APPENDICES

APPENDIX I

IPT Screening List

IPT screening No .....

Data collection date ...../...../...../ (Day/Month/Year)

Patients ID No. .....

Hospital.....(Hospital No.)

Name.....

Address.....

Interviewer.....

I. Screening of the risk of active TB

1.	**Cough more than 3 weeks**	1. Yes, for .....days	2. No
2.	**Hemoptysis**	1. Yes	2. No
3.	**Night sweating**	1. Yes	2. No
4.	**Chest pain**	1. Yes	2. No
5.	**Fatigue**	1. Yes	2. No
6.	**Anorexia**	1. Yes	2. No

II. Screening the risk of symptomatic HIV infection or AIDS

7. **History of AIDS related disease** (Candidiasis, Invasive Cervical cancer, Coccidiomycosis, Cryptococcosis, Criptsporidosis, Cytmegalovirus, AIDS dementia, Herpes Zoster more than 1 dermatome, Histoplasmosis, Isosporiasis, Kaposi's sarcoma, Lymphoma Burkitts, Lymphoma immunoblastic, Lymphoma primary in brain, Mycobcterium avium complex, Recurrent Pneumonia, Pneumocystis carinii, Penicillium marneffei, Progressive multifocal leukoencephalopathy, Salmonella septicemia, Toxoplasmosis, Waisting syndrome)

1. Yes 2. No

8. **Weight loss more than 10 kg** 1. Yes .....Kg. 2. No

9. **Asthenia more than 1 month** 1. Yes 2. No

10. **Fever more than 1 month** 1. Yes 2. No

11. **Oral thrush** 1. Yes 2. No

12. **Chronic / Recurrent diarrhea more than 1 month**

1. Yes 2. No

13. **Dysphasia** 1. Yes 2. No

14. **Convulsion** 1. Yes 2. No

15. **Decrease eyesight** 1. Yes 2. No

16. **Persistent dermatitis more than 1 month** 1. Yes 2. No

17. **Lymphadenopathy more than 1 cm, at least 2 noninguinal sites for more than 1 month** 1. Yes 2. No

18. Other symptoms 1. Yes (specify)..... ... 2. No

III. Screening of the risk of Isoniazid side effect

19. History of Jaundice or Hepatitis 1. Yes 2. No

20. Alcoholism 1. Yes 2. No

IV. Screening the risk of default

21. Uncertain address 1. Yes 2. No

22. Not allow to home visit 1. Yes 2. No

23. Drug addict 1. Yes 2. No

In question I to IV, if there are "yes" go to physical check

V. Exclusion criteria

24. Age under 15 or over 50	1. Yes	2. No
25. Pregnancy	1. Yes	2. No
26. Past history of TB	1. Yes	2. No
27. Tuberculin skin test less than 5 mm	1. Yes	2. No
28. Smear test is positive	1. Yes	2. No
29. Culture is positive	1. Yes	2. No
30. Chest X ray have active resion	1. Yes	2. No
31. Liver enzyme (T-Bil, AST, ALT) is increase more than 3 times the upper limit of normal value	1. Yes	2. No

In Question V, if there is yes, do not enroll IPT

Final decision

1. Enroll IPT ( )
2. Not enroll IPT ( )

APPENDIX II

IPT enrollment form

Characteristics of HIV Infected Persons registered for Isoniazid Preventive Therapy

Checklist No.....

Patient ID No.....

IPT No .....

Date of enrollment ...../...../..... (Day/Month/Year)

Hospital where enrolled ..... (Hospital No.)

Name and address of participants

Name .....

Address

Village.....Tumbon.....District.....Province.....

Telephone number .....

Name and address of a friend or family member

Name .....

Village.....Tumbon.....District.....Province.....

Telephone number .....

Interviewer.....

