HUMAN RESEARCH ETHICS COMMITTEE
KAZI NAZRUL UNIVERSITY

ETHICS REVIEW CHECKLIST FOR ETHICAL ISSUES IN RESEARCH PROPOSALS PERTAINING TO HUMAN PARTICIPANTS

Adopted from:

Iphofen, R. (2009) *Ethical decision making in social research. A practical guide*, London: Palgrave Macmillan – pages 185-199.

This checklist may be copied and used for any research project subject to quoting the source.

Following guidelines of Indian Council for Medical Research (ICMR), Govt. of India

How to use

This proforma can be used as an aide memoire, as a guide to ethical assurance for contracting parties, and as the basis for an ethical scrutiny protocol for research projects conducted by any individual researcher, research group or commissioning body. Completing this form is designed to help in 'thinking through' and anticipating harms and benefits at the outset of a project, but also to support on-going monitoring of such concerns throughout the life of a project. Use tick boxes to show decisions taken and fill in comment sections briefly to record rationales for decisions where necessary.

PROJECT IDENTIFIERS

REF. No.

SHORT TITLE:

PRINCIPAL INVESTIGATOR (PI)

CONTACT DETAILS:

RESEARCH SUPERVISOR (To whom PI is accountable):

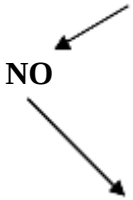
CONTACT DETAILS:

FORM COMPLETED BY: (NAME)

(SIGNED) **DATE**

DECISION TREE — WHERE ETHICAL APPROVAL WILL BE SOUGHT

1. Will this research be undertaken in an organisation/on subjects for which formal ethical scrutiny is legally needed? **DONE** **DATE**

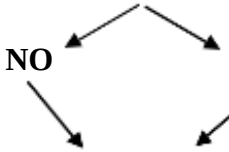


NO

YES → **Formal ethical scrutiny by relevant review board is required.**
AND
Formal research governance approval from the organisation is required. ☐ ☐

THEN GO TO 3.

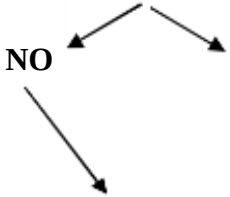
2. Will this research cover other areas of health and/or community care which legally require formal review?



NO

YES → **Ethical scrutiny by appropriate ethics committee required.** ☐ ☐

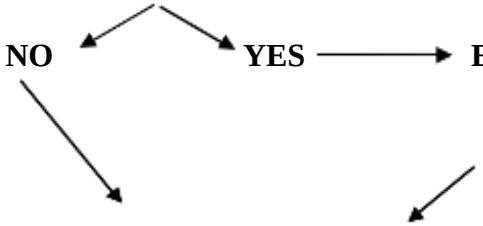
3. Is this research conducted by a research organisation based in a university/Higher Education Institution?



NO

YES → **Follow the institutional research governance procedures** ☐ ☐
AND
Seek scrutiny by internal university research ethics committee. ☐ ☐

4. Is this research conducted by an independent research organisation/individual? ☐ ☐



NO

YES → **EITHER establish own ethical scrutiny procedures using checklist to identify ethical sensitivities — if any sensitivities identified and don't have own scrutiny procedures seek external/independent scrutiny** ☐ ☐

5. If this research is to be conducted internally (within the organisation) ☐ ☐
Ensure full completion of this checklist AND — if any ethical sensitivities identified
→ **seek formal means to ensure sensitivities are addressed.** ☐ ☐

Key to Symbols used in Checklist:

 = Take special care

 = Link to…

 = Possibly talk to sponsor or other adviser

D = Consider at design stage

P = Consider at proposal stage

D RATIONALE FOR CONDUCTING THIS RESEARCH:

	Yes	No	Comment
Is this research necessary and justified as primary research?			
1) Can the required information be found elsewhere?	☐	☐	
2) Could the project be conducted as secondary research?	☐	☐	
3) Does existing research answer the research question adequately?	☐	☐	

If the answer to <u>any or all</u> of these questions is 'Yes', strong justifications must be made above for continuing to conduct this as a primary research project.

If the project becomes secondary research, many of the following criteria may still apply:

CONTINUE AS SECONDARY RESEARCH ☐

If the answer to all above is 'No': **CONTINUE AS PRIMARY RESEARCH** ☐

D P **CHECKLIST TO IDENTIFY SENSITIVE ETHICAL ISSUES**

RESEARCH QUALITY AND DESIGN **[Append or link to "Research Project Proposal (generic template)"].**

Consider the ethical implications of proposed research methods and instruments. Poor research wastes time and may produce more disbenefits.

