**Instructions for the Use of a Broad Consent Form**

**Background**

 Data collection is a common procedure in general work practices. To employ the data, consent from the owner of the information/ specimen must be collected and the research should be done for the benefits of the data owner. If the data is to be used in the future for other purposes such as for a research without benefits to the data owner and with the risks of violating his/her privacy, their consent should be asked in advance. This “Broad consent form” of King Mongkut’s University of Technology Thonburi is based on the International Ethical Guidelines for Health-related Research Involving Humans, 4th Edition, Council for International Organizations of Medical Sciences (CIOMS) 2016. The objective of the consent is to use the collected data for future research regarding the criteria of the international research ethics involving human subjects.

**Instructions**

 **1. The researcher** can adjust the ‘Broad consent form’ to suit his/her study by replacing the statement in […] in section 1 of this consent form with the scope of the study/ details of the study/ previous research done by the researcher.

2. **The researcher** has to submit “a Broad Consent Form,” attached with a Concept Proposal specifying the expected scope of the study, to be approved by the KMUTT Institutional Review Board before asking for consent from the subjects/ participants.

 3. **The researcher** has to specify the end period of the use of the data/ specimen.

 4. **The KMUTT Institutional Review Board** will stamp its approval on “the Broad consent form” that is properly adjusted. After that, the researcher can use the form to ask for consent of the subjects/ participants.

 5. **If the owner of the information/ specimen** agrees to give his/her consent for the storage of the data, the researcher and the owner of the information/ specimen must sign their names in “the Broad Consent Form.” Each keeps one copy of the document as an evidence.

 6. **Before starting the research project**, the researcher has to submit a research proposal and the Broad consent form with an IRB approval stamp to be reviewed by the KMUTT Institutional Review Board.

 7. For a research project using the data with prior broad consent, the researcher ***can use the data without asking for consent again***, except in case that the scope of the study is adjusted against the previous consent. This will be informed by the KMUTT Institutional Review Board upon the completion of the project review.

**Points to consider for the rights and safety of the owner of the information/ specimen**

 **The researcher** has to consider and respect the rights of the owner of the information/ specimen following the criteria specified by the international human research ethics. The points to be considered are as follows:

* The data obtained from the owner of the information/specimen is personal information. The researcher has to be responsible for the data confidentiality. This can be done by appointing a data keeper and establishing codes for each subject/participant in order to separate the information defining their identity from the data employed for the study. Moreover, the levels of accessibility to the confidential information have to be established
* Researcher can contact the owner of the information/ specimen to ask for further information or to inform him/her of the research findings only if the consent of the owner of the information/ specimen is obtained since the first data collection.
* In case the owner of the information/ specimen is an underage (below 20 years old) and the consent is given by his/her legal guardian, the researcher has to specify the procedures and state further in the consent form allowing the owner of the information/ specimen to make his/her own decision later when he/she is over 20 years old.
* In case the owner of the information/ specimen withdraws his/her consent (which can be done at any time without any negative effects upon any rights/ benefits), researcher has to specify the procedures and state further in the consent form that the owner of the information/ specimen can inform the researcher via the given contact information.

**Memorandum**

**Department/ institute** ............................................................. **Tel**....................................................

**No.** …………/........... **Date**.................................................

**Subject: IRB Research proposal submission form (Broad consent)**

**To** Chair of the KMUTT Institutional Review Board via IRB Subcommittee at the Faculty/Office/Institution Subcommittee of ….……………………………..……………..

My name is .........................................................................................Faculty/ Institute .............................................

I would like to submit a research proposal entitled .............................................................................................................

………………………………………..................................................................................................................................................................

to receive an exemption review. **One set of the documents** specified below is enclosed for the review:

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **List of Documents** | **Yes** | **No**(please indicate) |
| 1 | KMUTT’s Broad consent form |  |  |
| 2 | Concept Proposal |  |  |
| 3 | Certificate of IRB Training of the researchers (everyone)  |  |  |
| 4 | Document files: documents numbers 1-3 saved as PDF and Word files |  |  |

Please kindly consider the request.

|  |
| --- |
| Signature ................................................... |
| (............................................................) |
| Principal Investigator/ Student |
|  |
| Signature ................................................... |
| (............................................................) |
| Head of Department/Program Director/Advisor |

**KMUTT Broad Consent Form**

**Name(s) of researcher(s):** (please specify the names of all researchers in the team or the principal investigator/ Faculty or Institute/ email/ phone number)

**Broad Consent Number:**

**Section 1 Instructions**

 Data collection is a common procedure for conducting research. The data obtained can be used for a study to gain new knowledge beneficial to the society. To employ the data, consent from the owner of the information/ specimen must be collected for the respect of the person’s personal rights. However, as it is still not definite when and with what details the research will be conducted in the future, you are asked for a broad consent in advance in case your information is to be used in the future. **You have the rights to give your consent or reject the request for the keeping of the data.**

**The data to be kept for future research**

[The researcher has to specify the details of data/ specimen collecting for future research use]

 **1) Information to be used for the research:** such as information in a student’s record, grades, personal information, age, gender, income, underlying diseases

 2) **Human specimen:** specify what specimen is to be used such as blood and its amount used, or biopsy sent to a lab for diagnosis/ treatment

**The scope of the future research**

[The researcher has to specify the scope of the future use of the data/ specimen such as for education research, physical/ mental health research, future diseases that might occur, life success, etc.]

