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**Faculty of Natural and Agricultural Sciences**

***Guide for Research Ethics***

***Research involving human participants***

***July 2016***

Contents

[2 Introduction 2](#_Toc443490962)

[3 Do you need to apply for ethics? 2](#_Toc443490963)

[4 Where do you need to apply? 2](#_Toc443490964)

[4.1 Faculty of Natural and Agricultural Sciences research ethics committee 2](#_Toc443490965)

[4.2 Other Ethics Committees at the University of Pretoria 3](#_Toc443490966)

[4.3 Applications From External Entities 3](#_Toc443490967)

[5 Ethical considerations 3](#_Toc443490968)

[5.1 Key principles 3](#_Toc443490969)

[5.2 Privacy, Confidentiality and Anonymity 4](#_Toc443490970)

[5.3 Scientific integrity 4](#_Toc443490971)

[5.4 The risk-benefit ratio 4](#_Toc443490972)

[5.5 Selection of participants 5](#_Toc443490973)

[5.6 Informed consent 5](#_Toc443490974)

[5.7 Reimbursements and incentives 6](#_Toc443490975)

[5.8 Engagement of key role players 6](#_Toc443490976)

[5.9 Researcher Competence and Expertise 7](#_Toc443490977)

[5.10 Additional recommended reading for special cases 7](#_Toc443490978)

[6 Applications 7](#_Toc443490979)

[6.1 First applications 7](#_Toc443490980)

[6.1.1 Steps in application process 7](#_Toc443490981)

[6.1.2 Completing the “Human participants” form 7](#_Toc443490982)

[6.2 Amendments 11](#_Toc443490983)

[6.3 Overview of the ethical review process 12](#_Toc443490984)

[7 Reports 12](#_Toc443490985)

[7.1 Annual progress report / Final report 12](#_Toc443490986)

[7.2 Incidence reports 12](#_Toc443490987)

[8 Standard Operating Procedures **Error! Bookmark not defined.**](#_Toc443490988)

[9 Members of the NAS Ethics Committee 12](#_Toc443490989)

[10 Reference Documents 13](#_Toc443490990)

# Introduction

Ethical research practices are crucial to uphold human rights and to advance scientific research within the country. The faculty is therefore committed to ensuring that all research conducted within the faculty is subject to appropriate ethical review.

It is important to remember that the primary responsibility for ethically sound research practice resides with the individual researchers. Researchers should therefore familiarise themselves with the University of Pretoria’s (UP’s) policies on “CODE OF ETHICS FOR RESEARCH” [1], the “POLICY AND PROCEDURES FOR RESPONSIBLE RESEARCH” [2], and the “FACULTY OF NATURAL AND AGRICULTURAL SCIENCES ETHICS COMMITTEE: TERMS OF REFERENCE” [3]. Links to these policies can be found at the end of this document.

The role of the Research Ethics Committee is to support and guide researchers towards better/best ethical research practice. It is not our intention to unnecessarily impede your research, but we are committed to ensuring that all research conducted within the faculty is ethically sound. This guide was developed to improve researchers’ understanding of the ethical aspects of their work and to clarify the ethical review process at the Faculty of Natural and Agricultural Sciences (NAS).

# Do you need to apply for ethics?

All research involving human participants require ethical approval [1, 4, 5]. A Human participant is defined as: A living individual on whom the researcher is conducting research by (a) collecting data by intervention or interaction with the individual, or (b) obtaining identifiable private information [1, 4]. The application for engaging human participants extends also to the remains and data collected from deceased persons [4].

Ethical approval should be obtained from one of the research ethics committees at UP, if the research is done:

* On any of the UP premises, or if it uses any of UP’s facilities.
* Involves UP employees or students, including collaborative or multi-institutional or multi-country studies.
* If the research will be funded from UP funds or if funding for it was acquired through UP.

You need written approval from an appropriate ethics committee before you can commence with the research project [2, 4, 5].

