**Site Extension Application Form 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 on HKSTP premises, the company is responsible for obtaining ethics clearance from HKSTP CRECfor 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.

The granting of site extension approval is subject to compliance of all relevant safety, health and environment regulations and requirements applicable to the proposed venue and equipment listed in the submitted application.

Submit the followings to the CREC Secretariat at crec@hkstp.org

1) Completed Application Form

2) Copy of Approval Memo issued by another indepent ethics approval body\*

3) Copy of the protocol submitted for approval\*

\*Either (2) or (3) shall indicate the specific HKSTP address(es)

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

|  |  |
| --- | --- |
| **External Approval Body:** |  |

*To be eligible for site extension, the Project must have obtained ethics approval from another Indepent Ethics Approval Body that meets the ethics principles and standards acknowledged by HKSTP CREC. Procedures to be performed on HKSTP premise (subject to approval) must be identical to the protocol approved by the above-mentioned Independent Ethics Approval Body.*

#### 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’s Address in HKSTP: |  |
| Location(s) to undertake research project: |  |

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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#### 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. Summary of the experimental design and data collection procedures. Please specify parts of the experiment to be conducted on HKSTP premises. This 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.
	2. Intended duration of this project.
	3. Duration required to complete the experiment and data collection for each participant.
	4. 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. 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.

#### 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

#### 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. |