิดว่าอาจจะเป็นข้อดีและข้อเสียของการเก็บรักษาตัวอย่างเลือดสำหรับการศึกษาวิจัยในอนาคต

.....

.....

6. คุณรู้สึกอย่างไรถ้าเราขอตัวอย่างเลือดของคุณที่เจาะเอาไว้แล้วนำไปใช้การศึกษาวิจัยอื่นในอนาคต

.....

.....

7. คุณยินดีที่จะอนุญาติให้ใช้ตัวอย่างเลือดของคุณหรือบริจาคให้คลังเนื้อเยื่อเพื่อการวิจัยสำหรับการใช้งานวิจัยในอนาคต

.....

.....

8. คุณคิดว่าต้องได้รับการยินยอมจากคุณใหม่โดยการลงลายมือชื่อในใบยินยอมเข้าร่วมโครงการวิจัยใหม่หรือไม่ถ้าต้องการนำเลือดของคุณไปใช้

.....

.....

9. คุณคิดว่าผลประโยชน์อะไรที่คุณควรจะได้รับจากการให้ตัวอย่างเลือดของคุณแก่นักวิจัยอื่น หรือโครงการวิจัยอื่น

.....

.....

10. ข้อตกลงของคุณที่จะให้ตัวอย่างเนื้อเยื่อของคุณนั้นขึ้นอยู่กับชนิดตัวอย่างที่จะเก็บ เช่น ตัวอย่างเลือด / อวัยวะภายใน/ ดีเอ็นเอ ใช่หรือไม่

.....

.....

11. ใครที่คุณคิดว่าควรจะรับผิดชอบในการรักษาเก็บรักษาตัวอย่างเลือดของคุณให้ปลอดภัยและ ใครที่สามารถตัดสินใจเลือกว่าตัวอย่างเลือดของคุณจะถูกนำไปใช้

.....

.....

12. ระยะเวลาที่เหมาะสมที่คุณคิดว่าตัวอย่างเลือดของคุณจะถูกเก็บไว้และใช้สำหรับการวิจัย

.....

.....

13. ถ้าหลังจากคุณเสียชีวิตควรทำอย่างไรกับตัวอย่างเลือดของคุณ

.....

.....

14. คุณคิดว่าในแต่ละครั้งของการนำตัวอย่างเลือดของคุณไปศึกษาในงานวิจัยอื่น คุณควรจะได้รับการแจ้งและสอบถามว่าคุณเห็นด้วยกับการนำไปใช้หรือไม่

.....

.....

15. คุณต้องการที่จะรับข้อมูลของผลการศึกษาที่ใช้ตัวอย่างเลือดของคุณหรือไม่เพราะอะไร

.....

.....

16. อะไรคือสิ่งที่อาจมีผลต่อการตัดสินใจของคุณในการอนุญาติให้ใช้ตัวอย่างเลือดเพื่อการวิจัยในอนาคต

ศาสนา

.....

.....

ทัศนคติของครอบครัว

.....

.....

ผลประโยชน์ทางการเงิน –ถ้าโครงการนี้มีการต่อยอดในด้านพาณิชย์คุณคิดว่าท่านต้องการมีส่วนในผลประโยชน์นี้หรือไม่ และถ้าไม่ได้ผลประโยชน์จะยังยินดีเข้าร่วมโครงการวิจัยหรือไม่

.....

.....

มนุษยธรรม — การบริจาคตัวอย่างเลือดของคุณเพื่อการวิจัยทางการแพทย์ในอนาคตซึ่งอาจช่วยคนอื่น ๆ

.....

.....

ความไม่สะดวกสบาย — ถ้าคุณไม่เข้าใจจุดมุ่งหมายที่แท้จริง คุณจะไม่ต้องการที่จะเข้าร่วมในการศึกษาไบโอแบงค์เพราะมันเสียเวลามากและเอกสารมากมายที่ต้องอ่านและต้องให้ความยินยอม

.....

.....

ลูกหลาน/ญาติพี่น้อง — ความรู้เกี่ยวกับโรคใหม่ๆ ที่ได้จากตัวอย่างเลือดคุณอาจจะช่วยสมาชิกในครอบครัวของคุณในอนาคต

.....

.....

ปัจจัยอื่น ๆ.....

17. คุณจะรู้สึกอย่างไรถ้าตัวอย่างเลือดของคุณถูกนำไปใช้โดยนักวิจัยในต่างประเทศเพื่อใช้ในการศึกษาวิจัย

.....

.....

18. คุณจะรู้สึกอย่างไรถ้าตัวอย่างเลือดของคุณถูกนำไปใช้โดยนักวิจัยในเชิงอุตสาหกรรม (เช่น บริษัทยาที่อาจต้องการทำกำไรจากการวิจัยโดยใช้ตัวอย่างเลือดของคุณ)

.....

.....

คุณมีคำถามหรือข้อสงสัยก่อนจะจบสัมภาษณ์ในครั้งนี้หรือไม่

APPENDIX D

ATTITUDES_ In depth interview (PHASE I) English version

1. How do you feel about participating in the clinical study?

…….

…….

2. Were there particular factors influencing this decision?

Principal investigator…….....

Research nurse…….

Family……..

Access to better healthcare……...

Friends……

Knowledge of the study……...

Financial benefits……

Other…….....

3. Do you think you understand the aim of this study based on the information you have been given by the researcher before signing the consent form?

…….

…….

4. What do you understand by the word “Biobanking” after reading the information brochure?

…….

…….

5. What do you think might be the ADVANTAGES and DISADVANTAGES about keeping blood samples for future research projects?

…….

…….

6. How do you feel about being asked if your blood sample can be used in another study by us?

…….

…….

7. Are you willing to share your blood sample or donate it to a Biobank for future use?

…….

…….

8. If your blood sample could be used in future study, would you wish to complete another consent form?

…….

…….

9. Do you expect a benefit for sharing blood samples to other researchers or other studies could be?

…….

…….

10. Would your agreement depend on the sample type – Blood / Organ sample / DNA?

…….

…….

11. Who do you think should be responsible for safe keeping of your blood sample, and deciding what use it is put to?

…….

…….

12. How long do you think a blood sample could be stored and use for?

…….

…….

13. What would prefer to be done with your blood sample after your death?

…….

…….

14. Do you think that each time your blood sample could be used in other research, you should be asked whether or not you agree to its use?

…….

…….

15. Do you want to keep informed of the results of studies using your blood sample?

…….

…….

16. What things might influence your decision for biobanking your blood sample?

Religion

…….

…….

Family attitudes

…….

…….

Monetary benefit – would you be more likely to say yes if you were paid to donate a blood sample

…….

…….

Humanitarian – contributing to future medical research which might help other people

……..

……..

Inconvenience – if you don't understand the aims do you not want to be involved in a Biobanking study it (because it means more time and forms)

……

……

Children / Relatives – knowledge about disease may help members of your family in the future

……

……

Other……

17. How would you feel if blood samples were made available to researchers in another country?

……

……

18. How would you feel if blood samples were made available to researchers in Industry

(like Drug company) who might wish to make a profit out of research using your blood sample?

……

……

.Any questions from you before we finish

APPENDIX E

Round I Questionnaire (Open-end questionnaire) Phase II

DELPHI QUESTIONAIRE FOR RESEARCHERS: DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS: ROUND 1

1. What is your opinion of the usefulness of biobanking clinical samples (such as blood) for use in future research?

……..

……..

2. What is your understanding of the use and aims of biobanking? – do you have any comments as to the following statement as a proposed definition of biobanking?

"A biobank is a repository that stores biological samples (usually human) and associated data for medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by others"

……..

……..

3. What is the best way to explain the biobanking process to clinical research participants/patients in order to gain informed consent for their participation in biobanking trials – information sheets, preconsent interview, any others?

……..

……..

4. What are your concerns as an investigator/researcher about being involved in biobanking studies? (eg use of samples by other investigators or pharma, control of samples, responsibility for consent processes for a study which would not be your own etc.)

……..

……..

5. How do you feel about consenting patients/participants for a biobanking study, which may subsequently involve other research rather than just your own study?

……..

……..

6. What factors would make it easier for you to ask patients/trial participants to donate samples to a biobank, even if this is not the aim of your own study?

……..

……..

7. What factors do you feel might influence a patients decision to consent to donating a sample – eg religious beliefs, altruistic reasons, family interest, financial reward, confidentiality, governance of the biobank?

……..

……..

8. What specific uses of a sample do you feel should be mentioned on a general consent form? eg use of data, ensuring confidentiality, extraction of DNA, sharing with other researchers, use abroad or by pharma

……..

……..

9. Do you think patients should be entitled to compensation/payment for donating samples to a biobank? - if yes what form might this take? - Monetary payment, help with transport costs, access to free medical checkup as part of the workup for your study?

……..

……..

10. Regarding consent, under what circumstances do you think patients should be contacted to consent separately for each subsequent new study that a sample could be used for?

……..

……..

11. How long do you feel it is appropriate for a sample to be kept – is it acceptable to keep and use a sample after a patient death?

……..

……..

12. Do you think participants should be informed the results of subsequent studies using the biobanked sample, and if so how could this be done? eg email, letter, text

……..

……..

13. Do you think if a researcher would like to share samples with researchers abroad, or commercial organisations such as the pharma industry, they should notify participants?

……..

……..

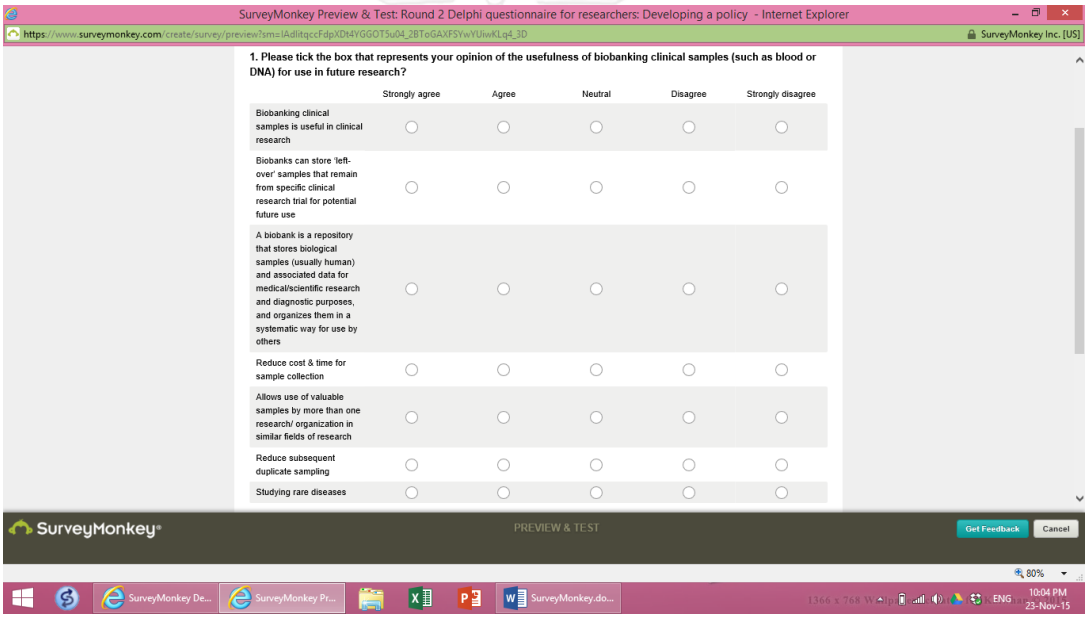
Thank you for your help with this study, please email your responses to Tharisara by 10 days (Toon@tropmedres.ac)