	Yes	No	Comment
Is there a clearly stated research issue, question or hypothesis?	☐	☐	
Is there a clearly written protocol indicative of unbiased/rigorous research?	☐	☐	
Is there an adequate review of the literature/summary of existing research?	☐	☐	
Is there a reasonable prospect of the project achieving its stated aims/objectives?	☐	☐	
Is the research capable of completion within the timescale?	☐	☐	
Is the research design appropriate?	☐	☐	
Are the methods of data collection, sampling etc. appropriate?	☐	☐	
Are the methods of data analysis appropriate?	☐	☐	
Is there opportunity for peer review of methodology?	☐	☐	
P Is the researcher(s) adequately competent/experienced to conduct this project? (Has evidence of 'track record' and/or CVs been sought?)	☐	☐	
Has consideration been taken of any sub-contracted work and/or training of fieldworkers on ethical matters – sensitivity, vulnerability etc.?	☐	☐	
OVERALL – Are you satisfied that the research design has done all that is possible, within the limits of its methodology, to minimise harm to all participants?	☐	☐	

D P **RISKS ASSESSED [Link to fuller "Project Risk Assessment Matrix"]**

Potential for harm (to individual/group/society)

	Examples of harm [redacted]	Possible	Unlikely	Comment
☐ Psychological	Lowered self-esteem; emotional distress; embarrassment; misperceptions of the research purpose could raise false expectations of gain to participants.	☐	☐	
☐ Physical	Illness/accident consequent on participation in study.	☐	☐	
☐ Social	Unwarranted exclusion from society; ostracised by neighbours/friends/family/significant reference or peer group	☐	☐	
☐ Economic	Economic deprivation as consequence of answering questions.	☐	☐	
☐ Legal	Legal penalties ensuing from answering questions in survey.	☐	☐	

Consider harm that may be consequent on:

☐ Participation	☐	☐
☐ Exclusion	☐	☐
☐ Dissemination of findings	☐	☐

	Consulted	Not Consulted
 Any tick under 'possible' here – consultation with ethical sponsors/mentors is advised: 	☐	☐

CONTINUE TO NEXT SECTION

D P Attempts made to minimise risks [Again link to fuller "Project Risk Assessment Matrix"]

With reference to potential risks assessed detail steps taken to minimise potential for harm:

	Examples:	**Detail:**
☐ Psychological	debriefing; counselling contact information.	
☐ Physical	damages/reparation.	
☐ Social	controlled dissemination; language use; ethnic match between researcher/researched; gender matching between interviewer/interviewee.	
☐ Economic	rewards and incentives.	
☐ Legal	immunity from prosecution; compliance with law.	

	Yes	No	Comment
Have research participants/service users participated in the research design?	☐	☐	

D P **RISKS ASSESSED**

Potential Benefit (to individuals/groups/society)		Likely	Unlikely	Comment
	Examples of benefit			
☐ Enhanced scientific Knowledge	Society/community gains from knowledge about problem. Scientific progress made. Contribution made to evidence base.	☐	☐	
☐ Education	Knowledge is used to further curriculum development. Individual participants receive education/training they would not otherwise have gained. Information provided that enhances life style/opportunities.	☐	☐	
☐ Service delivery	Study enhances provision of service to community; study participants may individually gain.	☐	☐	
☐ Individual gains	Participants may gain personally from opportunity to air concerns; potential catharsis from sharing problems with independent observer.	☐	☐	

Attempts to maximise benefits: With reference to potential benefits assessed - detail above steps taken to maximise potential for benefit.

OVERALL: Do the anticipated benefits of this project adequately outweigh the estimated potential for harm? **YES** ☐ **NO** ☐

If 'NO' reconsider ways of reducing potential for harm or recommend DISCONTINUE If 'YES' - CONTINUE

DP **EQUITABLE SELECTION**

Are research participants selected equitably?

	Yes	No	N/A	Comment
Are participants selected from groups unlikely to be among the beneficiaries of subsequent applications of the research?	☐	☐	☐	
Are participants systematically selected from groups for reasons not directly related to the research focus of study….	☐	☐	☐	
eg for …. easy availability compromised position manipulability				
Are participants systematically excluded for reasons of inconvenience, not related to research focus of study?	☐	☐	☐	
Has any consideration been given to non-participants' gains or losses?	☐	☐	☐	

In case of any deficiency assessed the researchers may intervene adequately and also recommend that to relevant authority.

P INFORMED CONSENT

Suggested Information Sheet Protocols should include:	Yes	No	N/A	Comment
Identify Researcher/Research Group/Research Organisation.	☐	☐	☐	
Identify Funding Source/Contracting Organisation.	☐	☐	☐	
Explain how/why subject selected.	☐	☐	☐	
Explain aims/purpose of study.	☐	☐	☐	
Explain research procedure, what their participation entails. and how long study will last.	☐	☐	☐	
Identify any risks/discomfort anticipated.	☐	☐	☐	
Outline benefits of study – and who benefits.	☐	☐	☐	
Explain how study findings will be released (inc. feedback to participants).	☐	☐	☐	
Explain that participation is voluntary – consent can be refused.	☐	☐	☐	
Explain that withdrawal at any time is possible.	☐	☐	☐	
Explain that withdrawal and/or non-participation will not jeopardise how they are treated by any organisation involved in commissioning or conducting the study.	☐	☐	☐	
[Alternatives to non-participation should be outlined – if relevant]				
Steps taken for confidentiality/anonymity outlined.	☐	☐	☐	
Limits to confidentiality/anonymity disclosed.	☐	☐	☐	
Compensation offered for significant risks (*eg* counselling/advice).	☐	☐	☐	
Are the following provided:				
Contact names/numbers/addresses for information/questions/complaint/concerns.	☐	☐	☐	
Samples of proposed information sheets to ethical scrutiny committee.	☐	☐	☐	

