Occasionally, circumstances leading to deviations from approved protocols in research projects become unavoidable. However, certain changes may affect the very core (including methodology and ethical risk level) of a previously approved study/project. Hence, a need for UZREC minimal review and confirmation. It is to be completed electronically by the principal investigator/researcher in accordance with the UZREC Standard Operating Procedures (SOP), and submitted for approval of modifications to previously approved protocols on research projects.

|  |  |  |  |
| --- | --- | --- | --- |
| Title of the study/Project: | **Type/ Level** | M | D |
| Departmental |
| Ethical approval number: | Research site: |
| Faculty: | Department: |
| Name & Qualification of principal investigator: | Name & Qualification of co-investigator:  |
| Student/staff Number: | Staff/student number: |
| Name & Qualification of Supervisor: | Staff # e-mail address of supervisor  |
| I request ethics approval of the following modifications/revisions to procedures in the above mentioned project/study:

|  |  |  |
| --- | --- | --- |
| **#** | Proposed Modification | **Selection**  (**X**) |
| **i** | Participant Recruitment Process |  |
| **ii** | Participant Sample/ Population |  |
| **iii** | Consent Form / Information Sheet/s |  |
| **iv** | Research Instrument/s (*e.g. questionnaires, etc.*) |  |
| **v** | Research Design/ Methodology  |  |
| **vi** | Location of Study |  |
| **vii** | Changes to research team |  |
| **viii** | Data confidentiality concessions |  |
| **ix** | Research subjects rewards arrangements |  |
| **x** | Details to giving back to community |  |
| **xi** | Other (please specify |  |

NB: In a separate attachment, describe the nature of each modification, with explanations and description of how it differs from the originally approved procedures. Submit a full proposal or relevant document – clearly marking all modified or added sections. |
| A-i. Motivation/ Reason/s): why are the changes necessary?  |
| A-ii. How the amendment affects aim & methodology of study: |
| **Effect on risk-benefit profile of participants:** |
| Please submit the following documentation:* Amended proposal (changes to be underlined)
* Changes to letter of information and consent
* Any other relevant documentation
 |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Principal Investigator*) Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Co-investigator/Supervisor*) Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Supervisor*) Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Head of Department*) Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*Dean/Deputy Dean*) Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **OUTCOME** |
| ***TO BE COMPLETED BY THE CHAIRPERSON OF THE UZREC.*** |
| Date received: | Review required: |
| Expedited |
| **The amendment is:** | *Indicate with an* **X** *next to the appropriate outcome decision:* |
|  | **Yes** | **No** | **NA** |
| Approved – no evidence for concern/further investigation. |  |  |  |
| Approved subject to minor changes |  |  |  |
| Needs to be re-submitted after recommendations are met |  |  |  |
| Approved however a site inspection is recommended. |  |  |  |
| Denied (please see attached) |  |  |  |

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| **Comment (UZREC Chair)** |
|  |

|  |  |
| --- | --- |
| **Signature:** | **Date:** |
| UZREC CHAIR |  |
| FRC CHAIR |  |