Central University Research Ethics Committee (CUREC)

Approved Procedure: IDREC_04_Version 3.0

Title: Studies Involving Administration of Clinical Interviews and Questionnaires

Note: This approved procedure can be combined with Approved Procedure CUREC_AP_IDREC_09 “Recruitment and testing of participants selected to score highly on measures indicating slightly higher than average vulnerability to psychological disorders”.

Users may also find it helpful to refer to Best Practice Guidance 08, which covers management of participant distress.

STUDIES INVOLVING ADMINISTRATION OF CLINICAL INTERVIEWS AND QUESTIONNAIRES

(Incorporating questions concerning current and past psychiatric symptoms, experience of traumatic events including childhood sexual and physical abuse, and questions concerning illegal drug use)

1. SCOPE

Many studies conducted in the Department of Psychiatry and other related departments include the administration of clinical interviews and questionnaires exploring current and past psychiatric symptoms, experience of traumatic events (including childhood sexual and physical abuse) and drug use. There is a risk that these interviews / questionnaires may elicit information concerning illegal behaviours or produce distress, therefore researchers using such interviews are likely to respond ‘yes’ to CUREC application decision tool questions asking whether the study has the potential to:

a) ‘induce anxiety, stress or other harmful psychological states in participants that might persist beyond the duration of the test/interview’;

b) ‘elicit information from participants that might render them liable to criminal proceedings (concerning drug abuse or child abuse)’; or

c) ‘involve exposing participants to any physical or psychological hazard, beyond those of their usual everyday life’.

As such studies incorporating clinical interviews or questionnaires asking about these sensitive topics cannot be reviewed via the CUREC 1 process alone, this Approved Procedure is intended to cover studies where the only factors that might result in the need for more detailed ethical scrutiny (CUREC 2) relate to the administration of clinical interviews or questionnaires.

The Approved Procedure may not be applied to anonymous online studies.

The Approved Procedure is intended to cover both studies in which individuals are recruited as a result of a clinical condition (for example individuals who respond to posters placed in community settings requesting volunteers with a history of depression or chronic pain) and studies on unselected community and student samples. It does not cover studies where individuals are recruited through NHS services or as a consequence of their contact with NHS services. Such studies should be submitted for HRA approval.
This Approved Procedure does not cover studies in which information is elicited from participants concerning their own participation in the abuse of children as such studies would raise ethical issues beyond the scope of the Approved Procedure.

2. **TRAINING OF RESEARCH STAFF**

Researchers need to be sensitive to Mental Health issues, and avoid working in situations that could leave them exposed to accusations of abuse. They must follow the guidance set out in the University’s ‘Safeguarding Code of Practice’, including completing the online training course ‘An Introduction to Safeguarding’, as well as undertaking risk assessments of the proposed research. Any risk assessment should also include details of how research participants can report concerns about any member of the University with whom they will be interacting.

Researchers should also take responsibility for complying with safeguarding regulations and research practices which relate to the setting(s) (country, institution) of their research. As well as such compliance, researchers should consult guidance from the relevant professional associations. 

**Clinical Interviews**: All staff administering clinical interviews should be thoroughly trained in their use by an individual with a clinical qualification (for example by a clinical psychologist, psychiatrist). Interviewers should receive ongoing supervision by an experienced member of staff (either by someone with clinical training or, at the discretion of the PI of the study, by non-clinical staff with significant experience in the use of clinical interviews with the participant group under investigation). If possible, professional training in the use of specific structured clinical interviews should be provided. If this is not possible, then training should be conducted by experienced interviewers using (a) observation of (live or video) interviews by trainees, (b) role play and (c) observation of trainees conducting clinical interviews including feedback. All staff should be aware of and discuss appropriate responses to situations in which participants reveal significant distress or suicidal ideation during a clinical interview (see Best Practice Guidance 08) and should be familiar with the CUREC guidelines and this Approved Procedure. A procedure should be put in place within each research team to deal with risk to participants and to record adverse events (e.g. cases of participant distress).

During conduct of the study individuals administering clinical interviews should always have another experienced member of staff available (in person or by telephone) who can be contacted in the event that a participant becomes distressed or appears to be at risk of serious harm. In the unusual situation in which an undergraduate student is conducting a clinical interview, an experienced member of the team should be physically available (i.e. contactable and within the same building), so that this more experienced member of staff can speak directly to the participant if necessary.