**Methods of data specimen storage**

**[The researcher has to give further details as follows:]**

For data storage, choose one of the following two topics:

1. **There is a data keeper (the person is not related to the research) who** separates defining information such as name, last name, ID number, phone number from **non**-defining information such as gender, age, weight, height, scores or grades, education, income.The data keeper will not disclose the coding that associates the two groups of information to the researcher, except for certain necessary cases.
2. **The** **researcher** stores all the information/ specimen (both defining and non-defining) together.

For specimen storage, choose one of the following two topics

1. **There is a data keeper (the person is not related to the research) who** converts name/ defining information of the specimen owners into codes, barcodes, or QR code, and keeps it with the specimen. The data keeper will not disclose the coding to the researcher, **or**

2. **The researcher** labels the specimen with the name, last name, and ID number of the patient, or other information identifying the owner of the specimen.

**Duration of Research**

Research Duration..................(months, years)

From: Month…………. Year………… To: Month…………. Year……………

**Duration for the storage of the data/ specimen**

* Specify the duration the data/ specimen expected to be stored.
* Specify the month/ year in which the storage will end.

**Data Destruction**

* How the information will be disposed of after the storage period.
* When the information will be disposed of after the storage period.

**Research implication**

[Specify further details as follows:

* The research findings yield only academic benefits, **or**
* The research findings might be in a form of a product that yields commercial benefits as well. The owner of the information/ specimen will not receive the commercial benefits obtained from the future research findings, **or**
* Both]\*

\* **The** **owner of the information/ specimen might not receive the direct benefits from allowing the future use of his/her information/ specimen. However, the research findings will be for academic benefits or for the benefits of the society as a whole.**

**The risks involved in using the information/ specimen in future research**

 The risks from the abovementioned research do not involve physical harm to the owners of information/specimen. **Rather, the risks might occur from the leakage of the personal information of the subjects/ participants** to others not related to the research. However, the researcher has strict measures for the data confidentiality.

 There might be certain cases when the information has to be disclosed to

* Government organizations with the authority to access the data for an examination
* KMUTT Institutional Review Board
* Funding organizations/ person for the research project might ask for an examination when necessary

**Informing the unexpected research findings to the owner of the information/ specimen**

 Through the research procedures, some unexpected information might be obtained, especially the information concerning health issues. The underlying problems might be found through the research procedures. For example, it might be found that the subject/ participant is in the first stage of certain diseases with no obvious symptoms, or contains the risks of occurrences of certain preventive illnesses. Informing the owner of the information/ specimen of the research findings might be beneficial for them. Therefore, it is necessary for the owner of information/ specimen to give their consent in advance. This involves both advantages and disadvantages to be carefully considered as follows:

1. If the owner of information/ specimen states that he/she does not want to be informed of any information obtained from future research.
	* **Advantages:** good for confidentiality of the personal information as the researcher will not know the identity of the owner of the information/ specimen.
	* **Disadvantages:** no chances of gaining benefits from the research
2. If the owner of information/ specimen states that he/she would like to be informed of any information obtained from the future research
	* **Advantages:** have chances of gaining benefits from the research
	* **Disadvantages:** the researcher will know the identity of the owner of the information/ specimen.

**The persons permitted to use the information/ specimen for future research**

 Apart from the researcher who asks for the consent to collect the data from the subjects/ participants, there might be other researchers interested in employing the information/ specimen for research. The owner of the information/ specimen has the rights to agree or reject this request.

**Contact information**

 If you have any questions concerning the storage, maintenance, or the use of the information/ specimen for future research, please contact [specify the names of the researcher/ Faculty or Institute/ email/ phone number] or an advisor [specify the name of the advisor/ Faculty or Institute/ email/ phone number].

 If you have any questions concerning **the rights** upon the storage, maintenance, or the use of the information/ specimen for future research, please contact

 Chair of the KMUTT Institutional Review Board

 Research, Innovation and Partnerships Office,

 7th floor, the Office of the President Building

 King Mongkut’s University of Technology Thonburi

 126 Pracha Uthit Rd., Bang Mod, Thung Khru, Bangkok, 10140

 Tel. 0-2470-9623 Fax. 0-2872-9083

 E-mail: irb@kmutt.ac.th

**Section 2 Consent for the collecting of information/ specimen to be used for future research**

 - The owner of the information/ specimen is asked to carefully read and consider the following statements. For certain statements, the owner of the information/ specimen can choose whether to give his/her consent or not by marking a ✓ **in the** 🞎 **preceding the statements**

 - After the owner of the information/ specimen carefully reads and considers the following statements, and agrees to give his/her consent to the researcher to collect the information/ specimen for future research, please sign and date the document in the final section.

