

## **Appendix I Ethical Review Checklist**

**How to use:**

**This pro forma 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 ongoing 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.**

**PROJECT IDENTIFIERS:** **REF. No. ....**

**SHORT TITLE:** .....

**PRINCIPAL INVESTIGATOR (PI):** .....

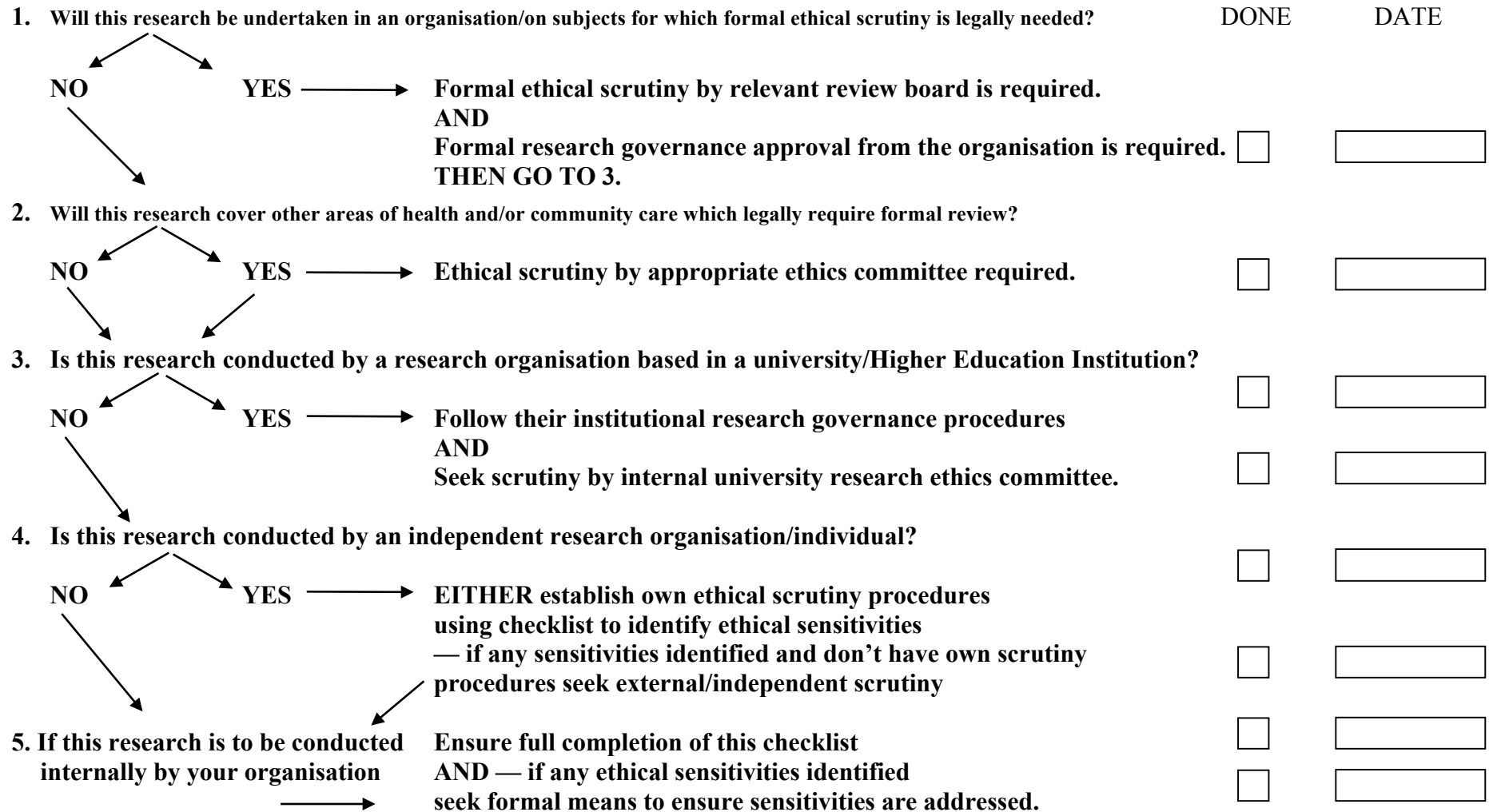
**CONTACT DETAILS:** .....

**RESEARCH MANAGER (To whom PI is accountable):** .....

**CONTACT DETAILS:** .....

**FORM COMPLETED BY: (NAME)..... (SIGNED).....**

**DECISION TREE — WHERE ETHICAL APPROVAL WILL BE SOUGHT (Separate trees for different locations will be included.)**



**Key to Symbols:**



= 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
<b>Is this research necessary and justified as primary research?</b>			
1) Can the required information be found elsewhere?	<input type="checkbox"/>	<input type="checkbox"/>	
2) Could the project be conducted as secondary research?	<input type="checkbox"/>	<input type="checkbox"/>	
3) Does existing research answer the research question adequately?	<input type="checkbox"/>	<input type="checkbox"/>	

**If the answer to any or all 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**


## DP CHECKLIST TO IDENTIFY SENSITIVE ETHICAL ISSUES

### RESEARCH QUALITY AND DESIGN



[Link to Appendix II Template for Research Proposals.]