# Where do you need to apply?

## 4.1 Faculty of Natural and Agricultural Sciences research ethics committee

If the study involves human participants (living or deceased) and the principal investigator (PI) is employed within the NAS Faculty you need to apply for ethical approval from the NAS ethics committee. Studies that have already received ethical approval from another ethics committee, but would like to include NAS staff or students also need to submit a full application to the NAS ethics committee and include their letter of approval. The only exception is previous approval from the UP Health Sciences ethics committee: these applicants can submit their Health Sciences application and approval letter and a cover letter with a detailed explanation of why they want to use NAS staff or students, including a statement that they will not deviate from the approved health Sciences protocol.

Link to the NAS ethics committee page: <http://www.up.ac.za/en/faculty-of-natural-agricultural-sciences/article/32597/ethics-committee>.

Submission deadlines: The 1st of every month.

Most researchers will use the “Human participants” form. If you are, however, using previously collected internal or external data please use “The use of internal and external numeric data sets in research” form. External data refers to data from a source external to the university i.e. data that were not collected by the University of Pretoria, or individuals in the University of Pretoria [3]. Examples of external data include data from government, banks, businesses or commercially provided information. Internal data refers to data that are generated by the company, i.e. procured and consolidated from different units or individuals within the organization. In the context of UP, internal data will for example be data obtained from BIRAP. Data that are collected by other researchers within the university will also be considered as internal data, since that data will belong to the university.

If your research also involves Biohazards or Genetically Modified Organisms (GMOs), also complete the appropriate forms on the NAS ethics committee page. All health research (and any research connected to the Health Sciences Faculty) also needs to be approved by the Health Sciences Research Ethics committee. You do not, however, need to apply directly to the Health Sciences Research Ethics committee. We will forward your application to this committee for approval once approval has been obtained from the NAS ethics committee. Such projects need written approval from both the NAS and Health Sciences ethics committee before they can commence. Health research also need approval from the Provincial Health Departments if the research is conducted in public health institutions. Once ethical approval has been obtained from the NAS and Health Sciences ethics committee, you can submit an application to the Department of Health (<http://nhrd.hst.org.za/Home/Index>).

## 4.2 Other Ethics Committees at the University of Pretoria

If the study involves human participants and the PI is employed within another faculty (such as Health Sciences or Humanities), you need to apply for ethical approval from your own faculty’s research ethics committee:

Health Sciences research ethics committee: <http://www.up.ac.za/healthethics>

Humanities research ethics committee: <http://www.up.ac.za/en/faculty-of-humanities/article/2043257/research-ethics-applications>

Please notify the NAS ethics committee, however, if your research involves staff from the NAS Faculty.

## 4.3 Applications From External Entities

Entities external to the university may submit an application for ethical review to the most appropriate ethics committee (e.g. the Faculty of Health Sciences, NAS, or Humanities). The application must still be in the prescribed manner and a service fee may be levied [3].

If the research is limited to South Africa, the PI should be a South African citizen. For international multi-centre research, at least one (co-) PI must be South Africa-based [4] and local ethics approval should be obtained from an appropriate ethics committee [5].

# Ethical considerations

This section describes the main ethical considerations in human research, but is not an exhaustive list of all possible ethical considerations. Researchers can obtain more in-depth information about ethical considerations from the documents noted at the end of the document.

## 5.1 Key principles

Researchers are obliged and responsible to apply key values in their research. These include:

* Social responsibility, in terms of which researchers accept the responsibility to address, where possible, by research and technology development the pressing problems in the broader South African communities [1]. Research should therefore be relevant and responsive to the needs of the people of South Africa [4, 5].
* Justice, in terms of which researchers accept the responsibility for the equitable treatment of all individuals and organisations involved in the research process [1, 2, 4-6].
* Benevolence, in terms of which researchers should be inspired not only to protect others from harm, but also to ensure and promote the well-being of all those affected by research [1].
* Respect for the individual, where the focus is on the interaction between the researcher and all people he/she may encounter during the research process. The researcher is required to recognise the dignity and autonomy of all individuals and to maintain humanity as well as freedom of choice in all situations [1, 4-6].
* Professionalism, in terms of which it is recognised that researchers form part of a specific profession and therefore should exhibit professional responsibilities such as integrity, quality and accountability [1].
* Refraining from: discrimination, abuse of supervisory authority, and sexual harassment [1].

