Study Protocol

for Submission to Single Joint Research Ethics Board, Department of Health

Republic of the Philippines

Evaluation of the New Residential Drug Dependence Treatment Model in the Philippines

1. Rationale

Drug abuse has been considered as one of the major public health issues in the Philippines. The prevalence rate of illegal drug use was estimated to be 2.3% or equivalent to 1.8 million of the population in 2015 within the age ranges of 10-69. In 2016, the Government of the Philippines launched the *Operation Tokhang* campaign to eliminate illegal drug use. In the wake of this national campaign, more than a million drug users surrendered to the authorities to seek for treatment and social support. This unprecedented demand for drug dependence treatment services highlighted the knowledge gaps as well as the capacity gaps of the existing Treatment and Rehabilitation Centers (TRCs), which provide compulsory and voluntary residential care for the drug users. Whereas there are 52 residential TRCs accredited by the Department of Health (DOH), of which 12 are operated by the DOH, no scientific study has been done on the characteristics of patients such as demographic profiles, the drug use pattern, the degree of relapse risk, and the effectiveness of treatment services provided at the TRCs.

In response to the increased demand for quality treatment and rehabilitation services for drug users, the DOH, which is mandated to strengthen capacity of treatment and rehabilitation services for drug users, turned to Japan International Cooperation Agency (JICA) for technical cooperation to introduce evidence-based relapse prevention programs at TRCs (called the *Intensive Treatment and Rehabilitation Program for Residential Treatment and Rehabilitation Centers*: INTREPRET). This request for a 5-year technical cooperation project was approved by the Government of Japan, and the *Project for Introducing Evidence-based Relapse Prevention Programs to Drug Dependence Treatment and Rehabilitation Centers in the Philippines*: IntERlaPP has been launched in December 2017.

This study, which is proposed as part of the JICA IntERlaPP project, aims to fill these knowledge gaps by conducting a scientific evaluation on the effectiveness of the residential drug dependence treatment model in the Philippines. In particular, in the Philippines, there is no study of antecedent that followed up patients discharged from residential TRCs to identify treatment outcomes including relapse rates in a scientific manner.

As the JICA project plans to establish the residential treatment model for national dissemination, the findings of the study are expected to bring long-term benefits to TRC patients and

communities alike by informing whether the treatment model works in the Philippine setting or there need further improvements before the project scales it up nationwide.

2. Objectives

The primary overall objective of this study is to evaluate the effectiveness of the new residential drug dependence treatment model (INTREPRET) in the Philippines.

To that end, this study is to analyze the causal impact of providing the residential drug dependence treatment model on the following patient outcomes:

1) Drug use
2) Psychological variables including relapse risk and coping skills
3) Psycho-social functioning

The study results, along with the JICA-assisted project's initiative in developing INTREPRET, will direct the policymakers at DOH toward the introduction of the more effective treatment program to TRCs and thus contribute to the improvement of the treatment services of drug users in the country.

3. Study Design/Methodology

3.1. Study Setting

The new residential drug dependence treatment model (INTREPRET) will be introduced to three DOH-operated TRCs; TRC Bicutan, TRC Dagupan, and TRC Tagaytay. These three pilot TRCs were selected out of the DOH-operated TRCs to maintain the representativeness of the pilot TRCs and thus keep the external validity of the study, given the varied characteristics of the TRCs (see Table 1).

Table 1. Characteristics of the Three Pilot TRCs

	Bicutan	Dagupan	Tagaytay
Location	Taguig, Metro Manila	Dagupan, Pangasinan	Tagaytay, Cavite
No. of Accredited Beds	550	300	100
No. of Residential Patients, as of April 30, 2019	477	189	183
Age group: 19 or less	40	4	12
Age group: 20-34	231	92	86
Age group: 35-49	167	82	69
Age group: 50 and above	39	11	16

Patients with Methamphetamine Addiction (%)	96	93	96
Plea-bargaining Patients, 2018 (%)	67	73	31
No. of Psychologists/ Psychometricians, as of April 30, 2019	24	7	8
No. of Medical Doctors, as of April 30, 2019	15	16	11

