

FACULTY OF SCIENCE

**APPLICATION FOR APPROVAL TO INVOLVE HUMANS IN RESEARCH**

**Instructions:**

* This document must be completed electronically;
* Complete all the sections (A – F);
* Sufficient details of the study have to be provided in the application. This will assist the Committee to understand the protocol detailing the background to the research project, the design of the study and all procedures;
* Should the project include the use of existing human-related data that were collected during a previous project/survey, the necessary supporting documents including ethical clearance and a permission letter for the use of the data need to be provided;
* If a specific question within a section is not applicable to your project, please briefly motivate why it is not applicable in the space provided;
* Ensure that your final submission document has all the required signatures;
* Please do not change the format of the form;
* Please submit the final, signed document in PDF format via email (*facultyethics@uj.ac.za*) to the Faculty Ethics Committee (FEC) before or on the scheduled agenda closing date;
* Meeting dates and agenda closing dates of the FEC are available on the “Faculty Meetings Schedule” provided annually by the Head of Faculty Administration;
* Whether written or verbal consent is to be obtained, the FEC requires the Participant Information Sheet/Consent Form to be used, written in friendly language, understandable to lay persons and explaining what will be required from a potential participant. This should include the following:
1. An invitation letter to participants to take part in the study;
2. A stipulation that participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled;
3. A stipulation that the participant may discontinue participation at any time without penalty or loss of benefits;
4. Provide a brief description of the research, its duration, procedures and what the participant may

 expect and/or will be expected to do;

1. Explain any foreseeable risks, discomforts, side effects or benefits, including those for placebo;
2. Disclose alternatives available to the participant (if risks are involved);
3. Explain where and how the data, photographs, videos and other materials will be used and published;
4. Explain how and when feedback will be provided on the final outcome of the study.

**In the case of medical and/or invasive procedures, the following are also required:**

1. A contact name and 24-hour telephone number;
2. Explanation whether medical treatment will be provided in the case of complications developing;
3. If required, that compensation for clinical trial-related injuries will be in accordance with the ABPI

guidelines;

1. A separate “Patient Information Sheet” and “Informed Consent Sheet” for blood / tissue samples taken for future testing;
2. The “Participant Information Sheet” may be incorporated into the consent form, or the consent form may be submitted separately.

**A: DETAILS OF APPLICATION**

1. **APLICATION TYPE** (MARK THE APPROPRIATE BLOCK WITH “X”)

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| **NEW PROJECT** | **ONGOING PROJECT** | **AMMENDED PROPOSAL** |
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1. **RESEARCH TYPE** (MARK THE APPROPRIATE BLOCK WITH “X”)

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| --- | --- |
| **ACADEMIC** (Research by academic staff or postdoctoral researchers i.e. not for degree purposes) |  |
| **CONTRACT** (Research for contract purposes) |  |
| **DEGREE** (Research for degree purposes – staff or students) |  |
| **PROTOCOLS** (Research for protocol development) |  |

1. **PROJECT TITLE / STUDY FIELD**

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**B: DETAILS OF RESEARCHERS**1. **PRINCIPAL INVESTIGATOR/RESEARCHER**

|  |  |
| --- | --- |
| **STUDENT / STAFF NUMBER** |  |
| **INITIALS AND SURNAME** |  |
| **TELEPHONE/CELL NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **STREET ADDRESS** |  |
| **PREVIOUS QUALIFICATION** |  |
| **CURRENT DEGREE REGISTERED FOR (E.G. MSc ENVIRONMENTAL MANAGEMENT)** |  |
| **BRIEFLY ELABORATE ON YOUR PREVIOUS RELEVANT EXPERIENCE IN HUMAN RESEARCH (Include number of years)** |  |

1. **SUPERVISOR**

|  |  |
| --- | --- |
| **STAFF NUMBER** |  |
| **INITIALS AND SURNAME** |  |
| **TELEPHONE/CELL NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **DEPARTMENT** |  |
| **HIGHEST QUALIFICATION** |  |
| **BRIEFLY ELABORATE ON PREVIOUS RELEVANT EXPERIENCE IN HUMAN RESEARCH (Include number of years)** |  |

 1. **CO-SUPERVISOR**

|  |  |
| --- | --- |
| **STAFF NUMBER** |  |
| **INITIALS AND SURNAME** |  |
| **TELEPHONE/CELL NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **DEPARTMENT/INSTITUTION** |  |
| **HIGHEST QUALIFICATION** |  |
| **BRIEFLY ELABORATE ON PREVIOUS RELEVANT EXPERIENCE IN HUMAN RESEARCH (Include number of years)** |  |