## 5.2 Privacy, Confidentiality and Anonymity

Research participants have the right to privacy and confidentiality [1, 5, 7]. Privacy deals with who has access to the participant’s personal information and data. Participants’ personal information should be kept safe and only appropriate people should have access to their data. Confidentiality, on the other hand, refers to the researcher’s responsibility to protect information entrusted to researchers for research purposes from unauthorised access, use, disclosure, modification, loss or theft.

Using reference numbers instead of participant’s names (or other identifiable data) are therefore strongly advised to ensure anonymity of the participants. Also consider your computer safety, record storage facilities, access to raw data (including completed informed consent forms) and how the results will be disseminated.

## 5.3 Scientific integrity

The research should be scientifically sound. A sound design and methodology are likely to result in reliable and valid data and outcomes that address the research objectives. Poor design and inappropriate methods may expose participants to unnecessary risk of harm and burden with little or no compensating benefit in the form of useful knowledge gained [4, 5].

That said, it is not the primary responsibility of the research ethics committee to ensure that the research is scientifically sound. Research projects should therefore be reviewed by an appropriate scientific review committee before applying for ethical approval. If the ethics committee conclude that the research might not be scientifically sound, they can refer the application back to the appropriate scientific review committee before giving final approval.

## 5.4 The risk-benefit ratio

Researchers should be conscious of the risks and benefits associated with their research. Consider any psychological, physical, social and economic harm that might come from the research to both the research participants and the researchers. Researchers should always strive to minimise the risk and maximise the benefit to participants, society and the knowledge that can be gained from the research [1, 4-7].

Risk can be categorised into:

* Low risk ─ where the only foreseeable risk is one of discomfort [4]
* Minimal risk ─ where the risk of harm expected in the proposed research does not exceed, given probability and extent, the risk that would be encountered normally in daily life or during the performance of routine physical and psychological examinations or tests [1, 4].
* Greater than minimal risk ─ where research procedures include risk beyond that ordinarily encountered by participants (e.g. maximal exercise testing, experimental drugs, stressful psychological testing) or vulnerable populations are used in research.

Here is a useful link if you need more information on assessing risks and benefits:

<http://research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html>

## 5.5 Selection of participants

The recruitment, selection, and the exclusion and inclusion of participants for research must be just and fair [1, 4-6]. No person may be unjustly excluded from the study and groups of people should not be overburdened with research participation. Provide a sound scientific reason if you want to limit your study to certain groups of people (e.g. women etc.).

Be especially careful when considering participants from vulnerable populations, such as children, people with intellectual and mental impairment, prisoners, people from low-income communities etc. Rather don’t involve them if research can be carried out in non-vulnerable communities [4, 5]. Participants who are in a dependent relationship with the researchers (e.g. students in their class) might feel pressured to take part in the research. If this is the case, the proposal should explain the measures that ensure that the potential participant’s ability to make a voluntary choice is unrestricted [4].

The number of participants must also be reasonable, since underpowered studies may be futile and overpowered studies might expose participants to unnecessary risks. It is therefore important to provide an explanation of how the sample size was determined [4]. The recruitment methods should be neutral and should be properly described in the application [4].

## 5.6 Informed consent

According to the Constitution of South Africa, research participants may not be subjected to medical or scientific experiments without their informed consent [8]. Participation in research must therefore be voluntary and participants should be able to make an informed choice about whether they want to take part in the research or not [1, 4-7]. In order to do so they (a) need sufficient information, and (b) the information should be understandable to them.