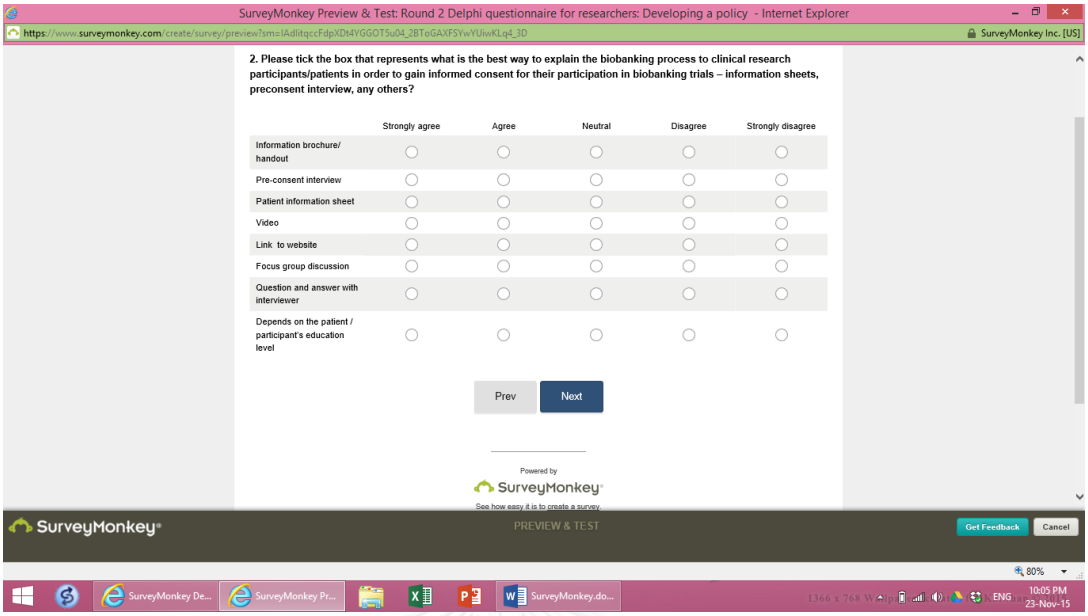
APPENDIX F

Round II Questionnaire (online rating scale questionnaire) Phase II

DELPHI QUESTIONAIRE FOR RESEARCHERS: DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS: ROUND 2

Link: https://www.surveymonkey.com/s/F6ZQKLY




SurveyMonkey Preview & Test: Round 2 Delphi questionnaire for researchers: Developing a policy - Internet Explorer
https://www.surveymonkey.com/create/survey/preview?sm=IAdItqccFdpXDt4YGGOT5u04_2BToGAXF5YwYUiwKLq4_3D
SurveyMonkey Inc. [US]
2. Please tick the box that represents what is the best way to explain the biobanking process to clinical research participants/patients in order to gain informed consent for their participation in biobanking trials – information sheets, preconsent interview, any others?
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
Information brochure/ handout
Pre-consent interview
Patient information sheet
Video
Link to website
Focus group discussion
Question and answer with interviewer
Depends on the patient / participant's education level
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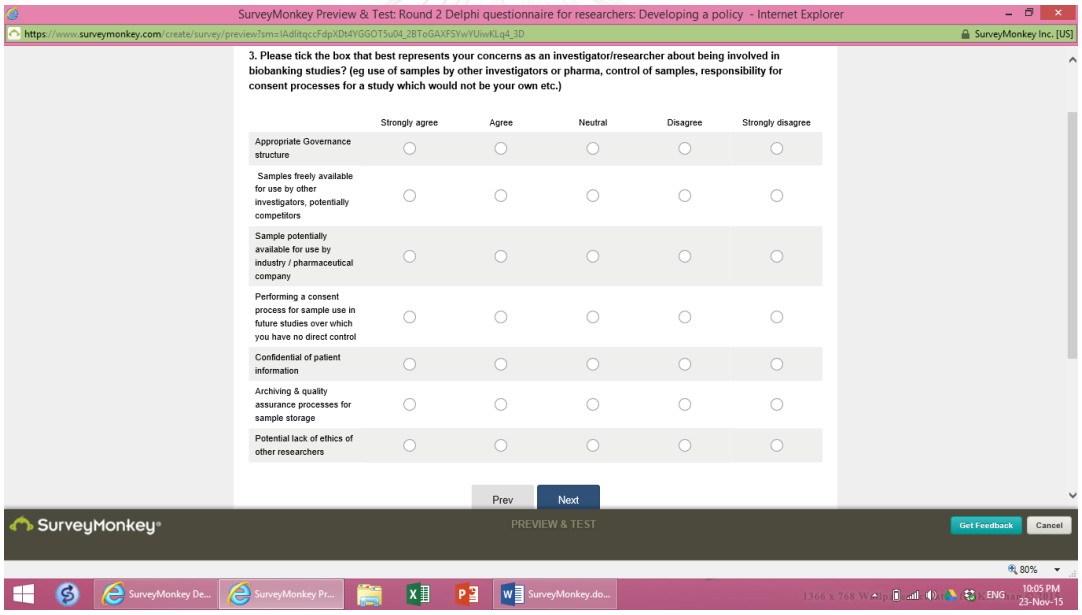
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SurveyMonkey Inc. [US]
3. Please tick the box that best represents your concerns as an investigator/researcher about being involved in biobanking studies? (eg use of samples by other investigators or pharma, control of samples, responsibility for consent processes for a study which would not be your own etc.)
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
Appropriate Governance structure
Samples freely available for use by other investigators, potentially competitors
Sample potentially available for use by industry / pharmaceutical company
Performing a consent process for sample use in future studies over which you have no direct control
Confidential of patient information
Archiving & quality assurance processes for sample storage
Potential lack of ethics of other researchers
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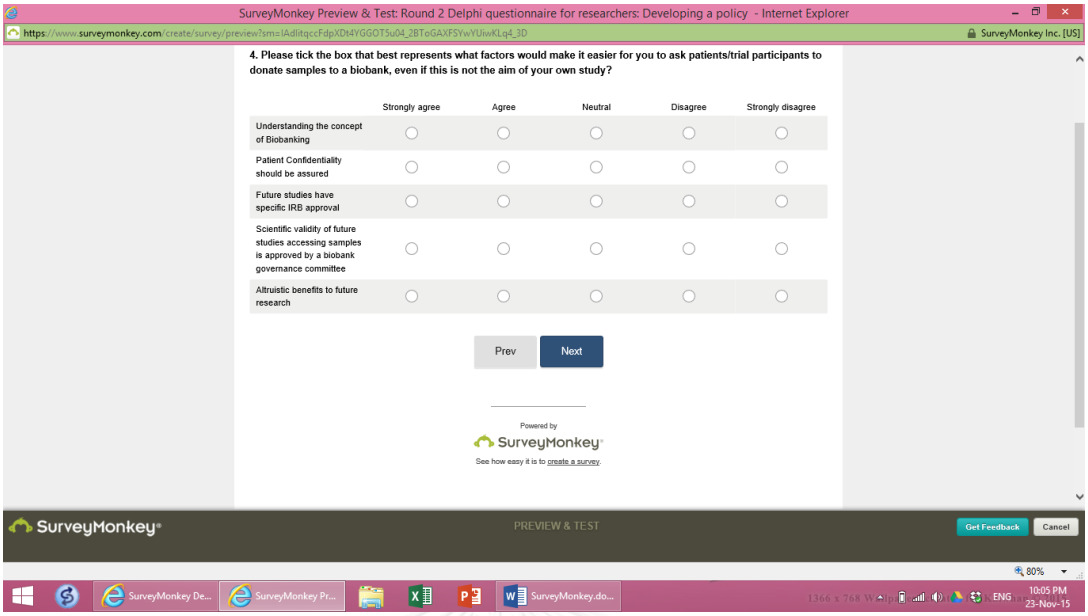
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SurveyMonkey Inc. [US]
4. Please tick the box that best represents what factors would make it easier for you to ask patients/trial participants to donate samples to a biobank, even if this is not the aim of your own study?
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
Understanding the concept of Biobanking
Patient Confidentiality should be assured
Future studies have specific IRB approval
Scientific validity of future studies accessing samples is approved by a biobank governance committee
Altruistic benefits to future research
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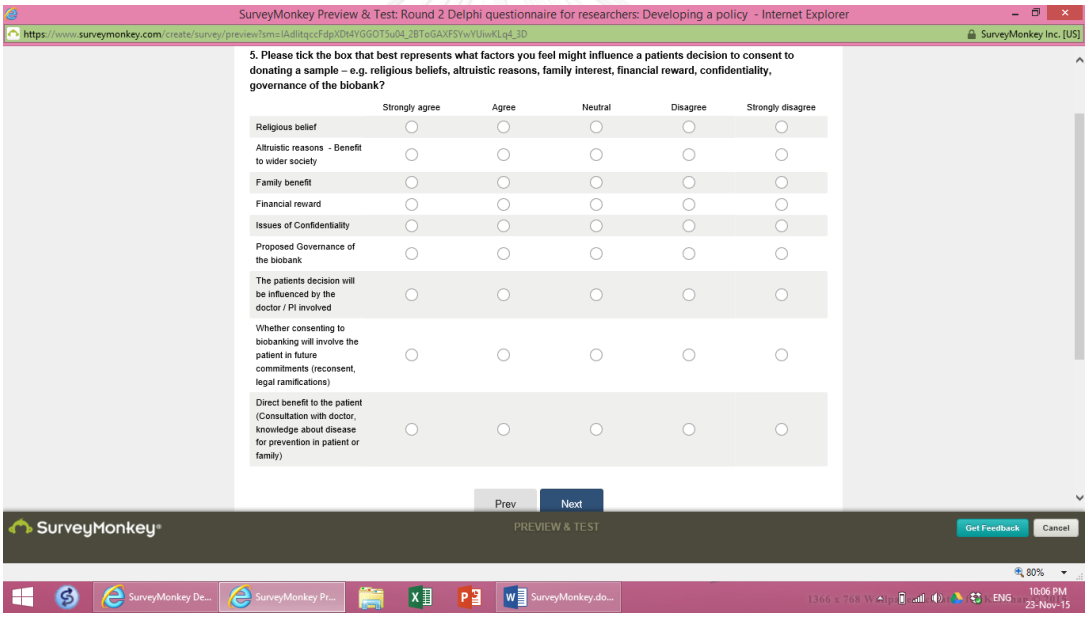
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SurveyMonkey Inc. [US]
5. Please tick the box that best represents what factors you feel might influence a patients decision to consent to donating a sample – e.g. religious beliefs, altruistic reasons, family interest, financial reward, confidentiality, governance of the biobank?
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
Religious belief
Altruistic reasons - Benefit to wider society
Family benefit
Financial reward
Issues of Confidentiality
Proposed Governance of the biobank
The patients decision will be influenced by the doctor / PI involved
Whether consenting to biobanking will involve the patient in future commitments (reconsent, legal ramifications)
Direct benefit to the patient (Consultation with doctor, knowledge about disease for prevention in patient or family)
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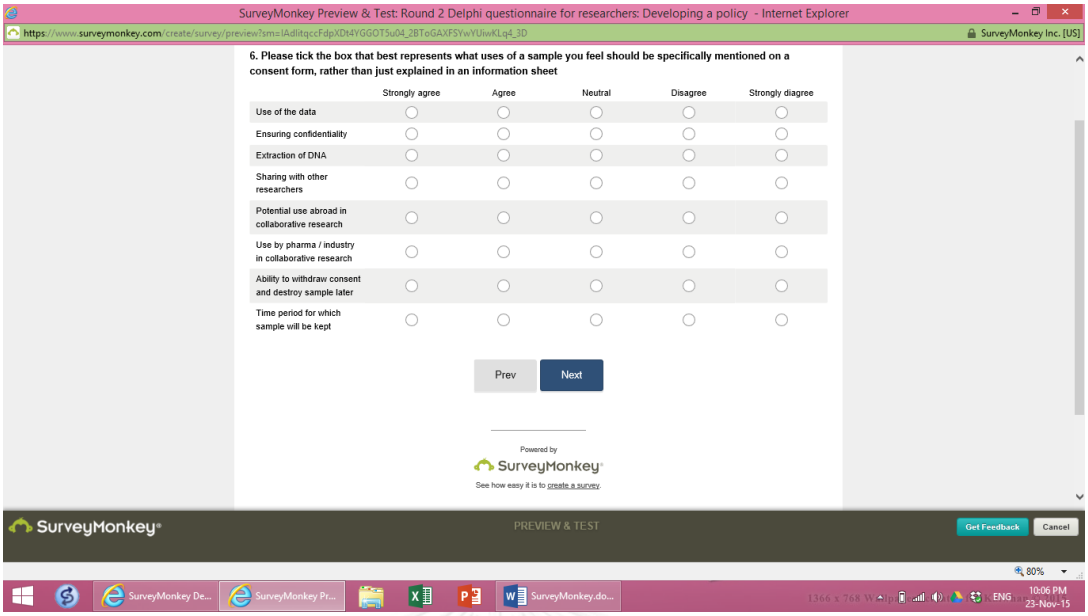
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https://www.surveymonkey.com/create/survey/preview?sm=IAditqccFdpXDt4YGGOT5u04_2BToGAXFSYwYUiwKLq4_3D
SurveyMonkey Inc. [US]