3.2. Sample Selection and Treatment Assignment

The participants in the study will be recruited from newly admitted residential patients at each of the three TRCs. First, among the patients who are admitted to the residential program of each TRC, only those who meet the eligibility criteria of the study will get selected as samples for the study (see the 3.3. Eligibility Criteria section). Then, for a randomized controlled trial, those selected eligible patients are to be assigned randomly either to the intervention group or to the control group. During the intervention that typically lasts for six months or more, the patients in the intervention group will receive the treatment that is based on the relapse prevention model (INTREPRET), while those in the control group will receive the existing treatment service (TAU: treatment as usual).

The randomizing the eligible patients will be done by the independent data collection team members who are not part of the TRC administration. When a new eligible patient is admitted to a pilot TRC, he/she will be randomly assigned to either of the groups by the data collection team using a pre-determined computer-generated random number table.

3.3. Eligibility Criteria

3.3.1. Inclusion Criteria

The inclusion criteria for this study are as follows:

1) Residential patients newly admitted to one of the three pilot TRCs
2) Male
3) 18 years of age or older
4) Ever used Methamphetamine

3.3.2. Exclusion Criteria

In addition, the following exclusion criteria are applied:

1) Those who are not capable of participating in group sessions
2) Those who cannot communicate in Tagalog

3) Those who have criminal records other than the possession of illegal drugs, possession of drug paraphernalia, or use of illegal drugs[1]
4) Those with severe medical conditions
5) Those who are not considered eligible by researchers

3.4. Intervention

3.4.1. Treatment Model

The new residential drug dependence treatment model (INTREPRET) has been formulated based on the Matrix Model, which is an intensive, comprehensive outpatient treatment program for stimulant users based on the relapse prevention model. The Matrix Model, whose treatment is delivered primarily in structured group sessions, was developed in the 1980s in the United States, and its efficacy has been researched by multiple scientific studies (Harada, 2010; Huber et al, 1997; Obert et al., 2000; Rawson et al., 2006).

As shown in Table 2, the INTREPRET is composed of the five components designed for psychological and social skill improvements of drug users.

Table 2. Components of INTREPRET

	Component (No. of Sessions per Week)	Contents of Sessions
1	Cognitive Behavioral Therapy (CBT) (3)	Group CBT sessions based on worksheets designed for each session. CBT sessions are composed of (1) Early Recovery Skill Program (12 sessions), (2) Relapse Prevention Program (36 sessions), and (3) Pre-discharge Program (6 sessions).
2	Cognitive Behavioral Therapy Review (CBT-R) (1)	Weekly review of the CBT sessions.
3	Psycho-Education (PE) for Patients and Family Members (1)	Interactive lectures to provide patients and their family members with accurate information about addiction, recovery, treatment and the resulting interpersonal dynamics. PE is based on recurring sessions over 12 topics.
4	Social Support (SS) (2)	Discussion group to practice resocialization skills. SS is based on recurring sessions over 40 topics.
5	Self-help Group Meeting (SHGM) (1)	Narcotic Anonymous-style group meetings facilitated by ex-users.

[1] Some patients, especially plea-bargaining patients, may be sent to prisons upon discharge from the TRCs, but their destinations cannot be informed until the court decision is made at the last moment. Therefore, the patients who have criminal records other than the possession of illegal drugs, possession of drug paraphernalia or use of illegal drugs are excluded from the study because they have a higher chance of being dropped out from the study in case they are court-ordered to be re-admitted to prisons.

	Total	(8)	

Each session in the five INTREPRET components is for 60 minutes. At the shortest, the INTREPRET can be completed in 26 weeks or six (6) months, as documented in details in Service Provider Manual (ANNEX 1).

Although the exact intervention period varies depending on the individual patient, the standard intervention period is approximately six (6) months at TRC Bicutan and TRC Dagupan but eight (8) to ten (10) months at TRC Tagaytay.

