**Application Form for Low Risk Ethical Review of a Research Project Involving the Use of Retrospective Clinical Data**

## This part will be completed by HKSTP CREC:

Proposal #:

Date received:

Approval date:

Expiration date:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

P POSAL #:

ROPOSAL #:

PROPOSAL #:

APPROVAL DATE:

EXPIRATION DATE:

**Important: Use of retrospective clinical data should not involve contacting patients. If pateints are required to be contacted for research purpose, please complete the *“Application Form for Ethical Review for Use of Human Participants in Research*”.**

Before a company is to start using human participants and/ or materials for any of its new/ revised/ extended R&D activities, the company is responsible for obtaining ethics clearancefor such proposed activities, to ensure appropriate ethical standards will be upheld.

Before completing this form, please refer to the **Laboratory and Research Safety Guidelines** in the **HKSTP Safety, Health and Environment (SHE) Handbook** issued by the HKSTP SHE Office.

This form shall be completed by the **principal investigator or staff in-charge** of the proposed project. Please complete all sections in wordings that are understandable to a lay person. Expand the text boxes as you type. Mark all applicable boxes. Enter “N/A” if a section is not relevant, instead of leaving it blank.

Submit this form and relevant attachments (see Application Checklist) to the CREC Secretariat at crec@hkstp.org

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| --- | --- |
| **Project title:** |  |

[ ]  New submission

[ ]  Extension of \_\_\_\_ years \_\_\_\_ months for approved project (HKSTP CREC ref. no.: \_\_\_\_\_\_\_\_\_\_\_\_)

[ ]  Amendments in Section(s): [ ]  Project title [ ]  A [ ]  B [ ]  C [ ]  D [ ]  E [ ]  F [ ]  G

 [ Notes:Pleasehighlight amendments in subsequent sections in yellow. ]

#### COMPANY & PERSONNEL INFORMATION

|  |  |
| --- | --- |
| 1. Company name:
 |  |
| Affiliated technology cluster or program in HKSTP: | ☐ Biomedical Technology ☐ Electronics ☐ Green Technology ☐ Information & Communications Technology ☐ Material & Precision Engineering☐ Incu-Bio ☐ Incu-Tech ☐ Incu-App ☐ Other program: \_\_\_\_  |
|  | ☐ Health@InnoHK ☐ AIR@InnoHK  |
| Company Address: (Building # & unit # in HKSTP) |  |
| Location to undertake research project:(Building # & unit # in HKSTP) |  |

1. Principal investigator or staff in-charge of this project:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name**(Please underline the surname) | **Position in the company** | **Direct phone number** | **Email address** |
|  |  |  |  |

1. All other personnel (including co-investigators, interns, etc.) that are authorized to conduct procedures involving human participants/ materials in this proposal:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name**(Please underline the surname) | **Role in this project** | **Position in the company** | **Direct phone number** | **Email address** |
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1. Brief description of experience in human participants and/ or materials experimentation (including types/duration of training attended) of **all the personnel named in (2) and (3) above**.

#### DESCRIPTION OF RESEARCH STUDY

* 1. Explain your objective and hypothesis for this research project that involves human participants and/ or materials.
	[E.g. What is the Aim, Objective, Research Question/s or Hypothesis of the research project? What is already known about this topic and what research has already been conducted on this topic or field of research? Why is it important to conduct this research project?]
	2. Justify on the necessity to use human participants including their data.
	3. Explain your elements of research methodology that involve human participants and/ or materials.
	4. State the risks and benefits of the research project and how will the risks be managed.
	5. Intended duration of this project.
	6. Specify the source of the original dataset.
	7. Will the research project require access to another location/ organization/ institute?

[ ]  Yes, please specify the location/ organization/ insititue and provide a copy of the approval letter (if appropriate): Click or tap here to enter text.

[ ]  No

* 1. Will the research project require collaboration with another location/ organization/ insititue?

[ ]  Yes, please specify the location/ organization/ insititue and provide a copy of the approval letter (if appropriate): Click or tap here to enter text.

[ ]  No

* 1. Has the project obtained approval by an external ethics approval body and/or will this project be submitted to an external ethics approval body for review?

[ ]  Yes, please specify the name of the external ethics approval body and the status of the application: Click or tap here to enter text.

[ ]  No

#### HUMAN PARTICIPANTS AND/ OR MATERIALS REQUIREMENTS

1. Who are the participants, whose Individual datasets/records the research project is seeking to collect? (select all options that apply)

[ ]  Adults (over the age of 18 years)

[ ]  Pregnant women and/or the human foetus

[ ]  Children / Young people (under age 18 years)

[ ]  Elderlies (over the age of 65 years)

[ ]  People in dependent or unequal relationships

[ ]  People highly dependent on medical care

[ ]  People with a cognitive impairment, an intellectual disability or mental illness

[ ]  People who may be involved in illegal activities or residents of custodial institutions

[ ]  People identifiable by their membership of a cultural, ethnic or minority group

[ ]  Others, please specify: Click or tap here to enter text.

1. Will any personal identifiers be collected?

[ ]  Yes, please specify type(s) of personal identifiers: Click or tap here to enter text.

[ ]  No

1. If personal identifiers are collected, will personal identifiers be later removed for data to be anoymised?

[ ]  Yes

[ ]  No, please justify why data can not be anoymised: Click or tap here to enter text.

1. Specify ALL types of personal data/ information to be collected for this project and how each type of data will be used. [e.g. Diagonsis, Demographic information, sexual preference, health status, criminal activity, etc.]
2. State and justify the number of individual datasets to be collected.
[The number of human participants should be the minimum number required to obtain statistically valid results.]
3. Explain how the data collected will be analysed to achieve the objective of the project.