6. Please tick the box that best represents what uses of a sample you feel should be specifically mentioned on a consent form, rather than just explained in an information sheet
Strongly agree
Agree
Neutral
Disagree
Strongly diagree
Use of the data
Ensuring confidentiality
Extraction of DNA
Sharing with other researchers
Potential use abroad in collaborative research
Use by pharma / industry in collaborative research
Ability to withdraw consent and destroy sample later
Time period for which sample will be kept
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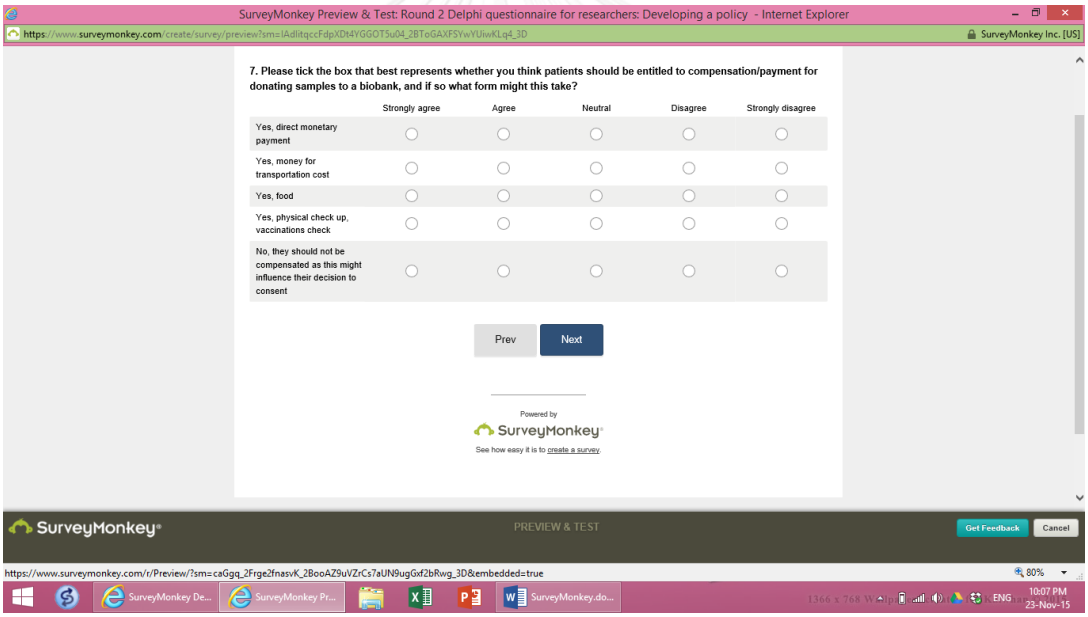
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SurveyMonkey Inc. [US]
7. Please tick the box that best represents whether you think patients should be entitled to compensation/payment for donating samples to a biobank, and if so what form might this take?
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
Yes, direct monetary payment
Yes, money for transportation cost
Yes, food
Yes, physical check up, vaccinations check
No, they should not be compensated as this might influence their decision to consent
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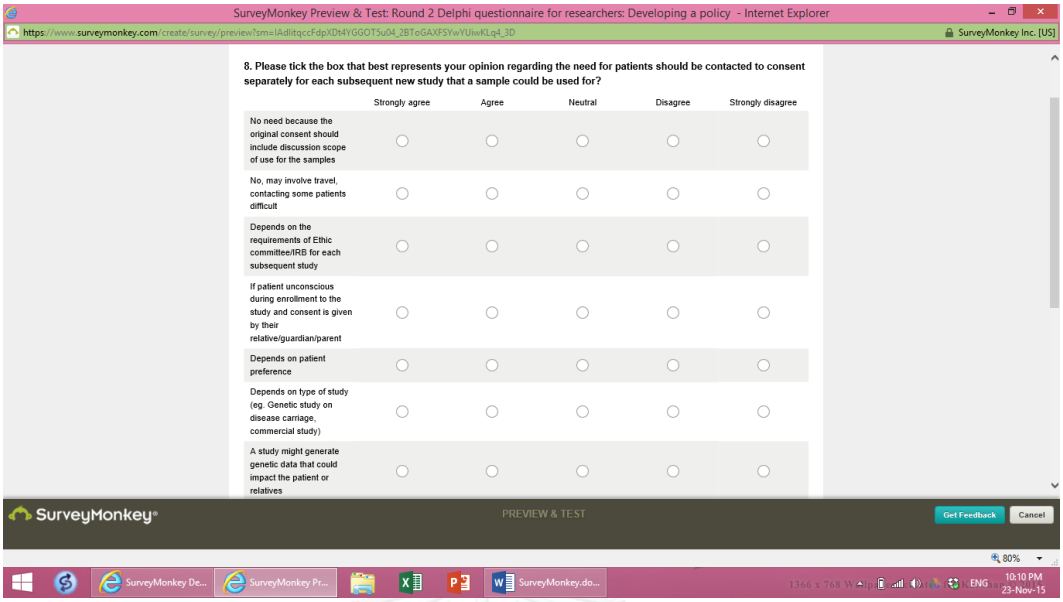
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SurveyMonkey Inc. [US]
8. Please tick the box that best represents your opinion regarding the need for patients should be contacted to consent separately for each subsequent new study that a sample could be used for?
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
No need because the original consent should include discussion scope of use for the samples
No, may involve travel, contacting some patients difficult
Depends on the requirements of Ethic committee/IRB for each subsequent study
If patient unconscious during enrollment to the study and consent is given by their relative/guardian/parent
Depends on patient preference
Depends on type of study (eg. Genetic study on disease carriage, commercial study)
A study might generate genetic data that could impact the patient or relatives
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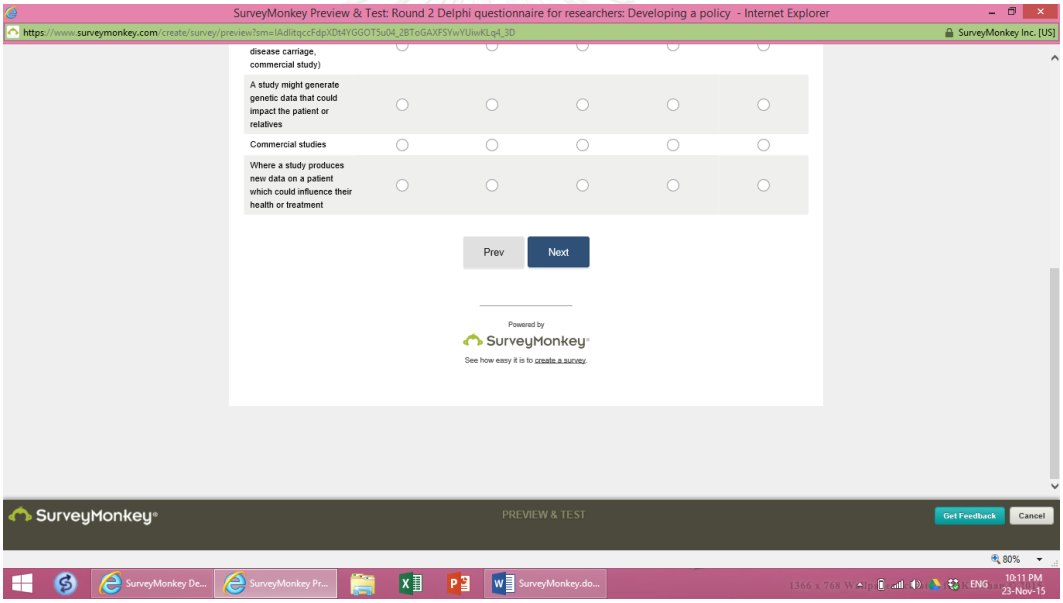
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disease carriage, commercial study)
A study might generate genetic data that could impact the patient or relatives
Commercial studies
Where a study produces new data on a patient which could influence their health or treatment
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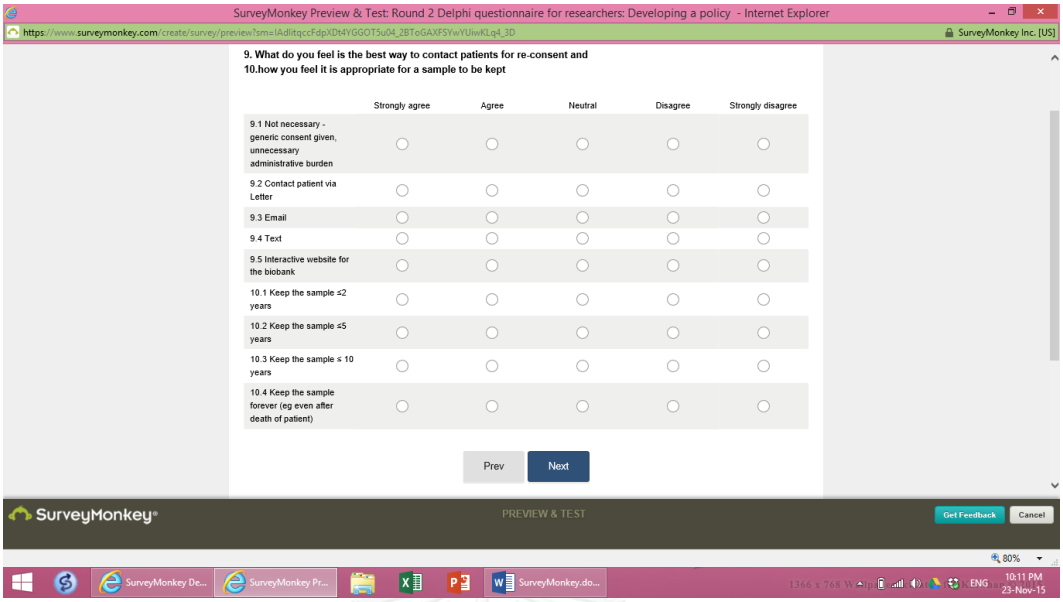
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https://www.surveymonkey.com/create/survey/preview?sm=IAdlitqccFdpXDt4YGGOT5u04_2BToGAXFSYwYUiwKLq4_3D
SurveyMonkey Inc. [US]
9. What do you feel is the best way to contact patients for re-consent and
10.how you feel it is appropriate for a sample to be kept
Strongly agree
Agree
Neutral
Disagree
Strongly disagree
9.1 Not necessary - generic consent given, unnecessary administrative burden
9.2 Contact patient via Letter
9.3 Email
9.4 Text
9.5 Interactive website for the biobank
10.1 Keep the sample ≤2 years
10.2 Keep the sample ≤5 years
10.3 Keep the sample ≤ 10 years
10.4 Keep the sample forever (eg even after death of patient)
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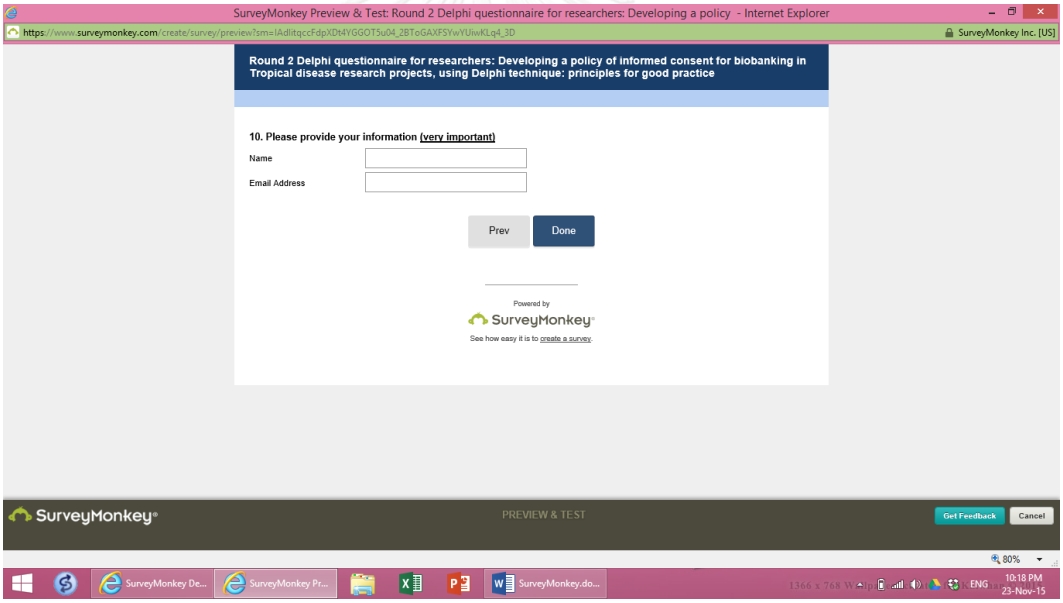
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https://www.surveymonkey.com/create/survey/preview?sm=IAdlitqccFdpXDt4YGGOT5u04_2BToGAXFSYwYUiwKLq4_3D
SurveyMonkey Inc. [US]
Round 2 Delphi questionnaire for researchers: Developing a policy of informed consent for biobanking in Tropical disease research projects, using Delphi technique: principles for good practice
10. Please provide your information (very important)
Name
Email Address
Prev
Done
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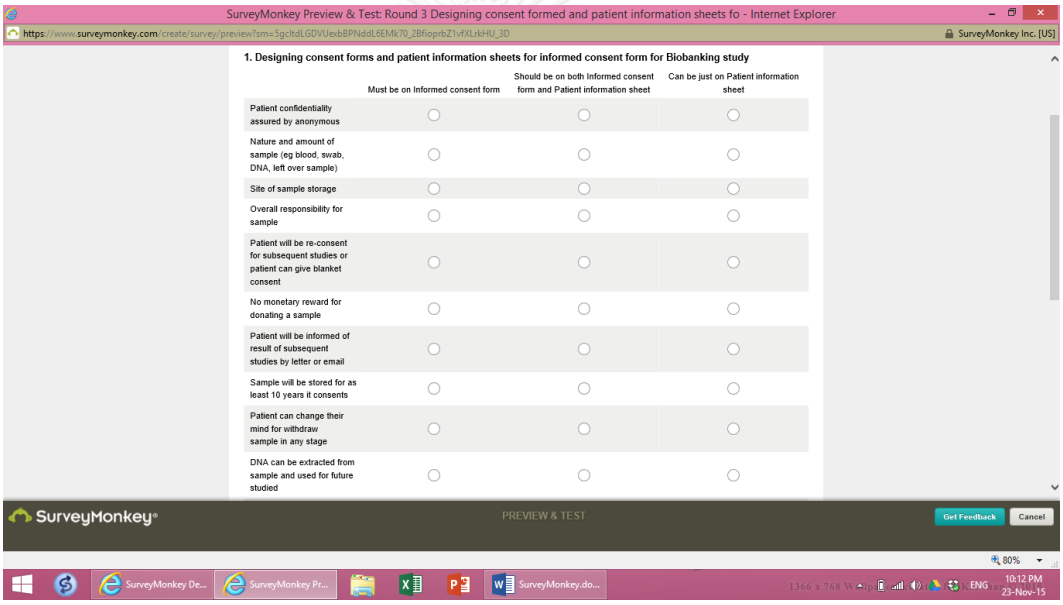
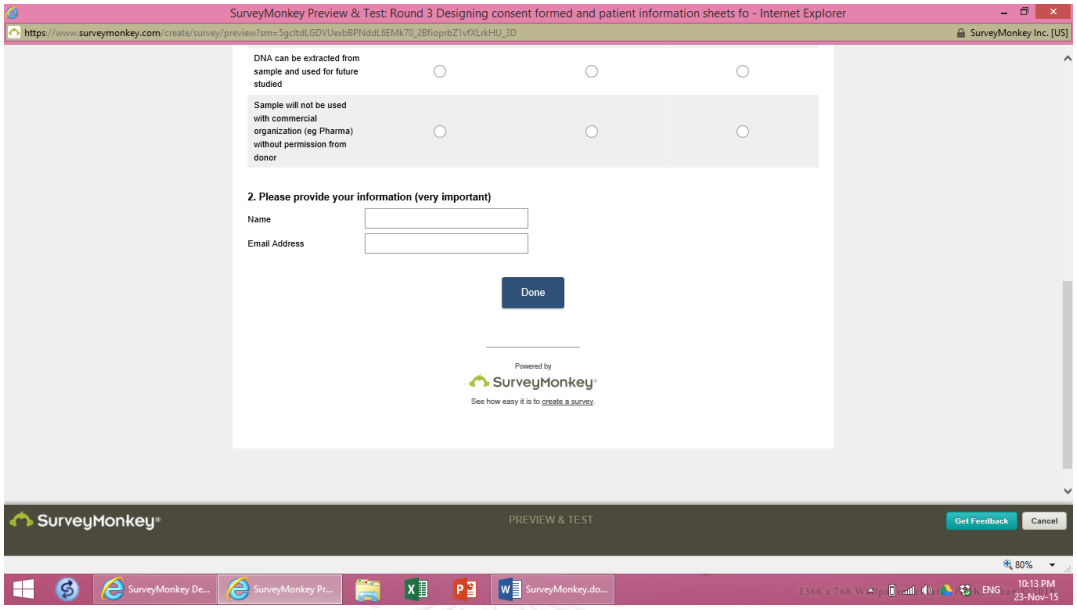
APPENDIX G

