GUIDELINES FOR SUCCESSFUL ETHICAL REVIEW

20/10/2021

Crucial documentation to be included in submission

- Completed PG 2a
- Participant information letter(s)
- Participant consent form(s)
- Data collection tool e.g. questionnaire (if applicable)
- Interview guide/schedule i.e. the list of questions to be asked (if applicable)
- Letters from researcher to respective gatekeepers asking permission to conduct research
- Copy of advertisements to be used (if applicable)
- Ethics Training Certificate/GCP Training Certificate (if applicable)

1. **The PG 2a**
    - Latest version off DUT website?
    - All signatures present – student, supervisor and FRC?

    Research methodology:
    - Research population and sample to be clearly explained
    - Inclusion and exclusion criteria to be clearly stated
    - Recruitment process to be clearly explained; how will potential participants be approached to participate
    - Process of obtaining informed consent to be clearly described
    - Sampling method/technique to be clearly stated
    - Data collection procedure to be clearly explained – include (if applicable) the dissemination and retrieval of questionnaires, and the application of measurement tools to collect data
    - Interviews: specify time required for the interview, state duration of interview and advice regarding venue
    - Provide a detailed explanation of what will be required of recruited participants
    - Describe who the gatekeepers are and how permission from such gatekeepers will be obtained
    - Describe how participant's identity will be protected; explain the way in which confidentiality and/or anonymity will be ensured
    - Incentives (if any) to be declared in the methodology

    Ethics checklist
    - Every question answered either, yes/no/n.a?
    - Comments provided where needed – questions read carefully and answered fully?
    - Signed by researcher and supervisor?

2. **Participant information letter**
    - The official IREC template used?

    Items to be included:
    - Friendly greeting i.e. Dear research participant, thank you for showing interest in this study
    - Title of the study
    - Names and qualifications of researcher
    - Names and qualifications of supervisor
    - Brief introduction and purpose of the study
    - Outline of the procedures – where, when, how, who, what?
    - Risks, discomforts to participants – if none state so
    - Benefits (to participant and researcher) – if any
    - Reasons why participant may be withdrawn or may withdraw themselves from the study
    - Remuneration of participants (if any) if none state so.
    - Costs of the study to the participant (if any) if none state so
    - Confidentiality – how will it be maintained/ensured – if responses are anonymous then say so and how

- Research related injury – if unlikely then state so.
- Storage of all electronic and hard copies including tape recordings – state how, where, who has access, security measures in place, duration of storage, fate of the data at the end of the study, etc.
- Persons to contact if problems or queries – standard as per IREC template.

General points to consider:

- Language style/word choice appropriate for the target population?
- Written in the first person – narrative style i.e. *I will* give you an information letter to read then *you will* have the opportunity to ask questions...
- Participants assured that participation is voluntary
- Participant assured that they can withdraw from the study at any stage should they wish to without providing a reason and without their withdrawal impacting negatively on them in any way.
- Translation into the dominant language spoken by the research population e.g. in KZN isiZulu and attached – see ethics checklist question 15.
- If illiterate participants are to be recruited space for a thumb print should provided as well as space for a literate observer known to the participant to verify that informed verbal consent was obtained.
- If there is more than one research group then individual letters for each research group included?

***For minors (participants below 18 years): information to these participants must be done using the IREC assent form.**

3. Participant consent form

- As per official IREC template layout

4. Data collection tool(s)

- Questionnaires to be used attached for review?
- Interview guide/schedule – list of questions to be asked in interviews or focus groups attached?
- If an existing questionnaire to be used – permission from the original author obtained?

5. Letter to gatekeepers

- Draft letter(s) to gatekeepers attached for review?
- Gatekeeper letters to be sent only after FRC and IREC approval
- Letters to follow IREC information letter format
- Sufficient information provided about the proposed research process for gatekeeper to make an informed decision?