This information is normally conveyed in an informed consent form, which should be signed by all participants 18 years or older (or their parent / guardian if they are younger than 18) before they can take part in the study [4]. If you are recruiting children, you will need consent from parents/ legal guardians and assent from the children, if they are able [5]. If the parents give consent, but the child refuses, the child’s decision should be respected [4, 5].

The following information should ideally be included in the consent form:

* The research procedure, including what will be expected of the participant, the expected duration of participation, etc.
* How privacy and confidentiality will be insured
* The purpose of the research
* Foreseeable risks and expected benefits.
* Any compensation/ gifts/ services or reimbursements that the participant will receive.
* Alternative procedures (in the case of therapy).
* The approximate number of participants that will be recruited.
* Information on how participants are selected (optional).
* Particulars of persons responsible for the research (optional).
* Any other information that the researcher deem necessary in order to obtain informed consent (optional).
* Indemnity
* Statements making it clear that:
  + Their participation is voluntary and there will be no penalty or loss of benefit if they decide not to take part.
  + They have the right to withdraw from the research at any time without having to explain why.
  + They have the opportunity to ask questions about the proposed study.
  + The participants have the rights of access to their data

The text should be in plain language and appropriate to the participant’s level of understanding [4, 5]. If participants are not expected to be competent in English, the information and consent forms should be translated to an appropriate language [4]. We added an example of an informed consent document at the end of this document (Appendix A).

## 5.7 Reimbursements and incentives

Reimbursements and incentives in research is a contentious topic. On the one hand, participants should not have to incur expenses to take part in the research [4, 9]. Researchers should therefore reimburse participants for any additional expenses they incurred to take part in the research. For example, travel and refreshments. If no travel or other expenses are incurred, reimbursement is not required, but participants may be reimbursed for inconvenience and time spent [4, 5]. On the other hand, incentives might cause “undue inducement” by inducing prospective participants to consent to participate against their better judgement [5, 10].

Dickert and Grady [10] recommend the wage-payment method as the most ethical approach to participant payment. In this model, research participants are paid on a set scale commensurate with unskilled but essential jobs. Assuming a reasonable scale is used for payment calculations; this wage-payment method greatly reduces problems with “undue inducement” and treats people similarly, irrespective of their social standing [10]. Moreover, the South African Department of Health recommends that a “fair rate of reimbursement should be calculated using the Time, Inconvenience and Expenses (TIE) method to determine the cost to participants for time expended, inconvenience and refreshments associated with research participation. This method costs expenses at the current hourly rate for unskilled labour in the market place, regardless of whether the participant is employed” [4, 9].

Please note that it is an offence for a person who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation [13].

## 5.8 Engagement of key role players

If community samples are used, researchers are encouraged to engage key role players, such as community leaders, throughout the research process. This engagement will likely improve the quality and rigour of the research, increase the acceptability of the research and offset power differentials where these exist [4].

## 5.9 Researcher Competence and Expertise

Researchers must be suitably qualified and technically competent to carry out the proposed research [3, 4]. We therefore require a brief CV of the PI and any other co-investigators or students that add specific expertise to the project.

## 5.10 Additional recommended reading for special cases

* Genetic research [4].
* Research involving deception or withholding information [4].
* Research regarding HIV and AIDS [11, 12].
* If tissue, blood, blood products or gametes will be removed from participants or used in research [13].
* Cloning of human beings [13].
* Access to health records [13].
* Databases and Biobanks [4].
* Vulnerable populations, including children [4, 5, 7, 14].

# Applications

## First applications

### Steps in application process

1. Read these guidelines before you apply for ethical clearance.
2. Complete and sign the appropriate application form/s (see section 3.1) available from <http://www.up.ac.za/en/faculty-of-natural-agricultural-sciences/article/32597/ethics-committee>
3. Send the form to your head of department or the chairperson of department’s or institute’s research committee for signing.
4. Send an electronic copy of all the forms (pdf or word format) to ethics.nas@up.ac.za. Submission deadlines are on the 1st of each month. Please combine all the documents (e.g. application, consent form etc.) into a single document.
5. Deliver a hardcopy of the signed document to Ms Nkosi Kgoogo, room 2-30, Agricultural Sciences building, Hatfield campus, University of Pretoria.

