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