P **Managing Valid Consent**

	Yes	No	N/A	Comment
Will participants be given an information sheet?	☐	☐	☐	
Will participants be given copy of consent form?	☐	☐	☐	
Do participants have adequate capacities of intelligence/rationality/maturity/language to comprehend what is being asked of them?	☐	☐	☐	
Consent only valid if voluntary…				
…so has no unreasonable coercion to participate (implicit or explicit) been applied?	☐	☐	☐	
…and has there been no undue persuasion to participate?	☐	☐	☐	
If **NO** to any of above				
Will consent be sought of 3rd parties?				
(a) parent/guardian in respect of immaturity	☐	☐	☐	
(b) 'representative' if mental incapacity is in question	☐	☐	☐	
(c) for any other 'vulnerability' – a responsible person	☐	☐	☐	
Is 3rd party competent and legally authorised to act on behalf of participant?	☐	☐	☐	
Will signed consent be sought?	☐	☐	☐	
If **NO or N/A** indicate if signed consent….				
….inconvenient/intrusive	☐	☐	☐	
….could pose additional risks to participants	☐	☐	☐	
…unnecessary since participants clearly refuse to participate by their behaviour (e.g not completing and returning a mailed survey questionnaire)	☐	☐	☐	

P **Exceptions to fully informed consent:**

By subject/participant

Yes	No	N/A	Comment

- Information about full nature of study restricted
  Incomplete disclosure justified if….

…demonstrably necessary to accomplish research goals

AND only minimal undisclosed risks to subjects

AND adequate debriefing is to be made available

AND dissemination of findings to subjects is provided for

- For observational study ….
  will retrospective consent be sought?

ONGOING MONITORING FOR SAFETY

P

During the course of the study are provisions made for monitoring the safety of

- participants?
- field researchers

Are there any anticipated risks to field researchers for participating in the activity?

Are there any anticipated benefits for field researchers for their participation?

Are their likely to be any study-specific needs for researchers that should be met?

Yes	No	N/A	Comment

P STRATEGIES ADOPTED TO MAINTAIN PRIVACY/CONFIDENTIALITY

	Yes	No	N/A	Comment
Is anonymity offered to and/or sought by any of research subjects?				
Is confidentiality promised? (High or low? Mention any threats to confidentiality?)				
Is temporary identification of responses for subject matching required?				
Is there a need for separately identified responses for tracking response rate?				
Can aliases/pseudonyms be used to link data from same source?				
Need for randomising responses (to disguise potentially incriminating information)?				
Will identifiers be separated from responses?				
Will identifying information kept in locked file with (named) restricted users/access?				
Will any identifying information be held in a foreign country? (Under different DP legislation)				
Can identifiers be destroyed if confidentiality/anonymity is under threat?				
Can key information in reports be changed to avoid inadvertent identification?				
Will information be reported in aggregate to minimise unwanted identification?				
Will <u>all</u> research participants sign a confidentiality agreement? (staff, subjects, funders etc.?)				
If data archiving for secondary analysis is sought, have subjects consented?				
Any other strategies?…….describe				
Is there any likelihood of legal requirement to disclose information gained?				

How to be dealt with…

Has advice of data protection officer been sought?

Are you familiar with data protection management guidance policy for your organisation?

D P **VULNERABILITY** Can the subject population be regarded as 'vulnerable' in any of the following ways?

	Yes	No	N/A	Comment
Children (minors)				
People lacking mental capacity				
Physically disabled persons				
Pregnant women				
Elderly persons				
Prisoners				
Students				
Armed services personnel				
Sexist (or other discriminatory)questioning/behaviour				

Any other perceived/anticipated vulnerability (specify) ……...

What steps taken to account for vulnerability? Comment

- 3rd party consent
- Chaperoning
- parent/guardian representation
- proxies

D P **DISSEMINATION OF FINDINGS/RESULTS**

	Yes	No	Comment/Detail
Will research results be disseminated?			
If so, specify the form dissemination will take:			
And to whom?			
Research participants			
General public			
Academic/professional audience			
Government			
Service users			
Other (specify)			
Is there opportunity for peer review of findings?			
Is there any anticipated potential harm arising out of this dissemination? Is there any intention to involve research participants/service users/the community in the dissemination of research findings?			
Has concern been given to intellectual property rights?			
Have all sources and contributions been acknowledged/referenced?			
Will research results be disseminated?			
Academic/professional audience			
Government			
Service users			
Other (specify)			
Is there opportunity for peer review of findings?			
Is there any anticipated potential harm arising out of this dissemination? Is there any intention to involve research participants/service users/the community in the dissemination of research findings?			

Will the research result in government and/or professionals becoming committed to implementing the 'best options' emerging from the project?		
Has concern been given to intellectual property rights?		
Have all sources and contributions been acknowledged/ referenced?		