For studies involving graduate students or other members of staff as interviewers, supervision arrangements should be decided on a study by study basis and will vary according to the population being investigated (i.e. the likelihood that the interview will induce distress or reveal information indicating risk) and the degree of experience of members of staff conducting the interviews. It is the responsibility of the PI of a study (or the supervisor in the case of graduate students) to ensure that adequate supervision is in place. It is good practice to produce a document containing the contact details of experienced members of staff and the circumstances in which they should be contacted, and for this to be readily available to interviewers at all times.
**Questionnaires:** Most questionnaires are designed to be completed by study participants with limited input from the researcher. However researchers should remain vigilant to any signs of distress and should be familiar with all questionnaires being administered so that they can answer any questions study participants might have.

3. **METHODS FOR RECRUITING PARTICIPANTS**

This approved procedure is intended to cover studies in which participants are recruited from the community (for example through the distribution of posters in local community buildings) and from student populations. It does not cover studies in which participants are recruited through NHS settings or as a consequence of their use of an NHS service.

4. **INFORMATION PROVIDED TO PARTICIPANTS**

The specific details provided will vary depending on the study, but should always be on University Headed paper, showing the Departmental name and address.

- the name of the study
- the name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them
- a brief rationale of the study, including its purpose and value
- why potential participants are being invited to take part in the research
- an explanation of what the potential participant would do, including estimated duration of the test session and where it would take place
- that potential participants can ask questions about the study before they decide whether to participate
- that potential participants can choose whether they participate and, if they agree, they may withdraw from the study without penalty at any time by advising the researchers of this decision
- information about any additional personal information that would be obtained
- information about who would have access to the data, how it will be stored and what will happen to the data at the end of the study
- statement that the data would be anonymised
- what benefits (direct or indirect) may accrue to the participants in the study
- what risks are involved in the study
- that the project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants.
- where applicable, a note to explain that the research will be written up as a student’s thesis and how the personal data included in that thesis will be published and stored
- the procedure for raising a concern or making a complaint

The Information Sheet is written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults.
5. CONSENT OF PARTICIPANTS

Written informed consent will be sought from all participants prior to the commencement of any clinical interviews. Consent will be obtained for each study by a researcher trained in taking informed consent.

Participants will sign, print and date their names and the researchers who secure the consent will also sign, print and date their names. A clause in the consent form to emphasise the limits of confidentiality can be inserted in studies where it is judged that there is a significant likelihood of participants expressing information indicating risk of serious harm (for example in studies of depressed or suicidal participants recruited from the community) or where researchers may be made aware of illegal behaviour.

In cases where the researcher has any doubts over the capacity of the volunteer to comprehend the study details or to give informed consent (for example in cases where a participant appears to be very distressed or confused) the participant’s involvement in the study should cease and the researcher should act to ensure the safety of the participant.

Please refer to the Consent Form associated with this Approved Procedure.

Guidance on the informed consent process can be found at:
http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent

6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Participants may be reimbursed for their time and travel expenses either through payment or vouchers. Researchers should be sensitive to the ethical issues surrounding offering of excessive inducements to participate in research. However it is equally unethical to fail to reimburse participants adequately for their effort and time simply because they are suffering or have suffered from psychiatric symptoms or are judged to be ‘at risk’. Posters will inform participants that they will be reimbursed for their time and expenses but the amount of reimbursement will not be revealed until potential participants contact the research team.

7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/Others AND WHAT WILL BE DONE TO MINIMISE
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7.1. Risks to participants
To minimise risk, participants should be thoroughly informed about the nature of any study before consenting to take part. Additionally participants’ right to withdraw from the study at any time should be emphasised at the start of the study and should be repeated if the participant shows undue distress. Participants should be asked to inform the researcher if they are feeling uncomfortable and interviewers should remain sensitive to signs of distress. Questions concerning childhood sexual and physical abuse (and other questions concerning particularly sensitive topics) should be preceded by a brief explanation and participants should be asked whether they would like to opt out of these questions. In rare situations in which a participant becomes very distressed the researcher should draw the study session to a close and should ensure the safety of the participant (see Best Practice Guidance 08).

Researchers should be careful not to make comments that suggest the presence or absence of diagnosable psychiatric disorders on the basis of the information described by participants in clinical interviews or questionnaires. Rather where necessary they should refer to the symptoms described by participants using the participant’s own words (for example not referring to a participant’s flashbacks or nightmares as ‘post traumatic stress disorder’ when the participant has not described their symptoms in these terms). Interviewers should not make comments that imply that a participant’s subjective experiences or responses to questionnaires or interviews are abnormal - this may provoke undue distress. Equally however, if a participant describes symptoms that are causing distress, for which they have no assistance, and which the interviewer believes may be amenable to treatment, it is responsible for the researcher sensitively to inform the participant that help might be available for the symptoms they describe, should they want it. Usually participants should be encouraged to contact their general practitioner for further advice in these circumstances (again see Best Practice Guidance 08).