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?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a clearly written protocol indicative of unbiased/rigorous research?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there an adequate review of the literature/summary of existing research?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a reasonable prospect of the project achieving its stated aims/objectives?	<input type="checkbox"/>	<input type="checkbox"/>	
Is the research capable of completion within the timescale?	<input type="checkbox"/>	<input type="checkbox"/>	
Is the research design appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
Are the methods of data collection, sampling etc. appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
Are the methods of data analysis appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there opportunity for peer review of methodology?	<input type="checkbox"/>	<input type="checkbox"/>	
Is the researcher(s) adequately competent/experienced to conduct this project? (Has evidence of 'track record' and/or CVs been sought?)	<input type="checkbox"/>	<input type="checkbox"/>	
 Has consideration been taken of any sub-contracted work and/or training of fieldworkers on ethical matters – sensitivity, vulnerability etc.?	<input type="checkbox"/>	<input type="checkbox"/>	
<b>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?</b>	<input type="checkbox"/>	<input type="checkbox"/>	

From: Iphofen, R. (2009) *Ethical Decision Making in Social Research: a Practical Guide*, Palgrave Macmillan. (July) ISBN 9780230210356

**PLEASE ACKNOWLEDGE SOURCE IF USED FOR ANY PUBLIC PURPOSE**

## **D P** RISKS ASSESSED


Potential for harm (to individual/group/society)

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

Consider harm that may be consequent on:

• Participation	<input type="checkbox"/>	<input type="checkbox"/>
• Exclusion	<input type="checkbox"/>	<input type="checkbox"/>
• Dissemination of findings	<input type="checkbox"/>	<input type="checkbox"/>



Any tick under 'possible' here – consultation with ethical sponsors/mentors is advised: 

CONTINUE TO NEXT SECTION

Consulted      Not Consulted

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

## **D P** Attempts made to minimise risks

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

	<b>Examples:</b>	<b>Detail:</b>
• 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?	<input type="checkbox"/>	<input type="checkbox"/>	



**D P** **RISKS ASSESSED**

Potential Benefit (to individuals/groups/society)		Likely	Unlikely	Comment
	<b>Examples of benefit</b>			
• Enhanced scientific knowledge	Society/community gains from knowledge about problem. Scientific progress made. Contribution made to evidence base.	<input type="checkbox"/>	<input type="checkbox"/>	
• 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.	<input type="checkbox"/>	<input type="checkbox"/>	
• Service delivery	Study enhances provision of service to community; study participants may individually gain.	<input type="checkbox"/>	<input type="checkbox"/>	
• Individual gains	Participants may gain personally from opportunity to air concerns; potential catharsis from sharing problems with independent observer.	<input type="checkbox"/>	<input type="checkbox"/>	

**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**

## **D P** EQUITABLE SELECTION

Are research participants selected equitably?

- 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?

Yes	No	N/A	Comment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**P**

**INFORMED CONSENT**

Suggested Information Sheet Protocols should include:

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.

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

**P**

**Managing Informed Consent**

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

From: Iphofen, R. (2009) *Ethical Decision Making in Social Research: a Practical Guide*, Palgrave Macmillan. (July) ISBN 9780230210356

**PLEASE ACKNOWLEDGE SOURCE IF USED FOR ANY PUBLIC PURPOSE**

**P**

**Exceptions to fully informed consent:**  
**By subject/participant**



- 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?

Yes	No	N/A	Comment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**P**

**ONGOING MONITORING FOR SAFETY**




During the course of the study are provisions made for monitoring the safety of...  
...participants?  
  
...field researchers?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?

**P**

**STRATEGIES ADOPTED TO MAINTAIN PRIVACY/CONFIDENTIALITY**

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

**D P** **VULNERABILITY**



Can the subject population be regarded as ‘vulnerable’ in any of the following ways?

	Yes	No	N/A	Comment
Children (minors)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
People lacking mental capacity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Physically disabled persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pregnant women	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Elderly persons	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Prisoners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Students	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Armed services personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Sexist (or other discriminatory) questioning/behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Any other perceived/anticipated vulnerability (specify) .....				

What steps taken to account for vulnerability?	Comment
<ul style="list-style-type: none"><li>• 3<sup>rd</sup> party consent</li><li>• chaperoning</li><li>• parent/guardian representation</li><li>• proxies</li></ul>	

## **D P** **DISSEMINATION OF FINDINGS/RESULTS**

	Yes	No	Comment/Detail
Will research results be disseminated?	<input type="checkbox"/>	<input type="checkbox"/>	
If so, specify the form dissemination will take: And to whom?...			
• Research participants	<input type="checkbox"/>	<input type="checkbox"/>	
• General public	<input type="checkbox"/>	<input type="checkbox"/>	
• Academic/professional audience	<input type="checkbox"/>	<input type="checkbox"/>	
• Government	<input type="checkbox"/>	<input type="checkbox"/>	
• Service users	<input type="checkbox"/>	<input type="checkbox"/>	
• Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	
Is there opportunity for peer review of findings?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there any anticipated potential harm arising out of this dissemination?	<input type="checkbox"/>	<input type="checkbox"/>	
Is there any intention to involve research participants/service users/the community in the dissemination of research findings?	<input type="checkbox"/>	<input type="checkbox"/>	
Will the research result in government and/or professionals becoming committed to implementing the 'best options' emerging from the project?	<input type="checkbox"/>	<input type="checkbox"/>	
Has concern been given to intellectual property rights?	<input type="checkbox"/>	<input type="checkbox"/>	
Have all sources and contributions been acknowledged/referenced?	<input type="checkbox"/>	<input type="checkbox"/>	

From: Iphofen, R. (2009) *Ethical Decision Making in Social Research: a Practical Guide*, Palgrave Macmillan. (July) ISBN 9780230210356

**PLEASE ACKNOWLEDGE SOURCE IF USED FOR ANY PUBLIC PURPOSE**