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**C: DETAILS ON FUNDING**

(MARK THE APPROPRIATE BLOCK WITH “X”)

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| --- | --- | --- | --- | --- |
| Is this project fully funded? | **YES** |  | **NO** |  |
| Does the funding of the project depend on the project being approved by the Faculty Ethics Committee? | **YES** |  | **NO** |  |
| **Please note:** Final approval of the project by the FHDC of the Faculty of Science will depend on the project being approved by the Faculty Ethics Committee. |

**D: COMMENCEMENT OF RESEARCH**

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| Expected starting date of the study or the part of the project requiring ethical clearance (e.g. 1 March 2020). This date cannot precede the FEC meeting date): |  |
| Expected completion date (e.g. 31 October 2020):  |  |
| **I DECLARE THAT THE PROJECT HAS NOT COMMENCED WITHOUT APPROVAL: (Print name and signature of principal investigator)** | **Name:****Signature:****Date:**  |

**E: DETAILS OF THE PROJECT**

###### BRIEF JUSTIFICATION

###### (Provide a brief introductory statement NOT EXCEEDING 500 WORDS and supported by relevant scientific literature that explains what problems, questions, needs or scientific or clinical observations or new ideas have led to the planning of the experiment)

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###### IN WHICH DEPARTMENT WILL THE RESEARCH BE CARRIED OUT?

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### WILL CLINICAL TRIALS BE DONE?

(MARK THE APPROPRIATE BLOCK WITH “X”)

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| **YES** |  | **NO** |  |

### If yes, complete the following

### Details of the investigator who initiated the clinical trials, good clinical practice (gcp) training (date and name of gcp course), date attended (dd/mm/year) for all investigators (investigators’ meetings do not qualify as gcp training).

FULL NAME:

GCP COURSE NAME:

DATE OF GCP COURSE: DAY/MONTH/YEAR:

**HOSPITAL/INSTITUTION WHERE EMPLOYED (IF APPLICABLE):**

**FULL-TIME OR PART-TIME EMPLOYEE:**

**HPCSA NO:**

1. **REQUIREMENTS FOR THE STUDY**

If radiation or isotopes are to be used, written approval must be obtained from the relevant authority. If drugs are to be used, written approval must be obtained from the relevant authority.

(MARK THE APPROPRIATE BLOCK WITH “X”)

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| Is the relevant authorisation letter attached? | **YES** |  | **NO** |  |

1. **STUDIES INVOLVING HUMAN CELLS, TISSUES OR CELL LINES (only applicable for new/de novo/ stem cells/transformation of cell lines isolated from patients/tissue)**

5.1. Does the study involve the use of human cells, tissues or cell lines?

5.2. Provide details on the source of the cells or tissues.

5.3. Provide details regarding the discarding of biohazard materials or biological waste as part of the study.

5.4. Are the samples provided by another institution or collaborator? If yes, please attach the necessary agreement letter and ethical approval documentation.

1. **STUDY PARTICIPANTS**
2. State the study area:
3. How will participants be invited to volunteer or how will they be selected?
4. Are the participants subordinate to the person doing the recruiting?
5. If yes, justify the selection of subordinate participants.
6. Will a control group of participants be used?
7. If yes, explain who they are and how they will be recruited.
8. Participant records: State what records will be used, how they were selected, and the approximate range of dates of records. Will the study be retrospective or prospective?
9. What is the age range of participants in the study?
10. If participants are minors (under 18 years), from whom will consent be obtained?
11. If participants are minors, is an informed consent document provided?
12. What is the gender of the participants (Male only, Female only, or both sexes)?
13. Number of participants and controls.
14. Will the research benefit the participants in any direct way?
15. If yes, explain how?
16. Will participants receive any remuneration?
17. If yes, describe the nature of the remuneration and if monetary, how much they will be paid.
18. Will participants be provided with food parcels? If so, how will potential allergies be dealt with?
19. Will participation, non-participation or withdrawal from the study disadvantage persons in any way?

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1. If yes, explain in what why.
2. Explain the steps taken to ensure **educated informed consent** (make sure that the participants fully understand what they are agreeing to).
3. Is a “Participant Information Sheet” attached for written consent?
4. If informed consent will be verbal, explain why.
5. If informed consent is not considered necessary, explain why not.
6. Is a questionnaire or interview sheet attached? (If not, the application cannot be considered).
7. How will confidentiality be maintained so that participants are not identifiable to persons not involved in the research? Please answer the questions below:
8. Will data be confidential?
9. Will identifiable data be coded and the ‘links’ kept separate?
10. Who will have access to data?
11. To whom will results be made available?

v. Does the procedures for capturing and processing of data comply with the eight principles of the