To implement the five components of the INTREPRET in the three pilot TRCs in the Philippines, the following materials were developed through the localization of the products of the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services[2,3], into Tagalog:

1) Patient's Workbook
2) Slides for Psycho-Education sessions
3) Flipcharts for Social Support sessions

The ongoing treatment programs implemented in the three pilot TRCs are based on the following approaches, although there are some variations in the manners to their delivery between the facilities: (1) multidisciplinary team approach, (2) therapeutic community approach, (3) Hazelden-Minnesotta Model, (4) spiritual approach, and (5) eclectic approach (Department of Health, 2013). The patients in the comparison group will receive a combination of these approaches or TAU.

INTREPRET's focuses are largely on implementation of the "(3) Hazelden-Minesotta Model" and "(5) the eclectic approach" in a more structured and organized manner based on standardized schedules and materials. It follows that the patients in the intervention group will also receive a combination of the above five approaches, but with INTREPRET components integrated into the "(3) Hazelden-Minnesotta Model" and "(5) eclectic approach".

[2] Center for Substance Abuse Treatment. Client's Handbook: Matrix Intensive Outpatient Treatment for People with Stimulant Use Disorders. HHS Publication No. (SMA) 15-4154. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2006.
[3] Center for Substance Abuse Treatment. Counselor's Treatment Manual: Matrix Intensive Outpatient Treatment for People with Stimulant Use Disorders. HHS Publication No. (SMA) 13-4152. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2006.

3.4.2. Study Participants

During the intervention, the patients in the intervention group will receive the INTREPRET treatment model by participating in: three (3) sessions of Cognitive Behavioral Therapy; one (1) session of Cognitive Behavioral Therapy-Review; one (1) session of Psycho-Education; two (2) sessions of Social Support; and, one (1) session of Self-help Group Meeting, per week. All these sessions are provided in groups. The patients in the control group will receive the TAU.

The patients in the intervention group are separated from those in the control group (and those not participating in the study) by residing in a dormitory designated just for the group. No specific dormitories are to be designated for the control group and will reside in non-intervention group dormitories together with those not participating in the study. New participants are enrolled on a rolling basis. Therefore, at the outset, patients newly join the intervention group will co-reside with those who have been in the intervention dormitory since before the start of the study (No data will be collected from these holdover patients.).

3.4.3. Therapists

The therapists for the both groups are psychologists or psychometricians. The psychologists who provide the Cognitive Behavioral Therapy sessions to the intervention group will receive specifically developed training for this study, consisting of lectures and hands-on group sessions on: a) INTREPRET Administration; b) Facilitation Standards; 3) Cognitive Behavioral Therapy; and, 4) Motivational Interviewing. The training materials include video clips that show both good and bad counseling practices. The psychologists who care for the control group will not receive any particular training for the study.

3.5. Data Collection and Research Instruments

As a means of collecting data on the primary outcome (i.e., drug use), the urine testing for stimulant is to be implemented in follow-up/endline. In addition, self-administered questionnaires are to be conducted to collect data on self-reported stimulant use. The self-administered questionnaires are also to be used to measure the patient's demographics, psycho-social functioning, and coping skills(See Questionnaire for Baseline Survey; ANNEX 2, Questionnaire for Pre-discharge Survey; ANNEX 3, and Questionnaire for Follow-up Survey; ANNEX 4). For the measurement of psychological variables, several psychometric scales will be employed in baseline, pre-discharge, and follow-up, as shown in Table 3.