#### PRE-EXISTING DATA FROM PARTICIPANTS

1. Are the original datasets publicly available, if yes, please provide access (e.g. web link), if no, please specify the approving authority. [Note: “publicly available” means that the data can be accessed without an approval process.]
2. Were the original dataset originally collected for academic research purpose? If yes, please attach a copy of the consent form for data usage, if no, please attach a copy of the personal information collection statement.
3. Explain how this research is consistent with the purpose and intended use of the original dataset.
4. Do the original dataset contain any direct or indirect personal identifiers, please specify and provide details. [e.g. direct identifiers: name, address, ID, medical record, etc., indirect identifiers: assigned code that can reasonably identify a subject.]

#### DATA MANAGEMENT & DISSEMINATION OF RESEARCH OUTCOMES

Under circumstances that HKSTP CREC considers necessary, the applicant may be asked to provide additional information for review by HKSTP Data Governance Committee (DGC). HKSTP DGC will review material related to data governance and security, based on factors including but not limited to: legal and compliance, information security and technology. If applicable, HKSTP DGC will provide recommendations on data governance and security-related aspects for HKSTP CREC’s consideration.

1. Duration and location where the data will be stored during the research project?
2. How will security and confidentiality of data be protected, maintained and retained?
3. Upon completion of research project, how will data be managed?
4. How will the outcomes of the research project be disseminated at the end? (ie. thesis, journal article, book, web page, conference paper, the media etc.)

#### WAIVER OF CONSENT

1. Explain why it is impractical to obtain consent from participants.
2. Explain how benefits of the research project outweighs any risks of harm associated with not seeking consent from the participants.
3. How will the participants’s privacy and confidentialilty be protected through the research and after disseminate of research study?
4. Is there any possible reason(s) for participants not to provide consent if they were asked. Please provide justification to your answer.
5. Will participants benefit from the outcome of the research project. If so, how will information from the research be made available to the participants?

 **‘**

#### CONFLICT OF INTEREST

Is there any affiliation or financial interest for researchers in this research project or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?

[ ]  Yes, provide details to explain how this will be managed: Click or tap here to enter text.

[ ]  No

#### CERTIFICATIONS BY PRINCIPAL INVESTIGATOR / STAFF IN-CHARGE

I, the undersigned, who have authority to make this declaration on behalf of my company and to bind the company to the matters stated in this form, hereby certify as follows:

1. All the information stated in this form and the materials provided are true, complete and accurate.
2. I have determined the proposed project (“Project”) is not unnecessarily duplicative of previously reported research projects.
3. I shall take reasonable care to ensure that the proposed work/experiment(s) in the Project is conducted in accordance with the best modern practice and in such manner so as to safeguard the welfare of human subjects involved. I assure that adequate measures are to be taken to minimise all risks and are yet compatible with the objectives of the work/experiment in the Project.
4. I have completed the requisite training course(s) or its equivalent (see **Application Checklist**) and all other necessary investigator training courses required by my company for the purpose of conducting research activities involving human subjects.
5. The individuals listed in **Section A** who will conduct procedures involving human subjects in this proposal have completed the required training course or equivalent (see **Application Checklist**), and have received training in:
* responsible conduct of research;
* research data and records management;
* laboratory safety in research (if necessary);
* methods and techniques required by the protocol (if necessary);
* the proper use and procedures of any equipment involved in the protocol (if necessary);
* and procedures for reporting accidents and incidents.
1. I will ensure that facilities, safety equipment and procedures are in place throughout the entire duration of the Project to enable this Project to be carried out safely.
2. I will obtain approval from the HKSTP CREC before initiating any changes in this Project.
3. I will notify the HKSTP CREC immediately regarding any unexpected study results that impact the human subjects involved. In addition, any unexpected incidents, as well as unanticipated pain or distress, morbidity or mortality will be documented and reported to the HKSTP CREC immediately .
4. I am familiar with and will comply with the **“Laboratory & Research Safety Guidelines”** stated in the **HKSTP SHE Handbook**, as well as all pertinent rules, policies and regulations of HKSTP.
5. I am familiar with and will comply with all applicable guidelines and regulatory and statutory requirements of the Hong Kong Special Administrative Region.
6. I further understand that if any information or materials provided in this application is false or if I or my team fails to adhere to any of the ethics guide and requirements referred to at **(9) and/or (10)** **above** (“Requirements”), HKSTP reserves the right to demand that part/all of the activities in this Project be ceased without any liability whatsoever towards my company. In the event of any serious violation of the Requirements, HKSTP may, at its absolute discretion, terminate my company’s lease with HKSTP.

**Principal Investigator / Staff in-charge:**

[The name below should match that in **Section A2**. Electronic signature is acceptable.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name: |  | Signature:  |  | Date: | Click or tap to enter a date. |

#### CONCURRENCES

Concurrence of resource capability in the indicated facility/location to support the proposed study:

I/We hereby endorse this application and confirm that the principal investigator / staff in-charge named in **Section A2** is appropriately experienced in the work proposed and that the company (listed in **Section A1**) has adequate facilities for the experiment(s)/ procedures to be conducted safely and in such a way as to safeguard the welfare and minimise discomfort experienced by the human subjects involved.

*Supervisor/person in-charge of managing the facility/location to be used in this project:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |

*Supervisor/person in-charge of managing the facility/location to be used in this project:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |

#### FINAL APPROVAL

 *(This part will be completed by HKSTP CREC)*

Certification of review and approval by the HKSTP Clinical Research Ethics Committee (CREC):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name: |  | Role: |  | Signature:  |  | Date: | Click or tap to enter a date. |