Round III Questionnaire (online rating scale questionnaire) Phase II

DELPHI QUESTIONAIRE FOR RESEARCHERS: DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS: ROUND 3

Link: https://www.surveymonkey.com/s/2WWN9LX



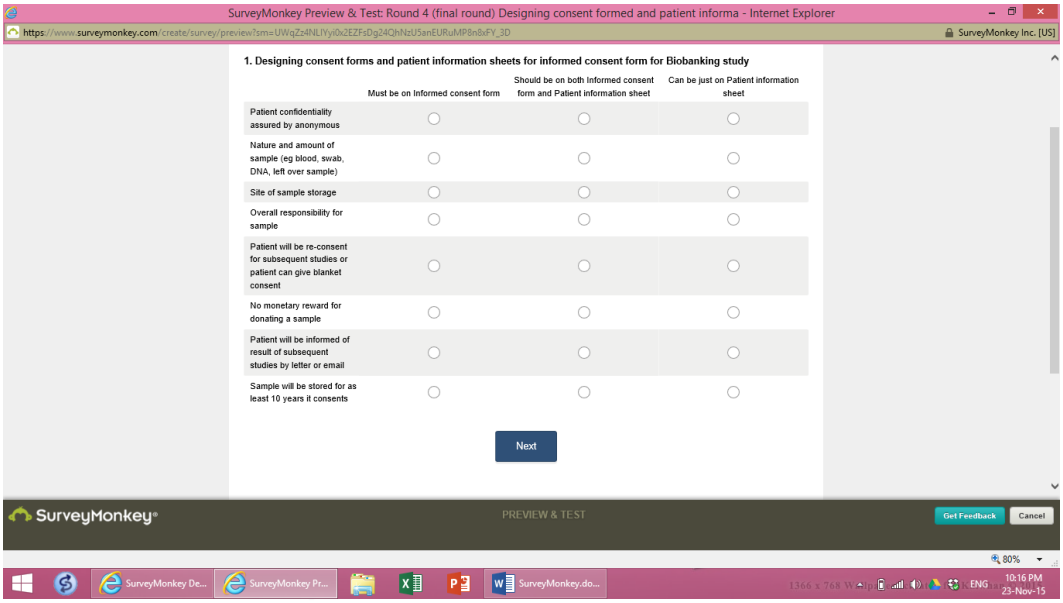


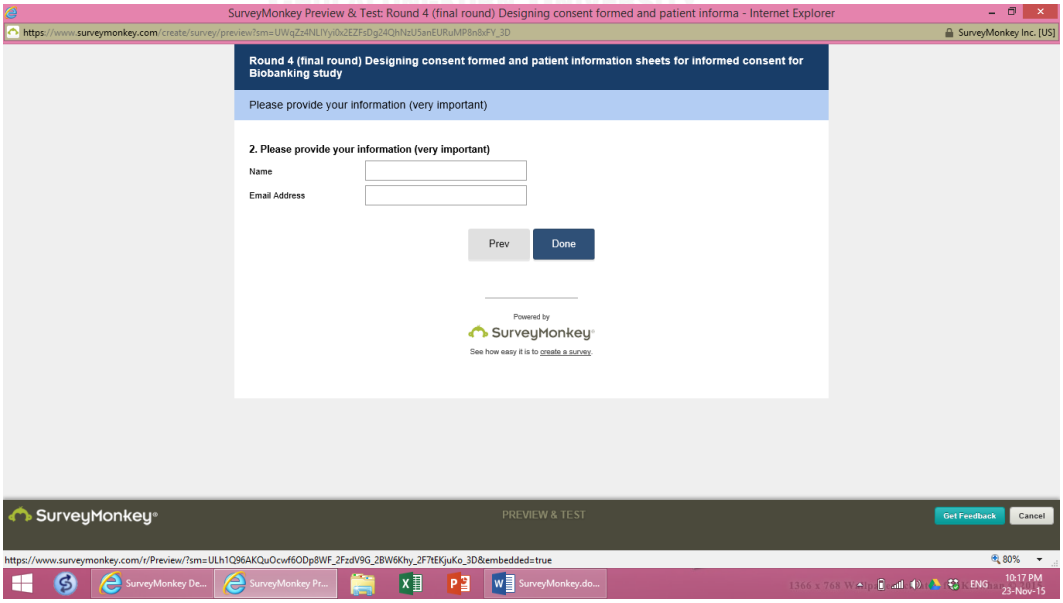
APPENDIX H

Round IV Questionnaire (online rating scale questionnaire) Phase II

DELPHI QUESTIONAIRE FOR RESEARCHERS: DEVELOPING A POLICY OF INFORMED CONSENT FOR BIOBANKING IN TROPICAL DISEASE RESEARCH PROJECTS: ROUND 4