Table 3. Research Instruments

Instrument	Baseline	Pre-discharge	Follow-up
Urine Test			**X**

Self-administered Questionnaire	**X**	**X**	**X**
Drug Use Experience	X		X
Socio-Economic Status	X		X
Cognitive and Skill Levels	X	X	X
DAST 20	X		X
ASI-SR	X		X
SRRS	X	X	X
VAS for Craving	X	X	X
CBI-Drug	X		X
Brief COPE	X	X	X
WHO-5 Well-being Index	X	X	X
EQ-5D-5L	X	X	X
BDI-II	X	X	X
POC		X	

Notes: DAST 20=Drug Abuse Screening Test (Gavin et al., 1989), ASI-SR=Addiction Severity Index-Self Report (Cacciola et al., 2008); SRRS=Simulant Relapse Risk Scale (Ogai, 2007); VAS for Craving=Visual Analogue Scale for Craving (Gould et al., 2001); CBI-Drug=coping Behaviours Inventory-Drug (Litman et al., 1983); Brief COPE=Brief Coping Orientation to Problems Experienced (Sica et al., 1997); WHO-5 Well-being Index=World Health Organization Five Well-being Index (Topp et al., 2015); EQ-5D-5L=Five Level EQ-5D (Whynes and the TOMBOLA Group, 2008); BDI-II=Beck Depression Inventory II (Beck et al., 1996); POC=Perceptions of Care (Eisen et al., 2002).

The translated version of DAST 20, SRRS, and VAS for Craving had been used and validated during a separate study conducted earlier in the Philippines[4]. The other study tools have been translated into Tagalog by professional translators, reviewed by addiction experts on several occasions, and pretested with at least 20 patients at TRC Bicutan and 20 patients at TRC Tagaytay. All the feedback from those patients and the staff members who observed the pretest sessions have been incorporated into the documents. The revised study tools have further been reviewed by several addiction experts before they were finalized.

In order to ensure the anonymity and privacy of the participants, all the data will be de-identified and managed by codes at the data entry and analysis stages. Data will be anonymized in a linkable fashion; a separate table that links the participants' codes and names will be developed and kept in a safe that can be opened solely by a designated personnel. All the data collected during the study will be handled in accordance with the National Ethical

[4] The study results are currently being analysed for publication in international journals.

Guidelines for Health and Health Related Research (Philippine Health Research Ethics Board, 2017) and in respect of the Data Privacy Act of the Philippines (Republic of the Philippines, 2012).

3.6. Sample Size

Based on recently published findings from the systematic review which includes studies with a similar design (Harada et al., 2018), this study considers a minimum detectable effect of 0.23 and a population standard deviation of 0.42. With a significance level of 0.05 and a power of 0.95, a sample size of 88 participants per group (or 176 patients in total) would become needed to test the causal impact of the intervention.

Moreover, judging from our preparatory field studies, more than a half of the participants may drop out of the study by not showing up for the follow-up interviews in three months after discharge. Given the coverage rate of 44%, the final required sample size needs adjusting to 200 patients per group (or 400 patients in total) to achieve a sample size of 88 patients per group (or 176 patients in total), as shown in Table 4.

Table 4. Sample Size Calculation

Significance Level	0.05
Power	0.95
Minimum Detectable Effect Size	0.23
Population Standard Deviation (SD)	0.42
Coverage Rate	0.44
Required Sample Size	200 per group

3.7. Data Analysis Plan

To estimate the causal impact of providing residential treatment on outcomes, the following two types of regression equations are to be estimated:

1) For the primary outcome indicator of the urine testing, which is to be measured only in endline, the regression model (1) is estimated to test if there is a statistically significant difference in means between the intervention and comparison groups:

$$Y_{ij} = \alpha + \beta T_i + \theta X_i + v_j + \omega_{ij} \quad (1)$$

where Y_{ij} is the urine test result of patient *i* at TRC *j*, α is a constant giving the value of the urine test result for the comparison group, T_i is the treatment dummy, X_i is the set of patient

characteristics to be controlled for, such as age and education, v_j is a TRC-level error term, and ω_{ij} is an individual error term.

This study estimates the coefficient on the treatment dummy (β) that shows the between-group difference. Since the urine test has a binary result, the log odds of the outcome are to be estimated as a linear combination of the independent variables using a logistic regression (i.e., logit (Y_{ij})), instead of using a linear regression.

