



Department of Nursing and Health Care Studies Research Ethics Validation Checklist

This checklist is designed to assist the Research Ethical Committee to demonstrate fairness and equity in the reviewing of research proposals and to provide an audit tool of the proposals reviewed. The checklist is based on the commonly agreed standards of good practice as are laid down in the Declaration of Helsinki and identified by The Irish Council for Bioethics.

Name of Researcher/ Named Applicant:

Research Project Title:

| Category: | Yes | No | N/A | Notes |
|--|-----|----|-----|-------|
| 1. Risk Assessment (Goodyear Smith et al (2002) define minimal risk as: <i>The potential participants could reasonably be expected to regard the probability of and magnitude of possible harms implied by participation in the research to be no greater than those encountered in everyday life</i>). | | | | |
| 1.1 Does it pose only minimal and predictable risk to the researcher? | Yes | No | N/A | |
| 1.2 Does it pose only minimal and predictable risk to the research participant? | Yes | No | N/A | |
| 1.3 Is physiological stress, pain, or pain more than mild discomfort likely to result from the study? | Yes | No | N/A | |
| 1.4 Could the study induce psychological stress or anxiety or cause harm or negative consequence beyond the risks encountered in normal life? | Yes | No | N/A | |
| 1.5 If there are possible risks, are there adequate provisions to deal with them? | Yes | No | N/A | |
| 1.6 Do the foreseeable benefits of the research outweigh the foreseeable risks? | Yes | No | N/A | |
| 2. Access to Participants | | | | |
| 2.1 Has access approval been obtained? | Yes | No | N/A | |
| 2.2 Is the access to participants and methods of recruitment appropriate? | Yes | No | N/A | |
| 2.3 Has the name of the site or sites if applicable been correctly identified? | Yes | No | N/A | |

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|---|-----|----|-----|--|
| 3. Informed Consent | | | | |
| 3.1 Will the consent of participants be obtained? | Yes | No | N/A | |
| 3.2 Are there proper procedures for obtaining informed consent from the participants or their parent or guardian? | Yes | No | N/A | |
| 3.3 Will the participants be fully informed about the purpose of the research? | Yes | No | N/A | |
| 3.4 Is the procedure for obtaining informed consent appropriate? | Yes | No | N/A | |
| 3.5 Is it clear to the participants that they may withdraw at any time? | Yes | No | N/A | |
| 3.6 Where participants are vulnerable because of their age, social, psychological or medical circumstances, has this been taken into account in obtaining consent? | Yes | No | N/A | |
| 3.7 If appropriate, where participants are vulnerable as described above, has the consent of an appropriate third party been obtained (i.e. parent, guardian, school principal, doctor, key worker) | Yes | No | N/A | |
| 3.8 Are there practical arrangements to provide information to potential participants who might not adequately understand verbal explanations or written information given in English? | Yes | No | N/A | |
| 3.9 Has the appropriate information sheet(s) for the participants been prepared? | Yes | No | N/A | |
| 3.10 If it is proposed to use the data from this study in further studies have participants been appropriately informed? | Yes | No | N/A | |
| 3.11 Will participants be aware of the researcher's stance in relation to their professional accountability regarding information obtained? | Yes | No | N/A | |
| 3.12 Is a mechanism for dealing with complaints made explicit? | Yes | No | N/A | |
| 4 Confidentiality | | | | |
| 4.1 Does the researcher(s) identify how confidentiality will be maintained? | Yes | No | N/A | |
| 4.2 Have the arrangements regarding confidentiality and/or anonymity been fully explained to the participants? | Yes | No | N/A | |
| 4.3 Is there notification of how records/data will be stored and for what time period? (normally 5 years) | Yes | No | N/A | |
| 5 Intervention | | | | |
| 5.1 Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use) | Yes | No | N/A | |
| 5.2 Are drugs, placebos or other substances (e.g. food substances, vitamins) to be administered to the study participants? | Yes | No | N/A | |
| 5.3 Does the study involve invasive or intrusive procedures such as blood taking or muscle biopsy? | Yes | No | N/A | |
| 5.4 Has the availability of any extra support that might be required by research participants resulting from their participation been identified? (if applicable) | Yes | No | N/A | |
| 5.5 Are monetary or inducements being offered to any personnel involved? | Yes | No | N/A | |

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|--|-----|----|-----|--|
| 6. Methodology | | | | |
| 6.1 Is the methodology congruent with the research question? | Yes | No | N/A | |
| 6.2 Are there issues with methodology that give rise for concern(s)? | Yes | No | N/A | |
| 6.3 Are arrangements for the supervision of the project appropriate? | Yes | No | N/A | |
| 6.4 Has this proposal been submitted to a Clinical Ethical Committee? | Yes | No | N/A | |
| 6.5 Should this proposal be submitted to a Clinical Ethical Committee? | Yes | No | N/A | |

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| Ethical Committee Outcome: | | | | |
| The following decision has been made: | | | | |
| a. Full approval | Yes | No | N/A | |
| b. Approval with recommendations | Yes | No | N/A | |
| c. Conditional approval subject to ratification by chairperson, | Yes | No | N/A | |
| d. Approval not granted but invited to resubmit | Yes | No | N/A | |
| e. Rejection | Yes | No | N/A | |

Other feedback Comments:

Signature of Chairperson: -----

Date: -----