Link: https://www.surveymonkey.com/r/VW8R5LZ





APPENDIX I

INFORMED CONSENT FORM (PHASE I)

	**Informed Consent Form** (FTM ECF-02-03)

หนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัย

(Informed Consent Form)

วันที่……เดือน……พ.ศ. ……

ข้าพเจ้า (นาย /นาง /นางสาว)……นามสกุล……อายุ……ปี

อยู่บ้านเลขที่……หมู่……ตำบล……อำเภอ……จังหวัด……

ขอแสดงเจตนายินยอมเข้าร่วมการวิจัย ในโครงการวิจัยเรื่องการพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยโดยใช้เทคนิคเดลฟาย

โดยข้าพเจ้าได้อ่านเอกสารคำอธิบายโครงการวิจัยและ หรือได้รับฟังคำอธิบายจาก/……(ระบุชื่อผู้ให้ข้อมูล) และได้รับทราบถึงรายละเอียดของโครงการวิจัยเกี่ยวกับวัตถุประสงค์และระยะเวลาที่ทำการวิจัย ขั้นตอนและวิธีการปฏิบัติตัวที่ข้าพเจ้าต้องปฏิบัติ ผลประโยชน์ที่จะได้รับ ผลข้างเคียงหรืออันตรายที่อาจเกิดขึ้นจากการเข้าร่วมโครงการ ตลอดจนค่าตอบแทนที่จะได้รับและค่าใช้จ่ายที่ข้าพเจ้าจะต้องรับผิดชอบจ่ายเอง

และข้าพเจ้ายินยอมให้ผู้วิจัยใช้ข้อมูลส่วนตัวของข้าพเจ้าที่ได้รับจากการวิจัย โดยให้นำเสนอเป็นข้อมูลโดยรวมจากการวิจัยนั้นแต่จะไม่เผยแพร่ ต่อสาธารณะเป็นรายบุคคล ทั้งนี้ สามารถถอนตัวหรืองด

เข้าร่วมการวิจัยได้ทุกเมื่อ โดยจะไม่มีผลกระทบและไม่เสียสิทธิ์ใดๆ ในการรับการบริการและการรักษาพยาบาลที่ข้าพเจ้าจะได้รับต่อไปในอนาคต

หากข้าพเจ้ามีข้อข้องใจเกี่ยวกับขั้นตอนของการวิจัย หรือหากเกิดผลข้างเคียงที่ไม่พึงประสงค์จากการวิจัยขึ้นกับข้าพเจ้า ข้าพเจ้าสามารถติดต่อกับ ธริสรา สกุลแถว หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ชั้น 3 อาคารเฉลิมพระเกียรติครบรอบ 60 ปี 420/6 ถนนราชวิถี เขตราชเทวี กรุงเทพมหานคร 10400 โทรศัพท์ 02-2036324 โทรศัพท์มือถือ 081-4238989

หากข้าพเจ้า ได้รับการปฏิบัติไม่ตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าสามารถติดต่อกับคณะกรรมการจริยธรรมการวิจัยในคน ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล โทรศัพท์ 0 2354 9100-4 ต่อ 1349, 1525 หรือคณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ชั้น 4 อาคารสถาบัน 2 ซอยจุฬาลงกรณ์ 62 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์ 0-2218-8147, 0-2218-8141 โทรสาร 0-2218-8147 E-mail: eccu@chula.ac.th

ข้าพเจ้า เข้าใจข้อความในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และหนังสือแสดงเจตนายินยอมนี้โดยตลอดแล้ว จึงได้ลงนามยินยอมเข้าร่วมโครงการ

ลายมือชื่อผู้เข้าร่วมโครงการวิจัย .....

(…….....)

วันที่……เดือน……..…พ.ศ…..……

ลายมือชื่อผู้ให้ข้อมูล/ ผู้ขอความยินยอม

.....

(…….....)

วันที่……เดือน……..…พ.ศ…..……

APPENDIX J

PATICIPANT INFORMATION SHEET (PHASE I)

	**Participant Information Sheet (**FTM ECF-020-01)

เอกสารชี้แจงผู้เข้าร่วมการวิจัย

(Participant Information Sheet)

ในเอกสารนี้อาจมีข้อความที่ท่านอ่านแล้วยังไม่เข้าใจ โปรดสอบถามหัวหน้าโครงการวิจัย หรือผู้แทนให้ช่วยอธิบายจนกว่าจะเข้าใจดี ท่านอาจจะขอเอกสารนี้กลับไปอ่านที่บ้านเพื่อปรึกษาหารือกับญาติพี่น้อง เพื่อนสนิท แพทย์ประจำตัวของท่าน หรือแพทย์ท่านอื่น เพื่อช่วยในการตัดสินใจเข้าร่วมการวิจัย

ชื่อโครงการ (ภาษาไทย) การพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยโดยใช้เทคนิคเดลฟาย

*** เทคนิคเดลฟายคือ วิธีสำรวจความเห็นจากกลุ่มผู้เชี่ยวชาญในสาขาหนึ่งๆ เพื่อให้ได้คำตอบที่น่าเชื่อถือมากที่สุด โดยให้ผู้เชี่ยวชาญในสาขานั้นๆ ตอบแบบสอบถามชุดเดียวกันหลายครั้ง การสอบถามจะหยุดลงเมื่อได้ข้อสรุปที่ชัดเจน ***

ชื่อผู้วิจัย ธริสรา สกุลแถว

ที่อยู่ที่ติดต่อ หน่วยวิจัยโรคเขตร้อนมหิดล อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ชั้น-3 อาคารเฉลิมพระเกียรติครบรอบ 60 ปี 420/6 ถนนราชวิถี เขตราชเทวี กรุงเทพมหานคร 10400 โทรศัพท์ 02-2036324 โทรศัพท์มือถือ 081-4238989 ตลอด 24 ชั่วโมง

สถานที่วิจัย โรงพยาบาลเวชศาสตร์เขตร้อน เขตราชเทวี กรุงเทพฯ

วัตถุประสงค์ของการวิจัย

เพื่อรวบรวมข้อมูลเกี่ยวกับความเข้าใจและความคิดเห็นของอาสาสมัครที่เข้าร่วมโครงการวิจัยทางคลินิค เรื่องการเก็บเนื้อเยื่อเพื่อนำไปใช้ในการวิจัยในอนาคต

ประโยชน์ที่คาดว่าจะได้รับคือ

ประโยชน์โดยตรงต่ออาสาสมัครของโครงการนี้ คือ เพื่อช่วยเพิ่มพูนความรู้แก่อาสาสมัครทางด้านประโยชน์ของการเก็บเนื้อเยื่อเพื่อนำไปใช้ในการวิจัยในอนาคต นอกจากนี้ ประโยชน์โดยรวมที่ได้จากโครงการนี้ คือ ช่วยลดระยะเวลา และ ค่าใช้จ่ายในการศึกษาวิจัยเรื่องการเก็บเนื้อเยื่อเพื่อนำไปใช้ในการวิจัยในอนาคตอื่นๆ โดยนำหลักปฏิบัติของโครงการนี้ไปใช้ได้เป็นแบบอย่างต่อไป

รายละเอียดของกลุ่มประชากรเข้าร่วมโครงการวิจัย

1. ท่านได้รับเชิญให้เข้าร่วมการวิจัยนี้เพราะท่านมีสัญชาติไทย

2. ท่านมีอายุ 20 ปี-60 ปี

3. ท่านสามารถอ่านและเขียน และพูดภาษาไทยได้

4. ท่านเคยเข้าร่วมการศึกษาหรือกำลังเข้าร่วมการศึกษาวิจัยทางคลินิคทางในโรงพยาบาลเวชศาสตร์เขตร้อนมาก่อน

5.ท่านเคยได้รับการเจาะเลือดจากการเข้าร่วมโครงการวิจัยทางคลินิคมาก่อน

5. ท่านลงลายมือชื่อยินยอมเข้าร่วมโครงการวิจัยทางคลินิค

6. ท่านเสียสละเวลาประมาณ 40 นาที เพื่อกรอกแบบสอบถามเกี่ยวกับข้อมูลส่วนตัวของท่าน และท่านจะถูกสัมภาษณ์จากผู้วิจัยในห้องที่เงียบและเป็นส่วนตัวในวอร์ดบีอี

โดยทั้งนี้จะมีผู้เข้าร่วมการวิจัยทั้งสิ้นประมาณ 24 คน

ขั้นตอนการปฏิบัติตัวหากท่านเข้าร่วมโครงการวิจัย

ถ้าท่านสมัครใจเข้าร่วมโครงการและลงนามในเอกสารยินยอมโดยได้รับการบอกกล่าวแล้ว ผู้วิจัยจะขอให้ท่าน ลงลายมือชื่อยินยอมเข้าร่วมโครงการวิจัย การทำวิจัยนั้นจะเป็นการสัมภาษณ์เท่านั้น และไม่มีการ

ปฏิบัติใดๆ ต่อตัวท่าน แต่ท่านต้องเสียเวลาและอาจรู้สึกอึดอัด เบื่อหน่าย ทั้งนี้ท่านสามารถยุติการตอบคำถามได้ตลอดเวลา

การเข้าร่วมโครงการวิจัยของท่านต้องเป็นไปด้วยความสมัครใจ

หากท่านไม่เข้าร่วมในโครงการวิจัยนี้จะไม่มีผลกระทบใด ๆ ทั้งในปัจจุบันและอนาคตด้านการรักษาพยาบาลของท่านโดยท่านก็จะได้รับการตรวจเพื่อการวินิจฉัยและรักษาโรคของท่านตามวิธีการที่เป็นมาตรฐาน

ผู้วิจัยที่จะสามารถติดต่อได้

หากมีข้อข้องใจที่จะสอบถามเกี่ยวข้องกับการวิจัย ท่านสามารถติดต่อคุณธริสรา สกุลแถว ที่อยู่หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ชั้น 3 อาคารเฉลิมพระเกียรติครบรอบ 60 ปี 420/6 ถนนราชวิถี เขตราชเทวี กรุงเทพมหานคร 10400 โทรศัพท์ 02-2036324 โทรศัพท์มือถือ 081-4238989 ตลอด 24 ชั่วโมง

ค่าตอบแทนที่จะได้รับ

เพื่อเป็นการแสดงความขอบคุณท่านในเข้าร่วมโครงการวิจัยในครั้งนี้ ผู้วิจัยขอมอบค่าเดินทางแก่ท่านเป็นจำนวนเงิน 150 บาท (หนึ่งร้อยห้าสิบบาทถ้วน)

ความเสี่ยงที่จะเกิดแก่ตัวท่าน

โครงการวิจัยนี้เป็นการเก็บข้อมูลเกี่ยวกับทัศนคติของอาสาสมัครต่อโครงการคลังเยื่อเยื่อเพื่อการวิจัย โดยท่านอาจรู้สึกอึดอัดในการตอบคำถาม แต่ขอให้ท่านทำตัวตามสบายในการตอบคำถาม

