**Application Form for Ethical Review for Use of Human Participants in Research**

## 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:** 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 other 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 [x]  G [ ]  H [ ]  I

 [ 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  |
| Location(s) in HKSTP premises:(Building # & unit #) |  |
| 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. Category of research study. [Please select all applicable boxes]

[ ]  Behaviourable / Non-clinical Studies (Do not involve any invasive surgery. Study may only involve interviews, observations, questionnaires or tests)

[ ]  Clinical Studies (May include surgeries, clinical interventions, drug testings, medical device and rehabilitation programs, analysis of clinical data, collection of specimen, etc.)

* 1. Explain your objective and hypothesis of study. Explain how the study is important to human health, the advancement of knowledge, or the good of society in language that a layperson can understand.
	2. Justify the necessity to use human participants for this research project.
	3. Explain your elements of research methodology that involve human participants and/ or materials.
	4. Intended duration of this project.
	5. 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

* 1. Summary of the experimental design and data collection procedures:
* Briefly explain the experimental design and specify all procedures involving human participants. This description should allow the CREC to understand the experimental course of a human subject from his/her entry into the experiment to the endpoint of the study.

A flowchart may be an effective presentation of the planned procedure.

🡨 Attach as separate document or show in the space below

* A best practice is to provide an acceptable range of the specific items described below to allow flexibility in the use of professional judgment and avoid non-compliance due to work conducted off protocol as a result of overly restricted parameters.

*[Please provide your summary below. Expand this space as you type.]*

#### 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:

1. Does the research project involve direct contact with human participants?

[ ]  Yes, specify how participants will be contacted: Click or tap here to enter text.

[ ]  No

1. What procedure(s) does the project involve? (select all options that apply)

[ ]  Blood Withdrawl

[ ]  Saliva Collection

[ ]  Investigational drug/ device

[ ]  Audiotapes/ videotapes

[ ]  Physiological measurements

[ ]  Imaging

[ ]  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.

#### RECRUITMENT & DATA COLLECTION

1. Source of Data: New data to be collected from human participants [Please select all applicable boxes]

[ ]  Experimental procedures/ treatment/ intervention

[ ]  Focus group

[ ]  Internet survery

[ ]  Observation

[ ]  Personal interviews

[ ]  Self-administered questionnaire

[ ]  Telephone survey

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

1. Recruitment and selection of study participants
	1. How will participants be recruited?
	2. Participants inclusion criteria with reasons. [e.g. Hong Kong residents ages 18 years and above]
	3. Participants exclusion criteria with reasons. [e.g. people with metal implants need to be excluded from MRI]
	4. Who will perform the data collection?
	5. Location(s) where the experiment and data collection take place?
	6. Duration required to complete the experiment and data collection for each participant.
	7. Are there any reimbursement or other incentives/benefits offered to participants. If yes, provide details on the form of reimbursement/ incentives/ benefits and explain why they are reasonable.

#### INSURANCE

It is the policy of HKSTP that appropriate insurance should be taken out for ALL projects involving trials/ tests on human subjects. Please provide supporting documents of such insurance along with the submission of this application form, with the exemption of the followings. [Please select all appropriate boxes]

[ ]  Project collects data through questionnaire/ survey/ interview/ focus group discussion

[ ]  Project studies the effectiveness of an educational programme/ training

[ ]  Project collects specimen such as blood/ urine/ saliva/ etc. by professionals who are covered by Medical Malpractice Liability in Hong Kong

[ ]  Project studies existing data

#### RISK ASSESSMENT

1. Will the study involve intervention, such as action research/ treatment of any type? If yes, please provide details. [e.g. intensity, duraction, etc.]
2. Will the study involve diagnostic procedures for human subjects. [e.g. X-ray, ultrasound, MRI, etc.]
3. ll the study involve deception of the full context of the study? If yes, explain what the deception will be and why this is necessary.
4. Before any attempts are made to minimize privacy risk (e.g. making the forms anonymous), will the study involve greater than minimal privacy risks to research participants, either due to collection of sensitive data, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct, or because there is some risk of re-identification using a unique identifier such as DNA?
5. Is it possible that the duration of the experiment will induce greater than minimal stress/ discomfort, in particular, for children, given their age and capacity? If yes, please provide details on procedures taken to minimize stress/ discomfort.
6. Is it possible that the study will induce greater than minimal psychological stress/pain/discomfort? If yes, please provide details on procedures taken to minimize stress/pain/discomfort.
7. Is it possible that the study will expose participants to greater than minimal physical or medical risk? If yes, please provide details on procedures taken to minimize risk. [Note: Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests]
8. Will the study involve prolonged and repetitive testing. If yes, please provide details and justification to why this is necessary.
9. Will photography/ video-recording/ audio-recording of participants be used during the study?If yes, please provide justification for the recording and storage strategies.
10. Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals. If yes, please provide details of the age group and/or vulnerability, and attach a Parent/Guardian Consent form.
11. Any potential conflict of interest. If yes, please provide details and how conflict will be addressed. [e.g. financial gain to the investigators, power over participants such as teacher/student relationship]
12. Will the study involve matching of personal data from different data sources, e.g. multiple questionnaires. If yes, please provide details on identifiers used for matching.

#### INFORMED CONSENT

* When conducting research where seeking written consent is not practical or too sensitive, audio-recorded oral consent or email recorded consent might be less of a privacy risk than written consent and can be considered as an alternative.
* The waiver of recorded informed consent is normally only applicable to newly collected data without personal identifiers. In this case, PIs are required to clearly specify that they are recording data without personal identifiers in their experimental setup.
	1. How will the informed consent be recorded? [Please select all applicable boxes]

[ ]  Written consent [ ]  Audio-recorded consent [ ]  Online/Email recorded consent

* 1. If recorded informed consent CANNOT or WILL NOT be performed, please answer questions (i) to (iii).
1. Please explain why the experimental setup presents no more than minimal risk to the participants?
2. Please explain why waiver of recorded informed consent does not adverselt affect the rights and welfare of the participants.
3. Do you know the identity of respondents? [Note: Knowing the identity of participant is distinct from whether their identity is recorded]

 [ ]  No [ ]  Yes, explain why it is not practicable to have recorded consent: Click or tap here to enter text.

#### 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 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.]
5. How long will the data containing personal identifiers be retained.
6. How long will the anonymized data be retained.

#### 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 discomfort 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 (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 material 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 has adequate facilities (listed in **Section E2**) 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. |