I: Demographic factor

1. **Gender** 1. Male 2. Female
2. **Date of birth** ...../...../..... (Day/Month/Year)
3. **Nationality**

   1. Thai (Chiang Rai province) 2 Thai (Other province) 3. Hill-tribe

   4. Burma 5 Laos 6. Other (specify).....
4. **Highest education** .....(years)
5. **Occupation** .....
6. **Family income per month**..... (Bath /month)
7. **Marital status**

   1. Single 2. Married, stay together 3. Married, separated stay

   4. Divorce 5. Widow (for.....years) 6. Other.....

II: Predisposed Factor

8. **Daily alcohol drink**

   1. Yes, how heavy drinking..... 2. No
9. **Daily cigarettes smoking**

   1. Yes, how heavy smoking?.....per day 2. No
10. **Continuation of active intravenous drug use**

    1. Yes 2. No

11. **History of imprisonment**

1. Yes When..... 2. No

12. **History of homeless**

1. Yes When..... 2. No

13. **The past history of Lung Disease**

1. Yes (specify when)..... 2. No

14. **The presence of Diabetes mellitus**

1. Yes (specify how long)..... .. 2. No

15. **The presence of chronic disease?**

1. Yes. disease ..... 2. No

16. **History of TB in family**

1. Yes When..... 2. No

17. **History of intimate contact with TB disease**

1. Yes When..... 2. No.

18. **Use of antiopportunistic infection prophylaxis**

1. Yes When..... 2. No.

19. **The use of antiretroviral drug**

1. Yes When..... 2. No.

20. **The use of other medications when start IPT**

1. Yes What..... 2. No.

III. Biological factors before receiving IPT

21. **PPD reactivity** .....mm

22. **Mumpus anergy skin test** .. ..mm

23. **Presence of BCG scar**

1. Yes 2. No

24. **Body mass index**

Height .....m, Weight .....Kg. BMI.....

25. **Baseline complete blood cell count**

White blood cell ..... Red blood cell.....

Hemoglobin ..... Platelet .....

26. **Baseline liver function test**

T-Bil..... AST ..... ALT .....

27. **Baseline CD4 lymphocyte count** .....

28. **Clinical review of symptomatic HIV infection (*)**

1. Yes (specify) 2. No

29. **Clinical review of prior opportunistic infection (*)**

1. Yes (specify) 2. No

30. **Clinical review of sputum smear (*)**

1. Ngative 2. No resut 3. Not done

31. **Clinical review of result of culture** (specimen: .....) **(*)**

1. No TB bacteria 2. TB bacteria 3. Other organism 4. No result

32. **Clinical review of result of Cheat X ray (*)**

1. Normal 2 Abnormal (specify)……..

3. No result 4. Not done

(*) This positive result is a not enrolled criterion but it might be mistakenly enrolled. Thus need the critical review. Also this form was used for retrospective review for data exercise.

IV: Behavioral factors

33. **The duration of IPT (Compliance)**

INH starting date ...../...../..... (Day/Month/Year)

INH stopping date ...../...../..... (Day/Month/Year)

Total duration of IPT ……month

34. **IPT outcome**

1. Complete 2. Defaulted 3. Develop TB during IPT

4. Died 5. Change diagnosis 6. Severe adverse reaction

7. Transfer out 8. Others (specify)……

35. **The number of INH pills were taken during 9 month IPT .....**

36. **The number of INH pills were taken after extend 9 month IPT .....**

Part IV: Part V: Factors of provider

37. **Distance from house to the hospital** About .....kilometer(s)

38. **The way to travel to the hospital**

1. Walking only 2. Own vehicle

3. Public/hired vehicle..... 4. Other.....

39. **The frequency of visiting to the Hospital during IPT**

1. Never visit or only family visit 2. Total 1or 2 time

3. Total 3 to 5 time 4. More than 5 times

5. hospitalized during IPT 6. Other.....

40. **Entering day care center.**

1. Yes 2. No

APPENDIX III

IPT follow up form during Isoniazid therapy

IPT number .....

Data collection date ...../...../...../ (Day/Month/Year)

IPT screening No.....

Hospital.....(Hospital No)

Name.....

Gender 1. Male 2. Female Age.....

Address.....

Interviewer.....

---

1. The date of start Isoniazid ...../...../...../ (Day/Month/Year)

2. The date of stop Isoniazid ...../...../...../ (Day/Month/Year)

3. The outcome of IPT

1. Complete
2. Died
3. Default more than 2 months
4. Severe adverse reaction
5. Develop TB during IPT
6. Transfer out
7. Other

Follow up sheet

Months Start IPT	Visit Date	Weight	Cough	Fever	Jaundice	Itching	Other	No of INH pill left	No of B6 pill left	Blood test Result
1										CBC T-Bil AST ALT
2										
3										CBC T-Bil AST ALT
4										
5										
6										CBC T-Bil AST ALT
7										
8										
9										CBC T-Bil AST ALT
10										
11										
12										

- 1, 3, 6, 9 month, complete blood cell count and liver function test. (T-Bil, AST, ALT) will be checked. If liver function tests shows an increase 3 times the upper limits of normal values they will take off medication while repeat tests were done.