การรักษาความลับ

1. ข้อมูลส่วนตัวของท่านจะถูกเก็บรักษาไว้ ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล แต่จะรายงานผลการวิจัยเป็นข้อมูลส่วนรวม ข้อมูลของผู้ร่วมการวิจัยเป็นรายบุคคลอาจมีคณะบุคคลบางกลุ่มเข้ามาตรวจสอบได้คือ คณะกรรมการจริยธรรมฯ และ ผู้ให้ทุนวิจัย
2. เทปที่อัดเสียงท่านและเอกสารที่จดบันทึกระหว่างสัมภาษณ์จะถูกทำลายหลังจากการศึกษาเสร็จสิ้นแล้ว 2 ปี ข้อมูลที่ได้จากการอัดเทปและจดบันทึกจะส่งไปให้ท่านได้อ่านหลังจากสัมภาษณ์ท่าน

ประมาณ 1 เดือนทางไปรษณีย์

การถอนตัวออกจากโครงการวิจัย

ท่านมีสิทธิ์ถอนตัวออกจากโครงการวิจัยเมื่อใดก็ได้ โดยไม่ต้องแจ้งให้ทราบล่วงหน้า และการไม่เข้าร่วมการวิจัยหรือถอนตัวออกจากโครงการวิจัยนี้จะไม่มีผลกระทบต่อการบริการและการรักษาที่สมควรจะได้รับแต่ประการใด

หากท่านได้รับการปฏิบัติที่ไม่ตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงนี้ต้องทำอย่างไท่านจะสามารถแจ้งให้คณะกรรมการจริยธรรมฯ ทราบได้ที่ ฝ่ายเลขานุการคณะกรรมการจริยธรรมการวิจัยในคน สำนักงานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล โทร. 0 2354 9100-4 ต่อ 1349, 1525 ต่อ 16-17 หรือคณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ชั้น 4 อาคารสถาบัน 2 ซอยจุฬาลงกรณ์ 62 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์ 0-2218-8147, 0-2218-8141 โทรสาร 0-2218-8147 E-mail: eccu@chula.ac.th

<u>หมายเหตุ</u> : อาสาสมัครจะได้รับสำเนาแบบยินยอมเข้าร่วมโครงการวิจัยพร้อมเอกสารคำชี้แจง 1 ชุด และผู้วิจัยจะเก็บเอกสารไว้ 1 ชุด

APPENDIX K

DEMOGRAPHIC INFORMATION (PHASE II)

Demographic information

1. What is your gender?
   - □ Male
   - □ Female

2. Have you ever been involved in clinical research?
   - □ Yes
   - □ No

3. How long have you been working in clinical research?
   - □ 0- 5 years
   - □ 5-10 years
   - □ 10-15 years
   - □ More than 15 years

4. What is your job level in your organization?
   - □ Manager
   - □ Senior
   - □ Middle
   - □ Junior

APPENDIX L

PATICIPANT INFORMATION SHEET (PHASE II)

	**Participant Information Sheet** (FTM ECF-020-01)

เอกสารชี้แจงผู้เข้าร่วมการวิจัย

ในเอกสารนี้อาจมีข้อความที่ท่านอ่านแล้วยังไม่เข้าใจ โปรดสอบถามหัวหน้าโครงการวิจัย หรือผู้แทนให้ช่วยอธิบายจนกว่าจะเข้าใจดี ท่านอาจจะขอเอกสารนี้กลับไปอ่านที่บ้านเพื่อปรึกษาหารือกับญาติพี่น้อง เพื่อนสนิท แพทย์ประจำตัวของท่าน หรือแพทย์ท่านอื่น เพื่อช่วยในการตัดสินใจเข้าร่วมการวิจัย

ชื่อโครงการ (ภาษาไทย) การพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยโดยใช้เทคนิคเดลฟาย

*** เทคนิคเดลฟายคือ วิธีสำรวจความเห็นจากกลุ่มผู้เชี่ยวชาญในสาขาหนึ่งๆ เพื่อให้ได้คำตอบที่น่าเชื่อถือมากที่สุด โดยให้ผู้เชี่ยวชาญในสาขานั้นๆ ตอบแบบสอบถามชุดเดียวกันหลายครั้ง การสอบถามจะหยุดลงเมื่อได้ข้อสรุปที่ชัดเจน ***

ชื่อผู้วิจัย ธริสรา สกุลแถว

สถานที่วิจัย

1. หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล กรุงเทพมหานคร
2. หน่วยวิจัยมาเลเรียโซโคล จังหวัดตาก
3. ศูนย์วิจัยโรคเมลิออยโดสิสมหิดล-อ๊อกฟอร์ด โรงพยาบาลสรรพสิทธิประสงค์ จังหวัดอุบลราชธานี

วัตถุประสงค์ของการวิจัย

เพื่อพัฒนานโยบายและรูปแบบของความหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัย เพื่อเพิ่มความปลอดภัยของข้อมูล และความลับของข้อมูลที่เกี่ยวข้องกับการวิจัย รูปแบบที่ได้จะนำไปใช้ในการขอความยินยอมในอาสาสมัครที่เข้าโครงการเกี่ยวข้องกับโครงการคลังเนื้อเยื่อเพื่อการวิจัยในอนาคตต่อไป และเพื่อให้แน่ใจว่าการขอความยินยอมสำหรับการศึกษาโครงการคลังเนื้อเยื่อเพื่อการวิจัยจะดำเนินการอย่างถูกต้องตามหลักจริยธรรมการวิจัยในคน

ประโยชน์ที่คาดว่าจะได้รับคือ

ผลของการศึกษาจะนำมาพัฒนาและกำหนดนโยบายหนังสือยินยอมเข้าร่วมคลังเนื้อเยื่อเพื่อการวิจัยเพื่อกำหนดให้เป็นรูปแบบมาตราฐานของเครือข่ายมหิดล-อ๊อกฟอร์ด ในประเทศไทย เพื่อลดภาระเจ้าหน้าที่ที่รับผิดชอบโครงการคลังเนื้อเยื่อเพื่อการวิจัยและในเวลาเดียวกันเพื่อป้องกันสิทธิของผู้เข้าร่วมการวิจัย ผลของการศึกษานี้ยังช่วยลดเวลา ค่าใช้จ่ายและกระบวนการของการขอความยินยอมเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัยในอนาคต

ท่านได้รับเชิญให้เข้าร่วมการวิจัยนี้เพราะท่านเป็นพนักงานหรือทำงานอยู่ในเครือข่ายของหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด มีประสบการณ์ด้านการวิจัยทางคลินิคโดยเป็นผู้วิจัยหลัก ผู้วิจัยรอง ผู้ประสานงานวิจัย พยาบาลวิจัย และผู้ออกนโยบายในหน่วยวิจัยโรคเขตร้อนมหิดลอ๊อกฟอร์ด โดยจะมีผู้เข้าร่วมการวิจัยนี้ทั้งสิ้นประมาณ 30 คน ระยะเวลาที่จะทำการวิจัยทั้งสิ้น 4 เดือน การวิจัยนี้เป็นการวิจัยช่วงที่สอง โดยจะนำข้อมูลจากการที่ได้จากช่วงแรกมาระบุปัญหาและพัฒนาแบบสอบถามช่วงที่สองให้สอดคล้องกับอิทธิพลที่มีผลต่อการเข้าร่วมโครงการคลังเนื้อเยื่อเพื่อการวิจัย ในการวิจัยระยะที่สองผู้วิจัยจะใช้แบบสอบถามโดยใช้เทคนิคเดลฟายโดยจะส่งให้ผู้เข้าร่วมโครงการวิจัย การวิจัยช่วงที่สองนี้จะมีการเปรียบเทียบมุมมองจากทั้งอาสาสาสมัครและนักวิจัยโดยใช้เทคนิคเดลฟายเพื่อพัฒนานโยบาย เพิ่มคุณภาพ มาตราฐานของรูปแบบของแบบสอบถามและเอกสารชี้แจงผู้เข้าร่วมที่ใช้ในโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยในเครือของหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คน โดยการส่งแบบสอบถามให้ผู้เข้าร่วมโครงการวิจัยแบ่งออกเป็นสี่รอบดังนี้

รอบที่ 1 : แบบสอบถามรอบที่ 1 จะเป็นแบบสอบถามแบบปลายเปิด ซึ่งเป็นการถามอย่างกว้าง ๆ ให้ครอบคลุมประเด็นปัญหาของการวิจัย เพื่อต้องการเก็บรวบรวมความคิดเห็นจากกลุ่มผู้เชี่ยวชาญแต่ละคน กำหนดเวลาในการส่งแบบสอบถามกลับคืนภายในเวลา 10 วัน สำหรับการวิเคราะห์คำตอบแบบสอบถาม

รอบนี้ ผู้วิจัยจะรวบรวมความคิดเห็นและวิเคราะห์คำตอบโดยละเอียดแล้วนำมาสังเคราะห์เป็นประเด็นต่าง ๆ เพื่อกำหนดกรอบของปัญหาในรอบต่อไป

รอบที่ 2 : แบบสอบถามรอบที่ 2 พัฒนาจากคำตอบของแบบสอบถามในรอบที่หนึ่ง โดยสรุปข้อมูลการวิจัยบนพื้นฐานของข้อมูลที่ให้ไว้ในรอบแรก ข้อมูลที่ซ้ำกันจะลบจากแบบสอบถามและพัฒนาแบบสอบถามสำหรับรอบสองแล้วถามผู้เข้าร่วมคนเดียวกันในเพื่อตอบแบบสอบถามอีกครั้ง ผลที่ได้จากรอบที่สองสามารถที่จะระบุถึงความคิดเห็นที่แตกต่างกันและเหมือนกัน ซึ่งผู้ทำวิจัยสามารถนำเสนอข้อมูลให้แก่ผู้เข้าร่วมการวิจัย

รอบที่ 3 : แบบสอบถามรอบที่ 3 เป็นการพัฒนาแบบสอบถามจากรอบที่ 2 โดยมีข้อคำถามเดียวกันกับแบบสอบถามรอบที่ 2 และเขียนเครื่องหมายแสดงข้อคำตอบที่ผู้เชี่ยวชาญผู้นั้นได้ตอบในแบบสอบถามรอบที่ 2 ลงไป แล้วส่งกลับไปให้ผู้เชี่ยวชาญคนเดิมอีกครั้งหนึ่ง เพื่อให้ยืนยันคำตอบเดิมหรือเปลี่ยนแปลงคำตอบใหม่ ถ้ามีการเปลี่ยนแปลงคำตอบที่นอกเหนือจากคำตอบเดิมให้ระบุเหตุผลที่ไม่ได้อยู่ในคำตอบเดิม ผู้ที่เข้าร่วมโครงการจะได้รับโอกาสในการชี้แจงเหตุผลของคำตอบที่ให้ เมื่อเปรียบเทียบกับรอบที่แล้ว อาจจะมีการเปลี่ยนแปลงความคิดเห็นเพียงเล็กน้อยเท่านั้นเมื่อเปรียบเทียบกับรอบที่ผ่านมา

รอบที่ 4 :แบบสอบถามรอบที่ 4 เป็นรอบสุดท้าย กระทำตามขั้นตอนเดียวกันกับรอบที่ 3 ซึ่งถ้าผลการวิเคราะห์ข้อมูลที่ได้ในรอบนี้ได้คำตอบที่สอดคล้องกัน แสดงว่า ความคิดเห็น ที่ได้จากผู้เชี่ยวชาญเป็นอันหนึ่งอันเดียวกัน ก็สามารถยุติกระบวนการวิจัยและสรุปผลการวิจัยได้ โดยทั่วไปการวิจัยด้วยเทคนิคเดลฟาย ความคิดเห็นของผู้เชี่ยวชาญในรอบที่ 3 และรอบที่ 4 จะมีความแตกต่างกันน้อยมาก