2) For the secondary outcome indicators of the psychometric tests, which are to be measured both at baseline and endline, the regression model with an interaction term (2) is estimated to calculate a difference-in-difference (DD) estimate that relies on a comparison of the intervention and comparison groups before and after the intervention (Khandker et al., 2010):

$$Y_{ijt} = \alpha + \beta T_{i1} t + \rho T_{i1} + \gamma t + \theta X_i + v_{jt} + \omega_{ijt} \quad (2)$$

where Y_{ijt} is the psychometric test result of patient i at TRC j at time t, α is a constant giving the average value of the psychometric test result for the comparison group at time t_0 (baseline), T_{i1} is the treatment dummy, t is the time dummy, X_i is the set of patient characteristics to be controlled for, v_j is a TRC-level error term, and ω_{ij} is an individual error term.

The study estimates the coefficient (β) on the interaction between the treatment dummy (T_{i1}) and the time dummy (t) that gives the average DD effect of the intervention. In addition to this interaction term, the variables T_{i1} and t are included separately to pick up any separate mean effects of time as well as the effect of being targeted versus not being targeted.

3.8. Intervention and Data Collection Activities

3.8.1. Study Schedule

The duration of this study (from intervention to data analysis) will be approximately 22 months (from September 2019 to July 2021). As shown in Table 5, the preparatory activities including the facilitator training and dry-run at the three TRCs are planned to start in September 2019. The intervention will be started in January 2020 and continued until January 2021. In parallel with the intervention, the data collection will be conducted in three phases (baseline, pre-discharge, and follow-up) between January 2020 and April 2021, followed by the data analysis to be conducted for three months. The findings of the study will be disseminated to a wide range of audiences through presentations and publications afterwards.

Table 5. Study Schedule

Year	2019				2020												2021						
Month	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7
Preparation																							
1. TRC staff training	x	x																					
2. Dry Run		x	x	x																			
Intervention																							
3. Implementation of INTREPRET and TAU					x	x	x	x	x	x	x	x	x	x	x	x	x						
Data Collection																							
3. Data Collection I: Baseline					x	x	x	x	x	x													
4. Data Collection II: Pre-discharge										x	x	x	x	x	x	x	x						
5. Data Collection III: Follow-up													x	x	x	x	x	x	x	x			
6: Data Analysis																					x	x	x

Pursuant to the approval transition plan of TRC Tagaytay and in accordance with the Memorandum dated August 28, 2019 issued by the Secretary of Health, it is in the process of transferring its function from the old facility in Tagaytay City to a new place in Trece Martires. As of October 2019, it is not accepting a new patient. However, the study schedule is based on the assumption that TRC Tagaytay will start admitting patients at the new location by the time it starts data collection in January 2020. In case the new facility's commencement lags behind the study schedule, the intervention and data collection plan in TRC Tagaytay will be adjusted in accordance with its actual operational schedule.

3.8.2. Outlines of Activities

The major activities involved in the study are outlined below.

TRC staff training: Prior to conducting the intervention and data collection, a training program targeting the facilitators and administrators will be conducted. They will be oriented on the INTREPRET administration, the study design and necessary local arrangements, and research ethics. The facilitators will also be training on the Cognitive Behavioral Therapy (CBT) and Motivational Interview (MI) skills.

Dry run: The intervention and data collection modalities will be tested through their dry run at the three pilot TRCs for three months following the training.

Implementation of INTREPRET and TAU: The pilot implementation of the treatment programs will target newly admitted patients in the three pilot TRCs. The eligible participants will be randomized into the intervention and comparison groups at their admission. INTREPRET will be implemented to the intervention group and TAU to the comparison

group. The implementation will be continued until the total number of the eligible participants reach 400 (200 intervention and 200 comparison).

Data Collection I: Baseline: The eligible participants will participate in a questionnaire survey just after their admission to the TRCs. The Questionnaire for Baseline Survey (ANNEX 2) will be used. The questionnaire survey will take about 60 minutes.

Data Collection II: Pre-discharge: The study participants will participate in the second questionnaire survey just before their discharge from the TRCs. The Questionnaire for Pre-discharge Survey (ANNEX 3) will be used. The questionnaire survey will take about 60 minutes.