- If participant do not finish 270 pills during 9 months, they will extend Isoniazid until finish all

APPENDIX IV

IPT follow up form after Isoniazid therapy

IPT number .....

Data collection date ...../...../...../ (Day/Month/Year)

IPT screening No.....

Hospital.....(Hospital No)

Name.....

Gender 1. Male 2. Female Age.....

Address.....

Interviewer.....

- Participants will be followed up every month at the day care center. If they do not enter day care activity, they will be followed up every 6 months.
- Every 12 month, participants will be checked Complete blood cell count, Chest X ray, and CD4 lymphocyte.

Follow up sheet

Month after IPT	Visit Date	Body weight	Cough	Fever	Other	Result of Test
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						CBC CXR CD 4
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						CBC CXR CD4

CBC: Complete blood cell count CXR: Chest X ray

APPENDIX V

Active TB case investigation form

Characteristics of active Tuberculosis case registered Isoniazid preventive therapy among HIV infected person in Chiang Rai

Checklist No.....

Data collection Date...../...../..... (Day/Month/Year)

Hospital ..... **(Hospital No.**)

PT Hospital ID No.....

IPT No .....

Name .....

Address

Village.....Tumbon.....District.....Province.....

Telephone number .....

Interviewer.....

Part I : Biological information before diagnosing TB

1. **The symptom(s) leading you to visit the hospital** .

		1. Yes specify	2. No
2.	**Cough**	1. Yes, for .....days	2. No
3.	**Hemoptysis**	1. Yes	2. No

4. **Fever** 1. Yes 2. No

5. **Night sweating** 1. Yes 2. No

6. **Chest pain** 1. Yes 2. No

7. **Fatigue** 1. Yes 2. No

8. **Anorexia** 1. Yes 2. No

9. **Weight loss** 1. Yes .....Kg. 2. No

10. **Oral thrush** 1. Yes 2. No

11. **Chronic diarrhea (more than 2 weeks)**

1. Yes 2. No

12. **Other symptoms** 1. Yes (specify)..... 2. No

13. **The use of antiretroviral drug**

1. Yes (specify when)..... 2. No.

Part II : TB Laboratory Results

14. **The date of TB registry entry** ...../...../..... (Day/Month/Year)

15. **The date of developing TB**

1. During .....month IPT

2. At the time of INH completion

3. After INH completion for .....month

16. **Type of TB**

1. Pulmonary 2.extra pulmonary TB

17. **CD4 lymphocyte count** .....

18. **Sputum Examination**

1 st Date..... Result 1. + 2. ++ 3. +++ 4. Non-seen 5. no examination

2 nd Date.....Result 1. + 2. ++ 3. +++ 4. Non-seen 5. no examination

3 rd Date.....Result 1. + 2. ++ 3. +++ 4. Non-seen 5. no examination

19. **Result of Chest x-ray**

1. Normal 2. cavity exist 3. Abnormal shadow and no cavity

4. No result 5. Others(specify).....

20. **Result of culture (Specimen;)**

1. No TB bacteria 2. TB bacteria 3. Other organism 4. No result

21. **Result of histology**

1. There is finding related to TB (Granulomas)

2. No finding related to TB 3. Others .....

22. **Result of Drug resistance**

1. No resistance 2.Resistance of INH

3. Resistance of other drugs 4. No result

23. **TB treatment**

1. 2HRZE/4HR 2. 2HRZES/1HRZE/5HRE

3. Other (specify).....

24. **TB treatment outcome**

1. Cure 2. Complete 3.Defalt

4. Died 5. Change diagnosis 6. Failure

7. Transfer out 8. Others (specify).....

APPENDIX VI

Consent form

All participants are asked for the consent about participation in project study: interview, skin reaction test, Blood test, Chest X-ray, Isoniazid pill taking.

