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|  | Application number | ※ |

**Ethics Application for Research Proposal**

**School of Tropical Medicine and Global Health, Nagasaki University**

To: Chair, Institutional Review Board, School of Tropical Medicine and Global Health

|  |  |  |  |
| --- | --- | --- | --- |
| Date of submission | Day: | Month: | Year: |

**1. Applicant**

|  |  |  |
| --- | --- | --- |
| Name |  | |
| Affiliation | School of Tropical Medicine and Global Health | |
| E-mail |  | |
| *If the applicant is a student, fill-in the following items* | | |
| Student ID number |  | |
| Course | Master  International Health Development (MPH)  Health Innovation (MSc)  Tropical Medicine (MTM)  Doctoral  PhD (TMGH-LSHTM Joint degree)  PhD (Global Health)  DrPH (Public Health) | |
| Name of primary supervisor |  | |
| Name of secondary supervisor |  | |
| Has primary supervisor approved the submission of this application. | | Yes, approved |

**2. Proposed research title**

|  |  |
| --- | --- |
| Title |  |
| Version number |  |

Please indicate the previous version number of the proposal and approved number from TMGH, when this submission is ‘Revised application’ or ‘Amended application’

|  |  |
| --- | --- |
| Version number |  |
| Approved number |  |

**3. Type of application and review process**

3.1 Type of application 1)

|  |
| --- |
| (1) New application  (2) Revised application  (applicable only for a revised version of the application not having been approved yet) 2)  (3) Amended application  (applicable only for any changes in the application having been previously approved) 2)  (4) Publication of study results  (5) Others (e.g. request for review exemption) (Specify: ) |

1) All types of applications should be submitted along with its research proposal or manuscript (Protocol). Combined file size needs to be maximum 5MB.

2) For (2) and (3), submit three files: (i) Ethics application form (C1-Form), (ii) Research protocol; and (iii) description of changes made in the research protocol. In the (iii), clearly specify revised parts by highlighting them in colors and using Before-and-After texts/table.

3.2 Type of review

|  |
| --- |
| Ordinary review process  Request for an expedited review process  Select the reason why you request for an expedited review process  (1) The research proposal for a joint research with other institution(s) has been already approved by the IRB or ethics committee of other organization(s) (e.g. organization(s) in research target countries).  (2) Minor amendment(s) of the research proposal either previously or conditionally approved by the TMGH-IRB  (3) Non-interventional study without invasiveness  (4) Non-interventional study with minor invasiveness  (5) Others (Specify: )  Request for a review exemption  Select the reason why you request for a review exemption  (1) Use of publicly available dataset(s).  (2) Use of existing dataset(s) that the applicant was officially permitted to use by data owner(s)  (3) Others (Specify: ) |

3.3 Ethics approval from institution(s) other than TMGH

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| --- |
| I/we have already the ethics approval from: [name(s) of other institution(s)] \* Please **submit the ethics approval certificate** along with: (i) ethics application form (A1 Form); and (ii) study protocol/proposal.    I/we have already applied for the ethics application at:  [name(s) of other institution(s)] , but have not received the ethics approval, yet.    I/we will apply for the ethics approval at:  [name(s) of other institution(s)]  I/we don’t apply for the ethics approval from any other institutions  \* Explain the reason: |

**4. Organization of research**

4.1 List of investigators（the applicant should be listed）

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Full name** | **Affiliation and position** | **Roles and responsibilities** |
| 1 |  |  |  |
| 2 |  |  |  |
| 3 |  |  |  |

*(Add rows, if necessary)*

4.2 Institutions

|  |  |
| --- | --- |
| Uni-center study |  |
| Multi-center study | Is TMGH the leading institute?  Yes  No If ‘No’, specify the leading institute and principal investigator. |
| Leading institute |  |
| Principal investigator |  |

4.3 Study period\*

|  |  |
| --- | --- |
| Planned study start month/year | From: Month Year |
| Expected study completion month/year | To: 　Month Year |

\* Not just data collection period but the entire study period should be specified.