Data Collection III: Follow-up: The study participants will be contacted three months after their discharge from the TRCs. If they are active in the aftercare programs conducted by the TRCs, they will be reached at the TRCs and a questionnaire survey (Questionnaire for Follow-up Survey; ANNEX 4) will be conducted. In addition, results of the urine tests conducted by the TRCs will be used as part of the study data. If the participants are not active in the aftercare programs, the study team will contact them individually and conduct the questionnaire survey and a voluntary urine test at a clinic near their residence. Telephone interviews will also be applied as the last resort, in case, the participants cannot be physically reached.

3.9. Study Outcomes

In short, the impact of the treatment model (INTREPRET) on participants will be demonstrated by significantly less relapse episode, decreased drug use, increased coping skills, and other psychological variables compared to the control participants in three months after the discharge

4. Ethical Considerations

This study does not expect that participants suffer from any adverse effects, either physically or mentally, regardless of whether they participate in the study or their treatment assignment. To our knowledge, the existing studies with a similar intervention have not reported any serious adverse effects.

On the other hand, study participants are expected to accrue direct benefits by receiving the intervention, as measured by lower relapse rates and improved psychological variables. Furthermore, if the treatment program is demonstrated to be effective in the Philippines, many future patients will gain as the INTREPRET is to be scaled up nationwide and thus, the study will contribute to improve drug treatment quality and capability in the country.

Although this study expects no adverse effects incurred to the patients at the pilot TRCs, the following measures are to be taken to uphold high research ethical standards:

1) Any patient who is in a physical/mental condition that is not appropriate to participate is excluded from the study (as mentioned as part of the exclusion criteria).
2) Any patient who does not agree to participate in this study is excluded from the study (as mentioned as part of the exclusion criteria). During the screening and prior to data collection, the Information Sheet for Study Participants (ANNEX 5) will be handed out to all participants. Participants will be informed that the participation to this study will be totally voluntary, and those willing to participate in the study will be asked to fill out the Consent Form (ANNEX 6). The patients who wish to withdraw from the study can contact the principal investigator, the local investigator, or the data collection team specifically commissioned to work at the TRCs on logistic arrangements under the study.
3) Patients participating in the study will be compensated for inconvenience and expense when they attend the follow-up interview. Specifically, participants showing up and cooperating in the follow-up will receive as honorarium 500 pesos, whereas those answering the interview through telephone will receive 200 pesos.
4) All patient data are treated as confidential. Any personally identifiable information is removed from datasets in a linkable anonymizing manner. Each participant is given a unique study identification number, which is linked to his/her personal information and the list for a linkable anonymizing is kept in a cabinet under lock and key in the project office.
5) No one other than the persons directly concerned with the implementation of this study, such as the study team members and the local consultants procured to conduct data collection, will be allowed to access the data. All study documents (such as participant registers, questionnaires, informed consent forms, urine/drug test results) will be kept in a cabinet under lock and key in the project office. The documents will be destroyed after a pre-determined storage period.
6) No intervention related to this study will take place unless the certificate of approval is obtained from the SJREB of the DOH.
7) In case any unexpected event occurs during its implementation or any modification of the study protocol becomes necessary, the SJREB will get informed immediately.

In order to ensure the data protection of the study participants, the Chiefs of the Hospitals and the staff members at the operational level in TRC Bicutan, TRC Tagaytay, and TRC Dagupan are included as research members (Table 6). The CVs of the TRC Chiefs are provided as ANNEX 7. They will attend the training on research ethics, together with other members of the TRCs, during the preparation stage of the study.