### Completing the “Human participants” form

*Checklist*

Answer all questions in sections 1 and 2.

*6.1.2.1 Declaration*

The declaration should be signed by the PI and every co-researcher.

*6.1.2.2 Project title*

Type the full title of the intended project

*6.1.2.3 Duration of project*

Complete the proposed commencement and finalisation dates for the project

*6.1.2.4 Where will the study be conducted?*

Indicate all locations where the study will be conducted. For example, UP Hatfield campus, Steve Biko Hospital, Shopping centres etc.

*6.1.2.5 Researchers*

*6.1.2.5.1 Principal Investigator (PI)*

The PI is the leader of the project and is overall responsible for the project from its inception to its finalisation. In order to be the PI on a UP ethics application you must be [3]:

* A permanent academic of any academic rank or researcher
* A person appointed in a contractual capacity as an academic or researcher that includes doctoral candidates, post-doctoral fellows and research fellows.
* A person appointed in a contractual capacity as the research leader of a project external to the university done through the University of Pretoria Business Enterprises (Pty) Ltd or an external entity that requires ethical clearance for a project.

You cannot be a PI if you are an undergraduate, honours and masters level student or a postgraduate diploma candidate. In these cases, the academic supervisor must serve as the PI.

Should the PI be no longer able to lead the project, a PI who takes over the project, must submit an addendum to the project to the Ethics Committee noting the change. The Ethics Committee will either accept or decline the replacement person and will communicate their decision to the nominated PI.

*6.1.2.5.2 Internal or external co-researcher*

A co-researcher is a person actively participating in the research and who can defend the research. It is usual that a co-researcher has rights to the results. These rights should be determined by agreement with the PI (Section 5.5). Academics appointed on a permanent or contractual basis (including research fellows, postdoctoral researchers and doctoral candidates), masters and honours level students can be co-researchers.

*6.1.2.5.3 Names of honours, masters or doctorate level students who might be intending to submit a dissertation or thesis based on this project.*

List all relevant honours, masters and doctorate level students. The same students may be listed in both 6.1.2.5.2 and 6.1.2.5.3.

*6.1.2.5.4 Student assistantships*

Student assistants are not necessarily co-researchers, but are assistants who participate in the project with the permission of the PI. Every student assistant is bound by the declaration (Section 1) signed by the PI. List the permitted student assistants.

*6.1.2.5.5 Agreement between the PI and the co-researchers and post-graduate students, post-doctoral fellows and student assistants.*

Indicate the rights of each co-researcher, post-graduate student, post-doctoral fellow and student assistant to:

* use the results in a dissertation or thesis for an academic qualification
* to present the results at a conference
* to publish the results in a science journal
* to publish the results through a non-science communication medium
* to co-authorship.

Complete this section by (a) listing each of the abovementioned persons in the first column, (b) marking the relevant cells with an X to indicate each listed person’s rights, and (c) asking each listed person to initial the last column of their row to indicate their agreement. By initialling this column the listed persons also agree to accept the PI as the unequivocal leader of the project.

6.1.2.6 *List all specialised services that will be used in the proposed research*

For example, Statisticians, Analysts, etc.

*6.1.2.7 State all the funders that will be funding the project*

For example, a university research fund or a third party (e.g., NRF, WRC, Welcome Trust, etc.). Duplicate the table for each funder separately.

*6.1.2.8 Data*

*6.1.2.8.1 How will the data be recorded and archived?*

In terms of the university regulation Policy for the Preservation and Retention of Research Data (Rt 306/07)[15], researchers must indicate the manner in which the data accumulated from this research trial or obtained from an external source is to be archived. This is to avoid disputes over authenticity and intellectual property. Indicate how data will be recorded (8.1.1) and archived (8.1.2).