4.4 Period of case registration at health facility(-ies) (e.g. hospitals)（*applicable only for prospective study*）

|  |  |
| --- | --- |
| From: | Month Year |
| To: | Month Year |

4.5 Period of other types of data collection (e.g. household survey)

|  |  |
| --- | --- |
| From: | Month Year |
| To: | Month Year |

**5. Summary of the study**

The outline should show that **the study is scientifically relevant**, and be written concisely

|  |
| --- |
| 5.1 Summarize what is already known on this topic [in maximum **100 words**] |
| [text here] |
| 5.2 Summarize justifications of the study [in maximum **100 words**] |
| [text here] |
| 5.3 Objectives [in maximum **100 words**] |
| [text here] |
| 5.4 Design [in maximum **50 words**] |
| [text here] |
| 5.5 Study settings and/or study sites [in maximum **50 words**] |
| [text here] |
| 5.6 Participants [tick all applicable choices]  (1) Healthy individuals  (2) Patients and/or the family members  (3) Pregnant and/or fetus  (4) Cognitively impaired person  (5) Neonates  (6) Children (Specify age range: )  (7) Persons under emergency situation  (8) Patients with incurable diseases and/or disabled  (9) Others (Specify: ) |
| 5.7 Inclusion criteria of the participants [in maximum **100 words**] |
| [text here] |
| 5.8 Sample size (incl. sample size calculation) [in maximum **100 words**] |
| [text here] |
| 5.9 Methods (e.g. primarily, data collection and data analysis) [in maximum **800 words**] |
| [text here] |
| 5.10 Will the study involve invasive procedures? |
| Yes Explain the procedure and degree of invasiveness:    Yes, but minimally invasive  No |
| 5.11 Will the study involve intervention? |
| Yes Explain contents of the intervention:    No 🡺Go to 5.14 |
| 5.12 Is this intervention study registered in a registry database? |
| Yes Describe the registry database:    No Describe the reason why not be registered: |
| 5.13　Will the study involve any randomization procedures? |
| Yes Specify the methods:    No |
| 5.14 Will the study use any human biological specimen? |
| Yes, newly collect human specimen Specify the specimen:    Yes, use existing human specimen　 Specify the specimen:    No |
| 5.15 Will the study use data/information existing at local institute(s)/organization(s)? |
| Yes Specify the type/nature of data/information (e.g. treatment records and patient registry):  No |

**6. Process to obtain informed consent**

6.1 Will informed consents be obtained?

|  |
| --- |
| Yes  No 🡺Go to 6.6 Specify the reasons for not obtaining informed consent: |

6.2　Methods to obtain informed consents

|  |
| --- |
| (1) Written consent  (2) Verbal consent  (3) Electronic consent  (4) Others (Specify: ) |

6.3 Describe the process to obtain informed consents [in maximum **100 words**].

|  |
| --- |
| [text here] |

6.4 Will informed consents be obtained from legally authorized representative of the participants?

|  |
| --- |
| Yes  Specify reason(s) why informed consent will be obtained from legally authorized representative:  (1) The participants are minors  (2) The participants have cognitive difficulties  (3) Others (Specify: )  Select who will be selected as legally authorized representative:  (1) Parent or parental authority  (2) Spouse or partner  (3) Brother or sister  (4) Child  (5) Others (Specify: )  No |

6.5 Will informed assents be obtained from the participant?

|  |
| --- |
| Yes Specify the method:    No |

6.6 Will the study provide the participants with opt-out option?

|  |
| --- |
| Yes Specify the method:    No |

6.7 Will the study take any measures of public announcement on the research?

|  |
| --- |
| Yes Specify the way of conducting public announcement (where, when, how): |
| No Describe the reason why public announcement measures will not be taken: |

**7. Protection of personal information and human rights**

7.1 Will the study collect, obtain and/or process any personal data/information?

|  |
| --- |
| Yes  No 🡺 Go to 7.2 |

7.1.1 Will the study anonymize personal data/information?

|  |
| --- |
| Yes  No Describe the reasons why the study will not anonymize personal data/information: |

7.1.2 Will the study prepare ‘decoding index’?

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| --- |
| Yes  No Describe the reasons why decoding index will not be prepared and go to 7.2: |

7.1.3 Describe where and how the ‘decoding index’ will be stored

|  |  |
| --- | --- |
| Name of institution |  |
| Specify the place |  |
| Responsible person |  |

7.2 Storage of information for the study

7.2.1 Will the study collect, obtain and/or keep the data/information **in printed forms**?

|  |
| --- |
| Yes  No 🡺 Go to 7.2.3 |

7.2.2 Describe the data management of **printed forms**

|  |  |
| --- | --- |
| Name of institution |  |
| Specify the place |  |
| Responsible person |  |
| Can the place above be properly locked? | Yes  No Describe the security of the room: |
| Will hard copies be kept with lock and key? | Yes  No Describe the security of the storage: |
| Duration of storage | years months from: (i) the date of master/doctoral course completion for students; and (ii) the date of data collection completion for others.  It is recommended that data and specimens should be maintained by storing them in appropriate locations for 10 years and 5 years, respectively, |