The TRC Chiefs will take the responsibility to implement measures to protect all the data of the study participants within the TRCs against natural dangers such as accidental loss or destruction, and human dangers such as unlawful access, fraudulent misuse, unlawful destruction, alteration and contamination. At each facility, the research participants will be coded to anonymize their identities and their codes will be used in the participants' register, questionnaire forms, and urine test results. A table linking the patients names and the codes will created and kept in a lockable place in the TRC Chiefs' office. Paper-based information of the study participants are handled in accordance with the Data Privacy Act of the Philippines (Republic of the Philippines, 2012). The data collection team, to be commissioned to conduct the data collection and compilation, will be requested to handle the data of the study participants outside the TRCs based on the Data Privacy Act of the Philippines. All the paper-based information of the study participants will be kept in places which are accessible by pre-determined members and electronic data will always be password protected and accessed by limited personnel.

The Consent Forms and the questionnaire forms will be kept in a lockable cabinet of at the Department of Health for five years after completing all the data collection. After the storage period, all the sheets will be shred and disposed.

5. Limitations of the Study

The possibility of applying a cluster randomized trial, making TRCs as clusters, was also explored to eliminate contamination between the intervention and comparison groups. However, due to the fact that there are only 14 DOH-run TRCs and the significant differences between the TRCs in size and the patients' attributes, such study method was considered impractical. Therefore, the study will apply the modality to randomize patients at each pilot TRC, despite the possible contamination of the intervention effects between the two groups.

The study team will place all the possible measures to minimize the contamination. Dedicated facilitators will be assigned to the intervention groups and all the group sessions of the intervention groups will be conducted in places which are physically separated from those of the comparison group to the extent possible.

6. Financial Considerations

This proposed study is part of JICA technical cooperation project. The cost of the study, including the training of facilitators for INTREPRET sessions, is to be funded by JICA. The Philippine DOH will be responsible for the day-to-day operations of the intervention at the three pilot TRCs, and the operating and maintenance costs of the TRCs will be borne by the Philippine-side. Because this study is conducted as part of a series of activities under IntERlaPP jointly funded by JICA and DOH, its budget cannot be singled out. Nevertheless, expenditures

expected from this study, except the personnel expenses (i.e. JICA experts, project staff members, research team members, and DOH personnel), are estimated and provided below.

Item	Total in PHP	Breakdowns
Training	265,000	Training venue and material: 265,000
Transport	920,000	Bicutan: 180,000 Tagaytay: 220,000 Dagupan: 520,000
Accommodation and Per Diem	360,000	Tagaytay: 180,000 Dagupan: 180,000
Communication	120,000	Phone Load: 60,000 Internet: 60,000
Printing	178,000	INTREPRET material : 150,000 Questionnaire : 24,000 Consent form/Information sheet : 2,000 Other reporting documents: 2,000
Incentive Payment to Study Participants	70,000	Face to face questionnaire: 50,000 Phone interview: 20,000
Data Processing	100,000	
Total	3,013,000	

7. Study Team Composition

The study team will be composed of Japanese and Filipino researchers. The principal investigator and research collaborators are listed in Table 6.

Table 6: Study team members

	Name	Title/Organization	Responsibilities
Principal Investigator			
1	Prof. Takayuki Harada	Professor Faculty of Human Sciences, University of Tsukuba	- To provide overall directions in study designing, data collection, data analysis, and paper writing.
Local Coordinator			
2	Dr. Jose Bienvenido Leabres	Medical Specialist III Dangerous Drug Abuse Prevention and Treatment Programs, Department of Health	- To serve as the Chair of the Technical Working Group and Research Working Group and give overall direction to their operation (from September 2019). - To provide technical inputs to the overall study design - To serve as a trainer to TRC staff members on the research framework and the ethical issues.
Research Collaborator (Japanese)			