POPIA (Protection of Personal Information Act)? For more information on the eight principles, see the following link: <https://www.werksmans.com/wp-content/uploads/2013/04/popifaq.pdf>. Also refer all relevant UJ documentation or policies regarding the POPIA.

vi. Does the project involve the use of existing/available human-related data? (i.e. from a previous study and/or from an existing database)

vii. Was the necessary permission obtained to make use of this data for research purposes? Please attached the necessary documentation to the application.

viii. Was the data originally collected following the necessary ethical approval? (Please attach the clearance letter as supporting documentation)

1. **HYPOTHESIS**

(State the hypothesis for the study and briefly summarize the expected results)

1. **AIMS/ OBJECTIVES OF THE PROPOSED STUDY**

(State these briefly and succinctly)

1. **POTENTIAL BENEFITS OF THE RESEARCH FINDINGS**

(What are the benefits of the study and how will these benefits be conveyed to the participants?

These are required to aid the reviewing committee in performing a harm/benefit assessment)

1. **JUSTIFICATION FOR THE USE OF HUMANS**

(If medical or invasive procedures are involved, briefly justify the use of humans and the number needed. If large numbers of participants are to be used, provide additional rationale for the numbers. State also what non-sentient model/s were considered and on what grounds they were rejected)

1. **EXPERIMENTAL DESIGN (What will be done?)**

(Explain the reasoning behind the study design and experimental planning, with particular reference to determination of sample size and statistical analysis. Describe how the subjects will be allocated to experimental or surveyed groups and where applicable, how the experimental treatments will be assigned to each group. The use of flow charts is recommended. The information should be presented in an easily understandable manner)

1. **EXPERIMENTAL PROCEDURES (How will it be done?)**

(Describe briefly in short annotated sentences IN SEQUENCE, all the steps that will be performed in conducting the proposed data survey or experiment. These include: duration of data survey procedure /experiment, and if relevant, the collection of samples (if body fluids are involved, give routes of collection and volumes). Are the procedures routine for diagnosis/management or specific to this research?)

1. **SEVERITY OF EFFECTS (RISKS) OF THE EXPERIMENTAL PROCEDURES ON THE SUBJECTS**

(Will the procedure cause physical or psychological discomfort or deprivation? In the case of data

surveys please justify the duration of the procedure i.e. what steps have been taken to minimize the time

taken for the survey and to avoid discomfort to the participants? List the procedures that may cause

deprivation, fear, distress and pain)

13.1. Describe what sensations the person may feel.

13.2. Categorise these as minimal, intermediate or high.

13.3. Give the likely duration in time.

13.4. Describe what specific steps will be taken to alleviate these conditions through the use of ataractics, dissociative agents, analgesics, anaesthetics or other methods. Estimate how effective these are likely to be.

13.5. Explain if no risks are anticipated.

1. **STATISTICAL ANALYSIS**

(Is the data descriptive only or will it be statistically analysed? Describe briefly how the data obtained from the study will be analysed statistically, explain this decision and state by whom the analyses will be performed. Do not just say which software will be used - explain the actual statistical tests and their relevance)

1. **REFINEMENT**

(Describe the specific steps that have been taken to refine the data survey method or experimental procedures to make them as humane as possible i.e. minimising the impact of the proposed procedures on the participants’ wellbeing)

1. **FEEDBACK**

(Will feedback of the final outcome of the study be provided to the participants? If YES, give details of how and when the feedback will be provided. If NO, explain why feedback is not considered necessary or appropriate)

1. **PERMISSION OF RELEVANT AUTHORITY/IES TO DO THE STUDY**

(State the name of authority/ies where applicable. Please attached copies of the permit, letters of approval)

1. **OTHER ETHICS COMMITTEES**

(Should the study require ethical clearance from other Ethics Committees, what is the status of those applications?)

1. **ANY OTHER INFORMATION, WHICH MAY BE OF VALUE TO THE COMMITTEE, SHOULD BE PROVIDED HERE.**

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**F: SIGNATURES:**

**THE APPLICANT/S CONFIRM THAT THE INFORMATION PROVIDED IN THIS APPLICATION IS CORRECT AND A TRUE REPRESENTATION OF THE PROPOSED RESEARCH**

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| **PRINCIPAL INVESTIGATOR /** **RESEARCHER:**   | **SIGNATURE & DATE:**  |
| **SUPERVISOR:** | **SIGNATURE & DATE:** |
| **CO-SUPERVISOR / COLLABORATOR****(add additional rows, if necessary):** | **SIGNATURE & DATE:** |

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| **Departmental screening by****FEC member or senior staff member prior to submission (NAME AND SURNAME):** |  |
| **SIGNATURE AND DATE:** |  |