7.2.3 Will the study obtain and/or keep the data/information **in electronic forms**?

|  |
| --- |
| Yes  No 🡺Go to 7.3 |

7.2.4 Describe the data management of **electronic forms**

|  |  |
| --- | --- |
| Responsible person |  |
| Specify the storage | (1) Computer (standalone, without connection to internet)  (2) Computer (standalone, with a connection to internet)  (3) Server  (4) Hard disk  (5) Others (Specify: ) |
| Specify place of the storage |  |
| Describe measures to restrict access to the soft copies | |
| [text here] | |
| Describe the security measures of the storage | |
| [text here] | |
| Duration of storage | years 　　months from: (i) the date of master/doctoral course completion for students; and (ii) the date of data collection completion for others.  It is recommended that data and specimens should be maintained by storing them in appropriate locations for 10 years and 5 years, respectively, |

7.3 Storage of specimens for the study

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| --- |
| 7.3.1 Will any specimens be kept for the study? |
| Yes　  No 🡺 Go to 7.4 |
| 7.3.2 Describe type of the specimen and methods of their storage (where, when, how) |
| [text here] |

7.4 Outsourcing

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| 7.4.1 Will any part of this study be outsourced? |
| Yes　  No 🡺 Go to 8 |
| 7.4.2 Item(s) for outsourcing |
| (1) Data management  (2) Statistical analysis  (3) Monitoring  (4) Others（Specify: ） |
| 7.4.3 Contractor |
| [text here] |

**8. Ethical considerations**

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| --- |
| 8.1 Describe possible burdens to be caused to the participants, and measures to minimize the burdens. |
| [text here] |
| 8.2 Describe if there are any predicted risks or adverse events among the participants, and measures to be taken for minimizing those risks or events. |
| [text here] |
| 8.3 Will participants be compensated for any risks or adverse events to their health resulting  from participation in this study? |
| Yes Specify the details:    No |
| 8.4 Will there be any financial burdens borne by participants (e.g. cost for transport to interview sites)? |
| Yes Specify the details:    No |
| 8.5 Will there be any compensation and/or remuneration to be paid to participants? |
| Yes Specify the details:    No |

**9. Funding and conflict of interest**

9.1 Is the fund secured for this study?

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| --- |
| Yes: Specify funding source(s):  Funding source 1:  Funding source 2:  Funding source 3: |
| No Describe how the study will be financially managed: |

9.2 Are there any conflicts of interest?

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| --- |
| Yes Specify types of conflict/interest, by selecting the following item(s) you receive from the parties (i.e. private companies/organizations/governments) responsible for or related to the services/commodities this study addresses.   1. From:   Name of organization  (1) Remuneration (e.g., salary, allowance, fees, honorarium): JPY  (Foreign currency to be converted into JPY）  (2) Stock or stock option  (3) Receipt of equipment, materials, drugs, medical writing, gifts or other services  (4) Other (Specify )   1. From:   Name of organization  (1) Remuneration (e.g., salary, allowance, fees, honorarium): JPY  (Foreign currency to be converted into JPY）  (2) Stock or stock option  (3) Receipt of equipment, materials, drugs, medical writing, gifts or other services  (4) Other (Specify )  *(Add if necessary)* |
| No |

9.3 Are there any Industry-Academia-Government trilateral collaboration activities\*?

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes:  Specify the following item(s) you receive from the parties (i.e. private companies /governments/universities) responsible for or related to the services/commodities this study addresses.   |  |  |  |  | | --- | --- | --- | --- | |  | Industry (private company) | Government | Academia (university) | | Name of organization | (1)  (2)  *(Add if necessary)* | (1)  (2)  *(Add if necessary)* | (1) Nagasaki university  (2)  *(Add if necessary)* | | Total amount of financial contribution  (Foreign currency to be converted into JP) | JPY | JPY | JPY | | Equity† | Yes  No |  |  | |
| No |

\* Industry-academia-government collaboration includes but not limited to collaborative research, sponsored research, consortium, technology transfer, patent transfer, technical training, committee membership, commissioned business trips, hosting of researchers/post doctoral fellows, grants/donation provision, commissioned examinations/analysis etc.

† "Equity” refers to stocks, capital investment, stock options, beneficiary rights, etc. of both publicly or privately held companies.

**10. List of attached documents**\*

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| --- |
| (1) Research proposal  (2) Explanation sheet for study participants  (3) Informed consent form  (4) Informed assent form  (5) Withdrawal form  (6) Questionnaire  (7) Others (Specify: ) |

[Note] All the attached documents should be integrated into **a PDF file**, while this application should be submitted in form of MS-Word format. Therefore, only two electric files should be submitted (i.e. MS-Word application and the integrated PDF file). Otherwise, the application may not be received.

END.