3	Dr. Toshiaki Baba	Medical Officer The National Center for Global Health and Medicine	- To provide technical inputs to the overall study design - To provide technical inputs to questionnaire development and validation of scaes. - To provide technical inputs in data analysis and paper writing.
4	Dr. Shogo Kanamori	Chief Advisor/JICA Expert The Project for Introducing Evidence-based Relapse Prevention Programs to Drug Dependence Treatment and Rehabilitation Centers in the Philippines (IntERlaPP)	- To provide technical advisory to development of INTREPRET - To provide technical inputs to the overall study design - To facilitate communications and coordination among Japanese and Filipino research team members, JICA, DOH, TRCs, and data collection team.
5	Dr. Kazutaka Nomura	Assistant Professor Faculty of Human Sciences, Waseda University	- To review literature on studies of antecedent and existing research instruments relevant to this study - To provide technical inputs to the overall study design - To provide technical inputs in data analysis and paper writing
6	Dr. Tomohiro Shirasaka	Director Department of Psychiatry, Teine Keijinkai Hospital	- To review literature on studies of antecedent and existing research instruments relevant to this study - To provide technical inputs to the overall study design - To provide technical inputs in data analysis and paper writing
7	Dr. Ayumi Takano	Associate Professor Department of Mental Health and Psychiatric Nursing, Tokyo Medical and Dental University	- To review literature on studies of antecedent and existing research instruments relevant to this study - To provide technical inputs to the overall study design - To provide technical inputs in data analysis and paper writing
8	Dr. Noriko Ishizuka	Researcher Education Bureau of the Laboratory Schools University of Tsukuba	- To review literature on studies of antecedent and existing research instruments relevant to this study - To provide technical inputs to the overall study design - To provide technical inputs in data analysis and paper writing
Research Collaborator (Filipino)			

9	Dr. Ivanhoe C. Escartin	Program Manager Dangerous Drug Abuse Prevention and Treatment Programs, Department of Health	- To serve as the Chair of the Technical Working Group and Research Working Group and give overall direction to their operation (till August 2019). - To provide technical inputs to the overall study design - To serve as a trainer to TRC staff members on the research framework and the ethical issues.
10	Ms. Madelaine Teresa T. Casimiro	Department Legislative Liaison Specialist Health Policy and Systems Development Team (HPSDT), Department of Health	- To provide technical inputs to the overall study design as a RWG member
11	Dr. Jasmin Peralta	Chief of Hospital TRC Cebu, Department of Health	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member
12	Dr. Alfonso Villaroman	Chief of Hospital TRC Bicutan, Department of Health	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member - To take responsibilities in the local arrangements and ethical conduct of the study at TRC Bicutan
13	Dr. Trinidad Geraldine Purugganan	Chief Health Program Officer TRC Tagaytay	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member - To assist in the local arrangements and ethical conduct of the study at TRC Tagaytay

14	Ms. Alpha Martin	Chief Psychological Services Section TRC Bicutan	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member - To assist in the local arrangements and ethical conduct of the study at TRC Bicutan - To serve as a trainer to TRC staff members on the Motivational Interview and Cognitive Behavioral Therapy
15	Ms. Ma. Alodia C. Mercado	Clinical Psychologist Max Psychological Services Professor Philippine National Police Academy	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member - To serve as a trainer to TRC staff members on the Motivational Interview and Cognitive Behavioral Therapy
16	Dr. Joseph Fama	Chief Health Program Officer TRC Dagupan	- To provide technical inputs to the overall study design and research instruments as a RWG member - To provide technical inputs to the development of INTREPRET as a TWG member - To assist in the local arrangements and ethical conduct of the study at TRC Dagupan
17	Dr. Ronnie C. del Mundo	Chief of Hospital TRC Tagaytay, Department of Health	- To take responsibilities in the local arrangements and ethical conduct of the study at TRC Tagaytay
18	Dr. Delfin P. Gubatan, Jr	Chief of Hospital TRC Dagupan, Department of Health	- To take responsibilities in the local arrangements and ethical conduct of the study at TRC Dagupan

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ANNEXES:

ANNEX 1: Service Provider Manual
ANNEX 2: Questionnaire for Baseline Survey (English and Tagalog)
ANNEX 3: Questionnaire for Pre-discharge Survey (English and Tagalog)
ANNEX 4: Questionnaire for Follow-up Survey (English and Tagalog)
ANNEX 5: Information Sheet for Study Participants (English and Tagalog)
ANNEX 6: Consent Form (English and Tagalog)
ANNEX 7: CVs of TRC Chiefs

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