The participant who enrolled in the project will sign in consent form. This study consists of:

1. Interviewing about previous history and the situation of health and medical treatment related to tuberculosis and AIDS.
2. Skin testing for PPD and Mumps
3. Blood examination of complete blood cell count, liver function and CD4
4. Chest radiograph and Sputum smear and culture test
5. Isoniazid tablets taking for 9 months and follows up 3 years.

We are inviting you to voluntarily join this study. The decision to participate is entirely yours. If you decide to take part in the study, you will be interviewed, PPD and Mumps skin test will be done. Regarding questionnaires, if the participants feel uncomfortable answering some of the questions, they have a right to skip or stop answering.

If the PPD skin test positive you will check chest radiograph and the sputum examination for Acid Fast Bacilli (AFB) for screening active TB and blood test. If everything from the tests looks OK for you to be part of the study, every month come to this hospital or day care

center to be checked and to get Isoniazid medicine for 9 month. "Being checked" means answering simple questions about your health, having the pills that are leftover from your last refill checked. After finish taking all medicine, you will be followed up at least every 6 month. You will be a part of the study for 45 months, or until you get sick with TB, cannot take the Isoniazid medicine because of side effects. You will not be charged for all test and medicine.

Risks: There are the risks related to tuberculin skin tests, blood draw (minor discomfort, hematoma, and infection at the bleeding site) and Isoniazid adverse reaction. This side effects are usually mild and do not last long, like a little rash or itching. But sometimes the side effects are serious, like liver disease. We will try not let this happen.

Benefit: Everyone in the study takes at least 9 months of the TB tablets which can greatly reduce the chance that you will get active TB. Also you will benefit in this study from a more active TB screening and follow-up than usual IPT participants. Those who have TB signs and symptoms will be consulting the physician for active TB screening immediately. This research may also help us care for other HIV infected persons in the future.

Confidentiality: Your name, and your result will be maintained in confidence by the directly involved staff within the hospital and will not be released to anyone outside.

Refusal to participate: Your decision to participate or refuse will not effect the treatment

and care of your medical problem. If you have any questions about this study, please contact the person who explained this or doctor in charge of tuberculosis at the hospital.

Date...../...../.....

I,(name)_____(last name)_____

Address: number_____mu_____tambol_____amphur_____

Province_____, have been explained and understand the information contained in this form explanation.

I understand that my participation is entirely voluntary, and that I can change the consent at any time when I wish. I voluntarily participate in the study.

Signature _____(participant)

Signature _____(responsible person)

Signature _____(witness)

CURRICULUM VITAE

NAME:	Kaori Hazama
GENDER:	Female
BIRSE DATE:	May 20,1967
NATIONALITY:	Japanese
MARITAL STATUS:	Single
PERMANENT ADDRESS:	45-8,Honjyo, Yanagawa, Fukuoka,832-0061,Japan,
	Tel/Fax: 81-944-74-2352

EDUCATION:

August 2000	Diploma of Tropical Medicine (DTM)
	The Institute of Tropical Medicine,
	Nagasaki University, Nagasaki, Japan
October 1995	Board of Internal medicine
	The Japanese Society of Internal Medicine
May 1994	Certificate in Residency (Internal Medicine)
	Saga Medical School Hospital, Saga, Japan

March 1992	Medical Degree Saga Medical School, Saga, Japan

TRAINING:

October 2000 (6 weeks)	Certificate of International Course on AIDS Prevention and Care in Asia, The Research Institute of Tuberculosis, Japan Anti-Tuberculosis Association, Tokyo, Japan
September 1999 (1 weeks)	The Project of Family Planning/Maternal and Child Health in Philippines Japan International Cooperation Agency (JICA)
September 1997(4 weeks)	Family practice residency training Santa Rosa General Hospital, California

PROFESSIONAL EXPERIENCES:

Sep.2000 – Present	Research Fellow, the Research Institute of Tuberculosis
May 1992 – Mar. 2000	Physician (General Internal Medicine)
	University Hospital in Saga Medical School, Japan
	St. Mary's Hospital ,Fukuoka, Japan
	Saga Rehabilitation Hospital, Japan
	Towa Village Clinic, Kouch, Japan

PROFESSIONAL MEMBERSHIP:

Internal Medicine Administration Japan

General Internal Medicine Administration Japan