**2.1 By giving consent, the owner of the information/ specimen agrees that he/she:**

🞎Has read this consent form (or the researcher read it to him/her) and asked questions from the researcher until it is fully understood

 🞎 Has been informed of the risks and benefits that might occur from this study

 🞎 Must be 20 years of age or older and willing to give information to be used for future research. *If “the owner of the information/ specimen” is an underage (with an age less than 20 years old), or is a patient, an incompetent person, or a quasi-incompetent person, this document must be signed by his/her legal guardian/ authorized representative.*

 🞎 He/she can withdraw his/her consent at any time during the period the data is stored without any negative effects upon any rights/ benefits he/she has prior to this. **The owner of the information/ specimen** can inform the researcher at [specify the names of the researcher/ Faculty or Institute/ email/ phone number] or an advisor [specify the name of the advisor/ Faculty or Institute/ email/ phone number].

**2.2 Permission to contact the owner of the information/ specimen in the future**

🞎 The owner of information/ specimen states that he/she does not want to be informed of any information obtained from the future research. - **Advantages:** good for confidentiality of the personal information as the researcher will not know the identity of the owner of the information/ specimen. **Disadvantages:** no chances of gaining benefits from the research, **or**

🞎 The owner of information/ specimen states that he/she would like to be informed of the information obtained from the future research. - **Advantages:** having chances of gaining benefits from the research. **Disadvantages:** the researcher will know the identity of the owner of the information/ specimen.

2.3 **Permission for the data to be used by other researchers**

🞎 Allow only the researcher who asks for consent to use the information, **or**

🞎 Allow other researchers to use the information/ specimen for future research

 🞎 Allow only the researcher from the same institute as the one who asks for consent, **or**

 🞎 Allow researchers from other institutes to access the information

 🞎 Allow only the researcher from domestic institutes, **or**

 🞎 Allow researchers from institutes abroad to access the information

 The owner of the information/ specimen has been informed and given explanation by the researcher of King Mongkut’s University of Technology Thonburi and well understands the storage methods of the information/ specimen to be used for future research. Therefore, he/she hereby shall sign this consent form, one copy of which is kept by the researcher and the other by the owner of the information/ specimen.

Signature ........................................................... Researcher Date ............................

 (......................................................... name in print)

Signature ........................................................... Owner of the information/ Date ……………………….

 Specimen who gives consent

 (......................................................... name in print)

Signature ........................................................... Legal guardian/ Date ……………………….

 Authorized representative

 (......................................................... name in print)

**Concept Proposal**

**1. Title of the research project**

 Thai ……………………………………………………………………….……………………………………................……………

 English …………………………………………………………………………………………..................…………………………

**2. Research team**

 **Principal Investigator** [specify the names of the researcher/ Faculty or Institute/ email/ phone number] or an advisor [specify the name of the advisor/ Faculty or Institute/ email/ phone number]

 **Researcher(s)** [specify the names of the researcher/ Faculty or Institute/ email/ phone number] or an advisor [specify the name of the advisor/ Faculty or Institute/ email/ phone number]

**3. Responsible Organization/ Institute**

**Organization/ institute:** ...............................................................................................................................

**Research/ data collection site:** ..................................................................................................................

**4. Rationale**

[Significance or necessity of the research project, requiring the broad consent from the owner of the information/ specimen]

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 **5. The scope of future research**

[- The scope of the future use of the data/ specimen

 - Duration for the information/ specimen to be stored

- Relations to other organizations (in case there is more than one organization responsible for the project, please specify the scope of one part of the project which is responsible by each organization]

**6. Research Duration**

Duration..................(months, years)

From: Month…………. Year………… To: Month…………. Year……………

[- Details about the starting and ending date of the information/ specimen storage]

**Data/ specimen Destruction**

* How the information will be disposed of after the storage period.

Please pecify………………………………………......................................................................................................………

…………………………………………………………………………………………………………………..................................………….......

* When the information will be disposed of after the storage period.

Please pecify………………………………………......................................................................................................………

…………………………………………………………………………………………………………………..................................………….......

**7. Methods for the collecting and storage the data/ specimen**

 [- Subjects/ participants

 - Methods of access to the subjects/ participants

 - Methods of data/ specimen storage (both defining and non-defining methods)

**8. Confidentiality**

 [- Methods and steps for the coding system

 - Data keeper

 - Methods of determining the rights to access confidential information]

**9.** **The risks that may occur when using the information/ specimen in future research**

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**10. Expected benefits obtained when the research is done**

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