



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	

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	

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	

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: -----