*6.1.2.9 Intellectual property and conflict of interest*

Declare the interests in the intellectual property of this research project by the participating institutions (9.a; university or other institutions) or persons (9.b). Examples:

* Section a: Data provided by FNB to study poverty in Gauteng. FNB relinquishes all IP to UP.
* Section b: Prof XYZ is the project supervisor, while Mr J is the PhD candidate analysing the data with the assistance of the IT Dept. The participants agree that the IP resides equally with all persons, and that the PhD candidate has the first option to be principal author of research papers.

If the data is owned by another entity, state any conflict of interest between researchers and the entity that owns the data in 9.c.

*6.1.2.10 Aims and objectives of the project*

State all the aims and objectives of the project.

*6.1.2.11 Short literature review that justifies the project*

Provide a brief scientific literature review that justifies the project, citing the relevant scientific literature (The references are added in Section 20). *Maximum 4000 words.*

*6.1.2.12 Risks and benefits associated with the research.*

Indicate whether the level of risk (e.g. low, minimal or greater than minimal [section 5.4]) and describe the specific risks and benefits associated with the research. Also indicate which measures were taken to minimise the risk. This is a crucial component of ethics review, so pay special attention to this section.

*6.1.2.13 Materials and Methods*

Provide a detailed description of the procedures that will be used, citing the relevant scientific literature that validate the procedures where available (The references are added in Section 20). *Maximum one page.*

*6.1.2.13.1 Full description of human participants to be used*

Provide a clear description of the human participants that will be recruited for the project, including the number of participants and inclusion / exclusion criteria. In other words, will you include or exclude certain races, genders, age groups etc. If you are only including certain groups in your research, explain why.

*6.1.2.13.2 How will the human participants be recruited?*

State how participants are to be recruited. Recruitment methods should be properly described and any posters, flyers and advertisements used should be included at the end of the application.

*6.1.2.13.3 Participants’ records*

*6.1.2.13.3.1 If the records of a generic group of participants are to be used, specify the nature of these records and indicate how they will be selected.* For example, the final marks for a class of students.

*6.1.2.13.3.2 State the permission given to use the records of a generic group of participants.*

State any permissions received to use these records.

*6.1.2.13.3.3 If the records of individual persons are to be used, state the information required.*

Complete the table indicating the names of the participant’s, their ID numbers, gender, race / ethnic identity, the record to be used, how the record will be used and the person who gave permission.

* If the details of the individuals are not available at the time of submitting the ethics application, the information must be filed as an addendum to the application as soon as the information becomes available.
* If the required information is of deceased persons, every effort should be made to obtain permission from a descendant. In the event that this is not possible, the PI must submit a letter to the Ethics Committee explaining the situation and requesting permission to continue with the research. In certain circumstance it may be necessary to obtain judicial permission.
* In the event of information being required from persons who are under legal supervision such as in prison or committed to an institution, permission must be obtained from the regulatory authority and the respective individual if the individual is competent.

*6.1.2.13.4 Estimation of literacy level of participants*

Mark the estimated literacy levels of the participants with an X. More than one level might apply.

*6.1.2.13.5 List proposed procedures to be carried out with participants to obtain data required.*

Mark all proposed procedures that will be carried out with the human participants.

*6.1.2.13.6 Give details of person(s) who will carry out the procedure(s)*

Provide details of each person that will carry out procedures with participants

*6.1.2.14 Informed consent*

*6.1.2.14.1 Competent persons (18 years or older)*

An informed consent form should be submitted together with the Ethics application form. In the event that the consent cannot be submitted together with the application, the PI must give reasons as to why it cannot be submitted and it must then be filed as an addendum before the research begins. This will be assessed and acknowledged by the Ethics Committee.

*6.1.2.14.2 Minors and incompetent persons*

*6.1.2.14.2.1 Will children (<18 years) or mentally or legally incompetent persons be included in the study?* Answer yes or no.

6.1.2.14.2.2 *If yes, indicate how consent and assent will be obtained.* See section 5.6.

*6.1.2.15 Language*

6.1.2.15.1 *Are the researcher, co-researcher or students competent in the mother tongue of the participants?* Answer yes or no.