ขั้นตอนการปฏิบัติตัวหากท่านเข้าร่วมโครงการวิจัย

ถ้าท่านสมัครใจเข้าร่วมโครงการและลงนามในเอกสารยินยอมโดยได้รับการบอกกล่าวแล้ว ผู้วิจัยจะขอให้ท่าน ลงลายมือชื่อยินยอมเข้าร่วมโครงการวิจัย การทำวิจัยนั้นจะเป็นการส่งแบบสอบถามไปให้ท่านทางจดหมายอิเล็กทรอนิกส์ และไม่มีการปฏิบัติใดๆ ต่อตัวท่าน แต่ท่านต้องเสียเวลาและอาจรู้สึกอึดอัดเบื่อหน่าย ทั้งนี้ท่านสามารถยุติการตอบคำถามได้ตลอดเวลา

การเข้าร่วมโครงการวิจัยของท่านต้องเป็นไปด้วยความสมัครใจ

หากท่านไม่เข้าร่วมในโครงการวิจัยนี้จะไม่มีผลกระทบใด ๆ ทั้งในปัจจุบันและอนาคตของท่าน

ผู้วิจัยที่จะสามารถติดต่อได้

หากมีข้อข้องใจที่จะสอบถามเกี่ยวข้องกับการวิจัยท่านสามารถติดต่อคุณธริสรา สกุลแถว ที่อยู่ หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ชั้น 3 อาคารเฉลิมพระเกียรติครบรอบ 60 ปี 420/6 ถนนราชวิถี เขตราชเทวี กรุงเทพมหานคร 10400 โทรศัพท์ 02-2036324 โทรศัพท์มือถือ 081-4238989 ตลอด 24 ชั่วโมง

ค่าตอบแทนที่จะได้รับ

เพื่อเป็นแสดงความขอบคุณผู้วิจัยขอมอบชุดน้ำชาเป็นของขวัญให้แก่ท่านจำนวน 1 ชุด

ความเสี่ยงที่จะเกิดแก่ตัวท่านและผู้อื่น

โครงการวิจัยนี้เป็นการเก็บข้อมูลแบบสอบถามเกี่ยวกับการหาความคิดเห็นร่วมกันของอาสาสมัครต่อหนังสือยินยอมคลังเยื่อเยื่อเพื่อการวิจัย เพื่อจะกำหนดนโยบายร่วมกันในเครือข่ายหน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ดโดยจะไม่มีความเสี่ยงทั้งทางตรงและทางอ้อมต่อผู้เข้าร่วมโครงการ

การรักษาความลับ

ข้อมูลส่วนตัวของท่านจะถูกเก็บรักษาไว้ ไม่เปิดเผยต่อสาธารณะเป็นรายบุคคล แต่จะรายงานผลการวิจัยเป็นข้อมูลส่วนรวม ข้อมูลของผู้ร่วมการวิจัยเป็นรายบุคคลอาจมีคณะบุคลบางกลุ่มเข้ามาตรวจสอบได้ คือ คณะกรรมการจริยธรรมฯ และ ผู้ให้ทุนวิจัย

การถอนตัวออกจากโครงการวิจัย

ท่านมีสิทธิ์ถอนตัวออกจากโครงการวิจัยเมื่อใดก็ได้ โดยไม่ต้องแจ้งให้ทราบล่วงหน้า และการไม่เข้าร่วมการวิจัยหรือถอนตัวออกจากโครงการวิจัยนี้จะไม่มีผลกระทบต่อตัวท่านแต่ประการใด

หากท่านได้รับการปฏิบัติที่ไม่ตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงนี้ต้องทำอย่างไร

ท่านจะสามารถแจ้งให้คณะกรรมการจริยธรรมฯ ทราบได้ที่ ฝ่ายเลขานุการคณะกรรมการจริยธรรมการวิจัยในคน สำนักงานบริการการวิจัย ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล โทร. 0 2354 9100-4 ต่อ 1349, 1525 ต่อ 16-17 หรือคณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ชั้น 4 อาคารสถาบัน 2 ซอยจุฬาลงกรณ์ 62 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์ 0-2218-8147, 0-2218-8141 โทรสาร 0-2218-8147 E-mail: eccu@chula.ac.th

<u>หมายเหตุ</u> : อาสาสมัครจะได้รับสำเนาแบบยินยอมเข้าร่วมโครงการวิจัยพร้อมเอกสารคำชี้แจง 1 ชุด และผู้วิจัยจะเก็บเอกสารไว้ 1 ชุด

APPENDIX M

INFORMED CONSENT FORM (PHASE II)

	**Informed Consent Form** (FTM ECF-021-03)

หนังสือแสดงเจตนายินยอมเข้าร่วมการวิจัย

(Informed Consent Form)

วันที่……เดือน……พ.ศ. ……

ข้าพเจ้า (นาย /นาง /นางสาว)……นามสกุล……..

อายุ……..ปี อยู่บ้านเลขที่……หมู่…….....ตำบล…….....อำเภอ.....…...

จังหวัด…….....ขอแสดงเจตนายินยอมเข้าร่วมการวิจัย ในโครงการวิจัยเรื่องการพัฒนานโยบายของหนังสือยินยอมเข้าร่วมโครงการวิจัยคลังเนื้อเยื่อเพื่อการวิจัยโดยใช้เทคนิคเดลฟาย

โดยข้าพเจ้าได้อ่านเอกสารคำอธิบายโครงการวิจัยและ/ หรือได้รับฟังคำอธิบายจาก ..... (ระบุชื่อผู้ให้ข้อมูล) และได้รับทราบถึงรายละเอียดของโครงการวิจัยเกี่ยวกับวัตถุประสงค์และระยะเวลาที่ทำการวิจัย ขั้นตอนและวิธีการปฏิบัติตัวที่ข้าพเจ้าต้องปฏิบัติ ผลประโยชน์ที่จะได้รับ ผลข้างเคียงหรืออันตรายที่อาจเกิดขึ้นจากการเข้าร่วมโครงการ ตลอดจนค่าตอบแทนที่จะได้รับและค่าใช้จ่ายที่ข้าพเจ้าจะต้องรับผิดชอบจ่ายเอง

และข้าพเจ้ายินยอมให้ผู้วิจัยใช้ข้อมูลส่วนตัวของข้าพเจ้าที่ได้รับจากการวิจัย โดยให้นำเสนอเป็นข้อมูลโดยรวมจากการวิจัยนั้นแต่จะไม่เผยแพร่ ต่อสาธารณะเป็นรายบุคคล ทั้งนี้ สามารถถอนตัวหรืองด

เข้าร่วมการวิจัยได้ทุกเมื่อ โดยจะไม่มีผลกระทบและไม่เสียสิทธิ์ใดๆ ในการรับการบริการและการรักษาพยาบาลที่ข้าพเจ้าจะได้รับต่อไปในอนาคต

หากข้าพเจ้ามีข้อข้องใจเกี่ยวกับขั้นตอนของการวิจัย ข้าพเจ้าสามารถติดต่อกับ ธริสรา สกุลแถว หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล ชั้น 3 อาคารเฉลิมพระเกียรติครบรอบ 60 ปี 420/6 ถนนราชวิถี เขตราชเทวี กรุงเทพมหานคร 10400 โทรศัพท์ 02-2036324 โทรศัพท์มือถือ 081-4238989 หากข้าพเจ้า ได้รับการปฏิบัติไม่ตรงตามที่ได้ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าสามารถติดต่อกับคณะกรรมการจริยธรรมการวิจัยในคน ชั้น 4 อาคารเฉลิมพระเกียรติฉลองสิริราชสมบัติครบ 60 ปี คณะเวชศาสตร์เขตร้อน มหาวิทยาลัยมหิดล โทรศัพท์ 0 2354 9100-4 ต่อ 1349, 1525หรือคณะกรรมการพิจารณาจริยธรรมการวิจัยในคน กลุ่มสหสถาบัน ชุดที่ 1 จุฬาลงกรณ์มหาวิทยาลัย ชั้น 4 อาคารสถาบัน 2 ซอยจุฬาลงกรณ์ 62 ถนนพญาไท เขตปทุมวัน กรุงเทพฯ 10330 โทรศัพท์ 0-2218-8147, 0-2218-8141 โทรสาร 0-2218-8147 E-mail: eccu@chula.ac.th

ข้าพเจ้า เข้าใจข้อความในเอกสารชี้แจงผู้เข้าร่วมการวิจัย และหนังสือแสดงเจตนายินยอมนี้โดยตลอดแล้ว จึงได้ลงนามยินยอมเข้าร่วมโครงการ

ลายมือชื่อผู้เข้าร่วมโครงการวิจัย .....

(…….....)

วันที่……เดือน……..….พ.ศ…...…

ลายมือชื่อผู้ให้ข้อมูล/ ผู้ขอความยินยอม .....

(…….....)

วันที่……เดือน……..….พ.ศ…...…

APPENDIX N

PARTICIPANT INFORMATION SHEET FOR INTERVIEW PROVIDER (PHASE II)

Participant information sheet

Provider interviews

This document may contain statements that you do not understand, please ask the study staff to explain to you until you completely understand them. You may discuss with your family, friends, or doctors to help you make your decision whether or not to take part in the study.

Study title:	Developing a policy of informed consent for research biobanking in MORU Thailand; using Delphi technique
Principle Investigator:	Ms. Tharisara Sakulthaew
Co-Investigators:	Dr. Kanchana Rungsihirunrat, PhD Dr. Gareth Turner, MD, DPhil Dr. Phaik Yeong Cheah, B.Pharm, PhD
Location of study	1.Mahidol-Oxford Tropical Medicine Reseach Unit; Mahidol University, Bangkok, Thailand 2. Shoklo Malaria Research Unit (SMRU), Tak, Thailand 3. Lab Melioidosis Mahidol-Oxford Tropical Medicine Research Unit; Sappasitthiprasong hospital, Ubon Ratchathani, Thailand
Funding:	Mahidol-Oxford Tropical Medicine Research Unit

Objective of the study

To design a model of informed consent and develop a policy of informed consent for biobanking studies to ensure confidentiality and security of related data. The master policy narratives will be derived through these consensus results. The tools will

reduce the burden placed on research staff responsible for the generic projects and, at the same time, maximize the protection of research participants.

Will this study help you or others?
We believe that this study will help developing appropriate models and policy of good sample sharing practice. Research on public opinion regarding privacy and the use of research information informs our understanding of public support for sharing of research information provides insights as to how to govern and organize so as to promote public engagement and trust.

What do you have to do if you decide to take part?
We are going to conduct the Delphi method, this is the second phase, using the results from phase I to identify and develop a content of informed consent of biobanking as a policy to improve the quality and standardization for affiliates of Mahidol-Oxford Tropical Medicine Research Unit (MORU); Bangkok Thailand. The instrument is oriented toward clinical participant perspective and agreement of experts to determine the policy for future study related to informed consent of biobanking. This phase is divided into four rounds.

Round I: The open-ended questionnaire will be used to collect opinions from the participants which will be used to determine different issues in order to develop the contents of questionnaire for the next round.

Round II: The questionnaire will be developed using the data collected from the first round. Duplicate data will be deleted. The new questionnaire will be used with the same participants. The results from round two will identify areas of disagreement and agreement. In this round, consensus begins forming and the actual outcomes can be presented among the participants.

