



UP OPEN UNIVERSITY
Institutional Research Ethics Committee

**INFORMED CONSENT
CHECKLIST**

| | |
|----------------------|-------|
| REC Form No. | 6 (F) |
| Version No: | 01 |
| Date of Effectivity: | |

| | | | | | |
|----------------|--|----------------|------------------|------------------------------|-----------------------------|
| Title of Study | | | | | |
| REC Code | | Type of Review | | | |
| Proponent | | Institution | | | |
| Reviewer | | | Primary Reviewer | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| | | Date Received | | | |

Guide questions for reviewing the informed consent process and form

Is it necessary to seek the informed consent of the participants?
IF NO, please explain:

| | |
|---|---|
| <input type="checkbox"/> Unable to assess | <input type="checkbox"/> Yes <input type="checkbox"/> No |
|---|---|

IF YES, are the participants provided with sufficient information regarding:

- | | | |
|---|------------------------------|---|
| • Purpose of the study? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Expected duration of participation? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Procedures to be carried out? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Discomforts and inconveniences? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Risks (including possible discrimination)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Random assignment to the trial treatments? | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| • Benefits to the participants? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Alternative treatments/ procedures? | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| • Compensation and/or medical treatments in case of injury? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Who to contact for pertinent questions and / or for assistance in a research- related injury? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| • Refusal to participate or discontinuance at any time will | <input type="checkbox"/> Yes | <input type="checkbox"/> No |



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| involve penalty or loss of benefits to which the subject is entitled? | | |
| • Extent of confidentiality? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Is the informed consent written or presented in simple language that participants can understand? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Does the protocol include an adequate process for ensuring that consent is voluntary? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you have any other concerns? | | |

Recommendation:

- Approved
- Minor revision/s required

- Major revision/s required

- Disapproved

Reasons for disapproval:

Name and Signature of Reviewer

Review Date