6.1.2.15.2 *If no, how will he/ she ensure that participants fully understand the content of the consent form?* Indicate all measures that will be taken, such as translating the consent form, using an interpreter etc.

6.1.2.15.3 *How will consent be obtained if the participants can’t read?* Indicate all measures that will be taken, such as getting someone to read the form to them in a language they can understand and including a verbal consent form.

*6.1.2.16 Remuneration or gratification towards human participant*

Will participants receive any form of remuneration or gratification for partaking in the study? If they will, please state the nature and amount of remuneration or gratuity. How was this determined? Any remuneration / gratuity must be in terms of the university’s policies on remuneration / gratuity.

*6.1.2.17 Conduct with regard to human participants when they become unfit for further participation / when the project is stopped.*

Please explain the procedure.

*6.1.2.18 Planned application of results.*

Indicate what the results will be used for. Mark with an X.

6.2.19 *Does the study require any other approvals/ formal permissions?* Answer yes or no.

6.2.19.1 If yes, indicate how these approvals/ permissions will be obtained

*6.1.2.20 Secrecy clause and Ltd Pty issues when outside entities are involved*

Are there any outside entities involved in the project? If so, state all such agreements or restrictions entered into. These might have a bearing on the application of results (Section 18).

*6.1.2.21 References*

List all the literature references used in the scientific justification and materials and methods sections. Use a standard format.

*6.1.2.22 Signatures*

Please obtain all relevant signatures.

*6.1.2.23 Research documents*

Include all relevant documents in the application form after the signatures, starting each new document on a new page. Depending on the study these documents might include:

* Email text, flyers, advertisements, or posters used for recruitment
* Information and consent forms for participants older than 18.
* Parent’s information and consent forms for participants younger than 18.
* Children’s assent forms for participants younger than 18.
* Any questionnaires that will be used in the study
* Interview templates
* Debrief forms
* Prior ethical approvals for this specific study

6.1.2.24 *CV’s*

* The PI’s brief 2 page CV, indicating that he/ she has the skills / expertise needed for the research. The Brief CV should consist of sections 1.1. (General information), section 1.2. (Academic qualifications), section 5.1 (Supervision or co-supervision of students who have completed degrees in the last three years) and 3-5 applicable publications or presentations.
* Also include brief CV’s of any co-applicants that contribute unique expertise to the study over and above the expertise of the PI (optional).
* Exception: if your research involves the collection of biological materials from participants, access to health records, staff or students from the Health Sciences Faculty, patients, healthcare workers or more than minimal risk: use the CV format provided by the Health Sciences Faculty (http://www.up.ac.za/healthethics/article/1949289/Templates).

## Amendments

Researchers that want to amend aspects of previously approved projects should apply for approval of amendments as follows:

* Complete the Amendment form available from the NAS ethics website.
* Use the “track changes” function in word to highlight all changes made to the original approved application, including any attached documents, such as consent forms etc.
* Send the completed Amendment form and amended application to ethics.nas@up.ac.za.
* You need written approval from the ethics committee before you can introduce the proposed changes in the research project

## Overview of the ethical review process

* The project is reviewed by an appropriate scientific review committee (e.g. a departmental review committee) before applying for ethical clearance.
* Submission of the NAS ethics application.
* Application sent to the relevant member of the NAS ethics committee.
* The committee member sends out the application to two reviewers.
* The reviewers provide feedback and a decision is reached.
* Health-related projects are sent to the Health Sciences ethics committee for further approval once approval has been obtained from the NAS ethics committee.
* Applications involving students or staff at UP as research participants (not researchers, co-researchers or assistants) are sent to the respective Dean’s offices for further approval.
* The final decision is reached and the chair of the committee provides written feedback to the PI.
* The whole process takes around 3-5 weeks, depending on whether further approvals are needed.

# Reports

## Annual progress report / Final report

Progress reports must be submitted to the Ethics Committee at the end of each whole year period from the time of commencement. The Annual progress report form is available from the NAS ethics website.