Round III: The questionnaire from the round two. The participants will receive the questionnaire that includes the items and ratings summarized by the researcher in the previous round and ask to revise his/her judgments or to specify the reasons for remaining outside the consensus. This round gives participants an opportunity to make further clarifications of both the information and their judgments of the relative importance of the items. However, compared to the previous round, only a slight increase in the degree of consensus can be expected.

Round IV: This is the final round. If the data collected in this round is consistent then the process will end and the data will be summarized. Generally, when using Delphi technique the differences of opinion from participant in round 3 and round 4 are minimal.

What are the disadvantages in taking part of this study?
We will make every effort to ensure that your confidentiality is protected. 4 rounds questionnaire will be sent to participants via email. This study will help developing appropriate models and policy of good data sharing practice that is appropriate to our context.

If you have questions about the research at any time, you should contact:
Ms. Tharisara SakulthaewnMahidol-Oxford Tropical Medicine Research Unit (MORU) Faculty of Tropical MedicinemMahidol University 3rd Floor, 60th Anniversary Chalermprakiat Building 420/6 Ratchawithi Rd., Ratchathewi District, Bangkok 10400, Thailand. Phone: +668 14238989 Email:toon@tropmedres.ac

Compensation
The authors will convey our gratitude to study participants with a small gift of a tea set.

Confidentiality

- Participant's demographics, data backups, paper copies of the transcripts, field notes and quantitative data will be kept in locked cabinets when they are not being used.
- We will never use your name or other personal information when we write reports about this study or present the results to others.
- We will not write your name on any study records. During transcription and in the compiling of field notes (observations) personal names will be anonymised; a list of participants and their pseudonyms (e.g. Trial Investigator 09, Patient 01) will be kept separately under lock/password. The data will be stored at the MORU office in Thailand.
- We will keep your information private. We will use it only for research. Access to these materials will be limited to the investigators or nominated representatives. These people are not allowed to share private study information about you with anyone else.

Your participation is voluntary
Please keep in mind that your participation is voluntary. You may withdraw from the study at any time for any reason without prior notice.

If you have not been treated as specified in this information sheet or you wish to know the participant's rights, you can contact the secretariat office of the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Research and Academic Services, 4th Floor, the 60th Anniversary of His Majesty the King's Accession to the Throne Building, Faculty of Tropical Medicine, Mahidol University, Tel. (02) 354-9100 ext. 1349, 1525 or Ethics Review Committee for Research Involving Human

Research Subjects, Health Sciences Group, Chulalongkorn University (ECCU). Institute Building 2, 4th Floor, Soi Chulalongkorn 62, Phyathai Rd., Bangkok 10330, Thailand, Tel: 0-2218-8147 Fax: 0-2218-8147 E-mail: eccu@chula.ac.th

Remarks:
Please think carefully about your decision to participate in the study. If you decide to participate in the study, we will ask you to sign two copies of the consent form, one for you and one for our records

APPENDIX O

INFORMED CONSENT FOR QUESTIONAIRES_DELPHI METHOD (PHASE II)

Informed consent form

Date……Month……Year……

I…… Age……..year would like to participate in the study titled "Developing a policy of informed consent for research biobanking in MORU Thailand; using Delphi technique" and ..... (Name of study staff whom obtained consent).....has informed me in details about:

- Objective of the study and time required in taking part in the study
- Procedures required to be performed
- Expected benefits from the research
- Potential risks of taking part in the research

I understand that I can withdraw or stop taking part in the research at any time without any affecting to which I am entitled to in the future. In giving my consent to take part in this study, I agree that the investigators can use my personal information obtained from this research, which will be presented as part of research result without revealing my name or identities.

If I have doubts about the study, I can contact Tharisara Sakulthaew at Mahidol Oxford Research Unit, Faculty of Tropical Medicine, Mahidol University 3/F 60th Anniversary Chalermprakiat Building, 420/6 Rajvithi Road, Rajthevee, Bangkok 10400. Tel no: 0814238989

If I have not been treated as specified on the participant information sheet, I can contact the Secretary Department of Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Research and Academic Services, 4th Floor, the 60th Anniversary of His Majesty the King's Accession to the Throne Building, Faculty of Tropical Medicine, Mahidol University, Tel. (02) 354-9100 ext. 1349, 1525.

I agree to participate in this study and I will be given a copy of this signed consent form. I fully understand the statements in the participant information sheet and this informed consent form, and consent to participate in this study.

_____	_____
Name of volunteer	Date
_____	_____
Volunteer's Signature	Date

_____	_____
Name of person conducting consent	Date
_____	_____
Person conducting consent's signature	Date

APPENDIX P

LIST OF PARTICIPANTS (EXPERTS) IN PHASE II

Principal Investigator

- Professor Arjen Dondorp
- Professor Daniel Paris
- Dr. Rupam Tripura
- Dr. Kyaw Myo Tun
- Dr. Richard Maude
- Yoel Lubell, PhD.

Co-Investigator

- Dr. Hugh Kingston
- Dr. Aung Pyae Phyo
- Dr. Angela Devien
- Dr. Rob van der Pluijm
- Naowarat Saralamba, PhD
- Tom Peto, PhD.

Project manager/ Study coordinator

- Piyanate Sunyakumthorn, PhD
- Mrs. Vanaporn Wuttieakanun
- Ms. Maliwan Hongsuwan
- Mr. Gumphol Wongsuwan

- Ms. Pornchalearm Deejai
- Mrs. Ampai Tanganuchitcharnchai

Lab technician

- Ms. Kemajittra Jenjaroen
- Ms. Kanlaya Sriprawat
- Ms. Pattamon Tharaphan
- Ms. Sornsuda Setaphan
- Ms. Jureeporn Duanguppama
- Mr. Patpong Rongkard

Study nurse

- Ms. Pornpan Suntornsut
- Ms. Somrutai Aurboonkasem
- Ms. Wasana Saohinkong
- Ms. Pichayanant Ariyaprasert
- Ms. Mayura Marasit
- Ms. Rattanaporn Rakpraidee

APPENDIX Q

ADVERTISING PAPER (ใบประชาสัมพันธ์โครงการฯ)

ขอเชิญอาสาสมัครที่เข้าร่วมโครงการวิจัยทางคลินิก
ที่มีอายุ 20-60 ปี เข้าร่วมโครงการ...

คลังเนื้อเยื่อเพื่อการวิจัยเพื่อรวบรวมข้อมูลเกี่ยวกับความเข้าใจ
และความคิดเห็นของอาสาสมัครที่เข้าร่วมโครงการวิจัยทางคลินิก
เรื่องการเก็บเนื้อเยื่อเพื่อนำไปใช้ในการวิจัยในอนาคต

เกณฑ์คัดเลือก

-สัญชาติไทย เพศหญิงหรือชาย
-พูด อ่าน และเขียนภาษาไทยได้
-ยินดีลงชื่อในใบยินยอมเข้าร่วมโครงการวิจัย
-เคยเป็นผู้มีส่วนร่วมในการเข้าร่วมโครงการวิจัยทางคลินิก
- เคยถูกเจาะเลือดในโครงการวิจัยทางคลินิก
- มีเวลาในการเข้าร่วมโครงการวิจัยประมาณ 40 นาที

สอบถามรายละเอียดเพิ่มเติมหรือสนใจเข้าร่วมโครงการ
กรุณาติดต่อคุณธริสรา สกุลแถว; หน่วยวิจัยโรคเขตร้อนมหิดล-อ๊อกฟอร์ด คณะเวชศาสตร์เขตร้อน; มหาวิทยาลัยมหิดล โทร 0814238989

APPENDIX R

SCHEDULE OF ACTIVITIES

Work plan for study																			
Research project/ activities	Time frame (Month)																		
	Feb-14	Mar-14	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15
Literature review and writing proposal																		
Proposal Exam																		
Tool development and approve from EC																		
Field preparation and conduct pilot study																		
Revise research instrument																		
Implement study phase I																		
Implement study phase II																		
Data collection phase I and II																		
Data analysis phase I																		
Data analysis phase II																		
Report writing phase I																		
Resport writing phase II																		
Publication phase I																		
Publication phase II																		

APPENDIX S

BUDGET PLAN

Description	Total amount (THB)
Data collection and processing	
Communication (telephone, fax, internet)	4,000
Stationary (paper, toner)	5,000
Local transportation cost (taxi, messenger)	2,000
Research nurse cost	12,000
Sub-total	*23,000*
Field survey and questionnaire implementation	
Instrument and equipment	4,000
Compensation for participants in phase I and phase II	12,600
NVIVO software	20,000
Sub-total	*41,600*
Expert consultation fee	
Questionnaire validity and reliability	6,000
Sub-total	*6,000*
Report (proposal, progress and complete paper)	
Publication fee (2 publications)	80,000
Sub-total	*80,000*
Total	*145,600*

VITA

THARISARA SAKULTHAEW

After graduating from the Assumption University, Bangkok, Thailand, with a degree in Nursing Science in October 2002, I began employment as a Research Nurse in Siriraj Hospital (one of the government hospitals in Bangkok) in the department of neurology. Experiences gained from two years as a research nurse enabled me to move on to a clinical research associate position. During this period I was trained to monitor studies for compliance with ICH GCP, Human Subject Protection, Research Ethics in Human Subjects and other applicable regulatory requirements and obtain a certificate from the Clinical Research Foundation Program in 2006.

My last work in the Wellcome Trust's Thailand/Laos Major Overseas Programme (MOP), based at the Mahidol Oxford Tropical Medicine Research Unit in Bangkok, and I am combining a full time post in the malaria team as a Clinical Trial Administrative Coordinator with my studies for a PhD. The clinical trial administrative coordinator is the liaison between the clinical scientist and the project sites, and I manage the day-to-day operation of a number of projects as well as providing coordinator to the team. In this role I played a central part in coordinating the AQUAMAT project, the largest ever trial on the management of inpatients with severe malaria and the TRAC study, a multi-center randomised trial to detect in vivo resistance of Plasmodium falciparum to artesunate in patients with uncomplicated malaria. Currently I am responsible for Senior Project Specialist at Medical Research Foundation (MedResNet Thai Medical School Consortium)

In the other hand, I am also interested in data protection, confidentiality and research ethics. For my independent research project, I do these topics for my PhD thesis. I would like to work as a researcher and as a coordinator in ethical field in my research area. I hope if I have the chance to study aboard to expand my experiences and ways of thinking to improve my research skill and language it make me have a power to do in a challenge research in the future.

Educational Background:

2012 – 2015

Doctor of Philosophy in Public Health, Collage of Public Health Science, Chulalongkorn University; Thailand.

2009 – 2011:

Master of Science (Health Education), Kasetsart University; Thailand.

1997 – 2002:

Bachelor of Nursing Science (B.NS), Assumption University; Thailand.

Certificate of Training:

1. Human Subject Protection: Faculty of Tropical Medicine, Mahidol University, Thailand; February 17th 2015

Risk Adapted Approaches to Compliance: Oxford University Clinical Research Unit Hospital for Tropical Diseases; Ho Chi Minh City, Vietnam; February 13th – 16th 2012

2. Good Clinical Practice (GCP): Faculty of Tropical Medicine, Mahidol University, Thailand; January 11th 2011

3. Monitoring training: Hospital for Tropical Diseases (HTD), Ho Chi Minh City; Vietnam February 05th – 06th 2009

4. Research Methodology and Design: Ethical Issues in Biomedical Science and Social Science Research: Faculty of Tropical Medicine, Mahidol University, Thailand; September 8th 2009

5. Research ethics in human subjects: Ethic Committee Thailand; February 16th −17th 2009