IRB Checklist

(Aug 2021)

**Checklist for Clinical Research**

|  |
| --- |
| **Important Notes**   * The purpose of this checklist is to help researchers to determine if their projects are “human subjects (non-clinical)” or “human subjects (clinical)”. Projects which are “human subjects (clinical)” require the Principal Investigators (PIs) to provide more detailed information for review by the Institutional Review Board (IRB)\*. * Please note that if the response to A2 is “Yes” or any of the responses to the questions in B, C and D is “Yes” on this checklist, it means that your project is “human subjects (clinical)”. * For enquiry, please contact Cherrie Mok at 2766-6378 or [cherrie.mok@polyu.edu.hk](mailto:cherrie.mok@polyu.edu.hk).   *\*As its 274th meeting on 5 November 2020, the RC decided that with effect from 1 December 2020, the Human Subject Ethics Sub-committee (HSESC) be renamed as Institutional Review Board (IRB).* |

**General Information**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Project Title: |  | | | | | | | |
|  |  | | | | | | | |
| 2. Project Account Code  (if applicable): |  | | | | | | | |
|  |  |  | | | | | | |
| 3. Project Type: |  | Staff Research | | |  | Student Research | | |
|  | Others (Please Specific): | | |  | | | |
|  |  | | | | | | | |
| 4. Funding Body/ Funding Scheme: | | |  | | | | | |
|  | | |  | | | | | |
| 5. Project Duration (dd-mm-yyyy): | | | Start Date: |  | | | End Date: |  |
|  | | |  |  | | |  |  |
| 6. Name of PI: |  | | | | | | | |

**Checklist**

|  |  |  |
| --- | --- | --- |
| 1. **Target Population** | | |
|  | **Yes** | **No** |
| 1. Is the human subject a patient (i.e. a person with a known diagnosis)? |  |  |
| 1. If the response to A1 is “Yes”, does your research project investigate about the known diagnosis of a patient described above? |  |  |
| 1. **Objectives of the Study** | | |
|  | **Yes** | **No** |
| 1. Prevention of diseases/ injuries |  |  |
| 1. Treatment of diseases/ injuries |  |  |
| 1. Making diagnosis of diseases or health screening |  |  |
| 1. Evaluation of medical, health and safety procedures, protective procedures/ devices |  |  |
| 1. Toxicity evaluation or defining therapeutic dosage |  |  |
| 1. Pharmacokinetic or pharmacodynamics assessment |  |  |

|  |  |  |
| --- | --- | --- |
| 1. **Type of Experiment** | | |
|  | **Yes** | **No** |
| 1. Does the study involve any treatments?   Treatments may include (but not limited to):   1. drugs (e.g. chemical drugs, biological drugs and vaccines); 2. medical devices (e.g. implants); 3. Chinese/herbal medicines (e.g. proprietary/ traditional Chinese medicines); 4. health/nutritional supplements (e.g. drinking of coffee); 5. cell therapies (e.g. stem cells); 6. gene therapies (e.g. viral vectors); 7. exercises and other physical activities (e.g. swimming); 8. manual techniques (e.g. massage); 9. cognitive or behavioral exercises (e.g. mindfulness); and 10. any health and safety measures (e.g. those carried out in workplace or laboratory). |  |  |
| 1. Does the study involve any clinical procedures?   Clinical procedures include (but not limited to):   1. clinical examination/assessments (e.g. venipuncture, intravenous drips); 2. invasive or surgical procedures (e.g. tumor resection); 3. procedures require a healthcare professional to carry out (including but not limited to) nurses, physiotherapists, occupational therapists, psychologists, speech therapists, optometrist, radiotherapist and medical laboratory professionals 4. alternative or complementary therapies (e.g. acupuncture, aromatherapies and hypnotherapies); 5. imaging methods (e.g. X-ray examination); 6. collection of samples (e.g. blood and tissue) from human subjects |  |  |
| 1. **Outcome Measures** | | |
|  | **Yes** | **No** |
| 1. Neuropsychological assessment (e.g. Electroencephalogram (EEG)) |  |  |
| 1. Medical diagnosis by any methods including questionnaires |  |  |
| 1. Clinical and anthropometric measurement (e.g. survival, toxic symptoms, blood pressure, muscle strength, balance performance, depression and anxiety etc.) |  |  |
| 1. Functional evaluation (e.g. Activities of Daily Living (ADL) and mobility) |  |  |
| 1. Assessment of any human tissues including DNA, blood, cells and tissues |  |  |