Where questionnaires rather than interviews are used to determine current levels of suicidal ideation or distress it is advisable for researchers to briefly and discreetly review participants’ responses to these items before the participant leaves the session. Occasionally a participant may reveal significant suicidal ideation on such measures and it is much easier for the researcher to respond to such information when the participant is still present. From time to time participants may become distressed when recalling information about past or current psychiatric symptoms or traumatic events either during clinical interviews or when completing questionnaires about similar topics. Very occasionally distress may persist beyond the experimental session. Participants should always be fully debriefed following administration of interviews / questionnaires of this type. The interviewer should acknowledge the difficult nature of some of the questions and enquire about the participant’s current emotional state. The interviewer should give the participant time to reflect on their experience of the interview / questionnaires and the opportunity to ask any questions they might have. Participants should be given the opportunity to contact the research team following the study session if they have any further questions. Where studies involve questions about use of illegal drugs, information may be revealed that would render a participant open to criminal proceedings should it be made public. As in all studies data should be stored in such a way that confidentiality is ensured following the IDREC guidelines (Best Practice Guidance 09). Participants’ right to decline to answer any questions they do not want to should also be emphasised prior to questions about illegal drug use.
7.2. Risks to Researchers
It should be acknowledged that interviewing individuals who are suffering from psychiatric disorders or who have experienced sexual or physical abuse during childhood can be stressful for interviewers as well as for participants, particularly when the interviewers are less experienced or when the interviews make up the majority of an individual’s work load. It is helpful if interviewers are able to discuss their day to day experiences with other members of the research team, even if no specific problems have arisen. Where interviewers have the opportunity for debriefing after difficult interviews they are more likely to be able to respond appropriately and sensitively when their participants experience distress.
Occasionally participants may become aggressive during clinical interviews. It is best practice for interviews to be conducted only when and another member of the research team is in the building and is available to be contacted (in person or by telephone) for advice. When interviews are conducted at a participant’s home details of the address to which the researcher has gone should be left with another member of the research team and the researcher should be telephoned to check that they are safe after an agreed period of time.

8. Monitoring and Reporting of Adverse or Unforeseen Events
If a participant becomes excessively distressed during an interview, the interview should be terminated and the senior investigator on the project informed. A record of the incident and the actions of the interviewer to ensure the participant’s safety should be recorded.

9. Communication of Results
In line with the General Data Protection Regulation (GDPR), individuals have a right to see data collected on them. Researchers should show participants their scores on questionnaires and task performance data, if asked, although this is rare. Researchers should be careful to avoid giving any interpretation of the individual level data collected. If necessary they can explain that the session is not intended to be a clinical or personal assessment and that those conducting it are not appropriately qualified to provide meaningful individual assessments. Instead, the researcher may explain that all data is treated anonymously, pooled and that analyses are carried out only on aggregate scores. All other aspects of data handling, storage and communication should follow the standards set out in Best Practice Guidance 09.

10. Duty of Care Issues / Confidentiality
Duty of care: As discussed above, occasionally in studies where participants are recruited by virtue of their experience of psychiatric symptoms or are asked about such symptoms as part of a clinical interview, they may present to the interview in distress or become distressed during the study session. In these cases researchers have a responsibility to ensure the safety of the participant, terminating the study session and enquiring whether the participant has appropriate support. Typically participants in distress should be encouraged to contact their GP.
Confidentiality: In studies where it is judged that there is a significant likelihood of participants expressing information indicating risk of serious harm (for example in studies or depressed or suicidal participants recruited from the community) a clause can be inserted in the consent form to emphasise the limits of confidentiality to enable researchers to contact the emergency services in the very rare circumstance in which a participant is judged to be at immediate and serious risk of harm but refuses to seek advice or help.

These issues are outlined in more detail in the IDREC guidelines covering appropriate responses to participants in distress (Best Practice Guidance 08).

11. DATA PROTECTION ISSUES
Data protection guidelines should be followed to ensure that all data is safely secured (see https://researchsupport.admin.ox.ac.uk/policy/data). In cases where participants are audio-recorded it will be made clear to participants that a) they have the right to decline audio recording, b) that audio recordings will be identified only by a number code and that c) audio recordings will only be available to the research team. Participants will not be identifiable in any publications arising from information collected.

12. CHANGE HISTORY

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<td>Updated links to new ‘Best Practice Guidance’ documents</td>
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<td>Update to references within document</td>
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<td>Clarification that the Approved Procedure may not be applied to anonymous online studies administering clinical questionnaires Updated section 9 about communication of results Revised sections on information provided to participants and obtaining consent Updated references to Best Practice Guidance documents</td>
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