## Incidence reports

Reports of incidences that might affect a human research participant in any way, or the removal of a human research participant from the research programme, or that might jeopardise the outcome of the research, must be reported to the Ethics Committee within seven days (7 days) of the incident occurring, quoting the project number, title, the incident, cause, any remedial action taken if necessary and the potential effect that the incident could have on the outcome of the project.

# Members of the NAS Ethics Committee

|  |  |  |
| --- | --- | --- |
| Chairperson | Prof Brenda Wingfield | brenda.wingfield@up.ac.za |
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**Appendix A: Example of informed consent form**

**Ref:**

|  |
| --- |
| **PARTICIPANT INFORMATION & INFORMED CONSENT FORM** |

**TITLE OF STUDY**: **[Add your own title here]**

**1) Introduction**

We invite you to take part in a research study. This information leaflet will help you to decide if you want to participate. Before you agree to take part you should fully understand what is involved. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask the research personnel.

**2) Why are we doing the study?**

[Give a short explanation of why you are doing the study. Also include information on: how many participants will be recruited for the study]

**3) What will we ask you to do in this study?**

[Give a detailed explanation of what you will ask participants to do in the study. Also tell them how much of their time it will take]

**4) Risk and discomfort involved**

[Explain any risks of discomforts they might experience]

**5) Possible benefits of the study**

[Explain any benefits of the study to them and society in general]

**6) Optional aspects of the study (optional section)**

*Please indicate your choice by ticking yes or no and initialising next to it.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Initial** |
| Can we… |  |  |  |
| Can we… |  |  |  |

**7) What are your rights as a participant?**

Your participation in this study is entirely voluntary. You may choose not to answer particular questions. You can refuse to participate or stop at any time during the study without giving any reason. If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled. Once you have completed the study you have the right to access your data.

**8) Will you be paid to take part in this research study?**

[Explain whether they will be paid or otherwise remunerated and if so, how much will they be paid or how will they be remunerated]

**9) Has the study received ethical approval?**

This study has received written approval from Research Ethics Committees of the Faculty of Natural and Agricultural Sciences, tel 012 420 4356. [Also include any other relevant approvals if applicable]

**10) Information and contact person**

If you have any questions or comments about the study please contact [Add your name and contact details]

**11) Confidentiality**

All information that you give will be kept strictly confidential. Research reports, presentations and articles in scientific journals will not include any information that may identify you.

|  |
| --- |
| CONSENT TO PARTICIPATE IN THIS STUDY |

I confirm that the person asking my consent to take part in this study has told me about the nature, process, risks, discomforts and benefits of the study. I have read this form (Information Leaflet and Informed Consent) and I understood the information regarding the study. I am aware that the results of the study, including personal details, will be anonymously process­ed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment in any way.

I have received a signed copy of this informed consent agreement.

Participant's name .............................................………………………........................... (Please print)

Participant's signature: ........................………………… Date.............................

Investigator’s name .............................................………………………........................... (Please print)

Investigator’s signature ..........................………………… Date.…........................

Witness's Name .............................................………………………........................... (Please print)

Witness's signature ..........................…………………... Date.…........................

[If participants cannot give written consent, you could also include the following section]

|  |
| --- |
| VERBAL INFORMED CONSENT |

I, the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the participant whom I have asked to participate in the study.

The participant indicates that s/he understands that the results of the study, including personal details regarding the interview will be anonymously processed into a research report. The participant indicates that s/he has had time to ask questions and has no objection to participate in the interview. S/he understands that there is no penalty should s/he wish to discontinue with the study and his/her withdrawal will not affect any treatment in any way. I hereby certify that the client has agreed to participate in this study.

Participant's Name ..................................................................………...(Please print)

Person seeking consent ...................................................…….............(Please print)

Signature ..................................……………….............Date..................................

Witness's name .............................................……………..…...........(Please print)

Signature ..................................…………………………Date.….........................