STUDIES WHERE THERE IS A POSSIBILITY OF IDENTIFYING PSYCHOLOGICAL DISTRESS OR DISORDER IN NON-NHS PARTICIPANTS

Several research groups in the University (in particular in the Departments of Psychiatry, Experimental Psychology and Clinical Psychology) conduct research which involves psychiatric screening or assessment of psychological distress or symptoms in participants recruited from the community. This includes studies on student volunteers. This practice may occur both in studies that aim to recruit individuals with current psychiatric or psychological symptoms (for example depression or dysphoria), and studies which need to ensure that such individuals are excluded from research participation. Additionally, psychological distress or symptoms may be a variable of interest in an unselected sample, which may well then include individuals with high levels of distress or symptoms. The IDREC checklist requires that studies using research methodologies which either expose participants to psychological hazards beyond those of their everyday life, or which may induce anxiety, stress or other harmful psychological states with the potential to persist beyond the duration of the test or interview complete a full ethics application. However researchers conducting a range of other studies may be concerned about how to proceed when information about pre-existing or previously unknown psychological distress comes to light spontaneously, or is either deliberately or accidentally elicited during an experimental interview. This document provides guidance on studies where there is a likelihood that some individuals will be recruited who have high levels of pre-existing distress, or may include individuals who pose a threat or danger to themselves. The ethical issues raised when individuals presenting to an experimental session, or who participate and are discovered to be experiencing significant distress, to be at risk of harm or to have a treatable but undiagnosed psychiatric disorder are discussed. Guidance on appropriate responses to these situations are also discussed.

1. Recruitment

1.1. As in all studies recruitment materials should be designed to ensure that individuals have an accurate idea of what the research will entail. This will reduce the likelihood that participants end up disclosing information that they are uncomfortable about sharing with other people. It will also reduce the likelihood that individuals contact the research team because they are primarily seeking access to treatment when this is not the aim of the study.

1.2. If a psychiatric screening interview is to be used (e.g. DSM-IV SCID) it should be made clear in the study information sheet that the interview will ask in some detail about current and past psychiatric and psychological symptoms. If an interview contains questions about past traumatic experiences or past abuse this should be stated explicitly in the information sheet to participants. If the study involves completion of measures of psychological or psychiatric symptoms/distress (e.g. BDI), then this should also be stated. This will enable individuals who would find such questions distressing or who do not wish to reveal such information to opt-out at an early stage.
2. Training and Administration of Psychiatric/Clinical Interviews

2.1. In general, psychiatric screening should be conducted using well-validated clinical interviews or questionnaires. These have the advantage that they have been extensively tested and are likely to be acceptable to participants. They will also have been designed to elicit essential information whilst minimising distress and avoiding unnecessary or intrusive questions.

2.2. Psychiatric interviews should only be conducted by individuals trained to do so. Although it may not be feasible for all members of a research team to receive formal training or qualifications to administer psychiatric interviews, it is recommended that a qualified user should take responsibility for training other members of the research team, to ensure that interviews are conducted and interpreted appropriately.

2.3. It is crucial that senior researchers in the team ensure that those working under their supervision are able to obtain a good rapport with research volunteers and to deal sensitively with the disclosure of extremely personal information. Researchers should remain vigilant for signs of distress or discomfort during psychiatric interviews and should sensitively reiterate the participant’s right to decline to answer questions or to terminate the interview if these are noted.

2.4. Where psychiatric interviews are conducted by non-clinical research staff it is advisable to have at least one clinically trained colleague available on the research team. This individual can then be consulted in cases where decisions need to be made about how to respond to the elicitation of information suggesting the presence of an undiagnosed psychiatric disorder, or where information is disclosed that involves risk to the individual.

2.5. Researchers may sometimes wish to use informal clinical interviews or sets of questions to screen or question an individual about their psychiatric history, or any psychological symptoms. These may be relatively brief, and designed for example, to exclude potential participants who have ever received treatment for a psychiatric or psychological disorder. Ideally, such questions should be developed in consultation with an experienced researcher, and those working under supervision in the team must have the skills to deal sensitively and appropriately with individuals who disclose sensitive or distressing personal information.

3. Dealing with Participants in Acute Distress

3.1. It may become apparent during an experimental session that an individual is experiencing severe psychiatric or psychological distress. In these circumstances it is important that researchers have a procedure in place that enables them to respond appropriately and sensitively and which minimises risk both to the study participant and the researcher.

3.2. In all circumstances in which a participant appears to be acutely distressed researchers should bring the experimental session to a close. They should then sensitively ask questions to ascertain whether or not the participant is receiving any support for their distress, and if not whether they feel they would benefit from support. It may also be helpful to ask whether anyone (e.g. friends, family) is aware of how the participant is feeling and whether they have already considered contacting their general practitioner or another professional to discuss their problem(s). In cases
where the individual states that they are currently receiving support or treatment for the problem(s) discussed, it would usually be sufficient to encourage the participant to re-contact their healthcare provider. If an individual indicates that they are not currently receiving support then the researcher would usually encourage them to contact their General Practitioner in the first instance.

4. Dealing with Suicidal Participants

4.1. Sometimes suicidal ideation may be present to the extent that the researcher has serious concerns for a participant’s immediate safety. If a participant is in acute suicidal crisis or indicates that they have already harmed themselves (for example taken an overdose) researchers should encourage the participant to seek immediate help from the emergency services. The researcher should offer to contact healthcare providers on behalf of the participant only if the participant feels unable to do so themselves, to avoid compromising the participant’s autonomy. The researcher should try to ensure that the participant stays with them in a safe place until help arrives.

4.2. When conducting research in high risk populations (for example currently depressed volunteers) researchers should consider inserting a clause into the consent form to indicate the limits of confidentiality, i.e. a statement that confidentiality may be breached in situations where it is judged that the participant or another individual is at high risk of serious harm (see Box 1). This would enable a researcher 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.
Title: Studies where there is a Possibility of Identifying Psychological Distress or Disorder in non-NHS Participants

Box 1. Sample Consent Form with Confidentiality Clause

CONSENT FORM

Title of project:

Name of Responsible Investigators:

University of Oxford Central University Research Ethics Committee Protocol:

Have you read the Participant Information Sheet? [Please circle your answer] Yes / No

Have you had an opportunity to ask questions and discuss this study? Yes / No

Have you received satisfactory answers to all your questions? Yes / No

Have you received enough information about the study? Yes / No

Who has explained the study to you? Dr/Mr/Mrs/Ms ___________________

Do you understand that you are free to leave the study:

- at any time
- without having to give a reason for leaving
- and without affecting your future medical care? Yes / No

Do you understand that this study has been approved by University of Oxford Central University Research Ethics Committee: Yes / No

Do you understand that personal data will be identified using only a number code, will be accessed only by members of the research team and will be destroyed after a period of 10 years. Yes / No

Are you aware that all information will be kept strictly confidential except in the rare circumstances in which it is judged that you or someone else is at risk of serious harm? (in which case only information necessary to an emergency would be communicated) Yes / No

Do you agree to take part in this study? Yes / No

Signature of Participant ________________________________

Date ________________________________

[NAME IN BLOCK LETTERS] ________________________________

Signature of Researcher ________________________________

Date ________________________________

[NAME IN BLOCK LETTERS] ________________________________

One copy is for the Participant to keep; one for the researcher

4.3. In all circumstances researcher should only breach confidentiality as a last resort and should keep the participant informed of their actions throughout (e.g. who they have contacted and what information they have disclosed).
4.4. Only information that is directly relevant to ensuring a participant’s immediate safety should be disclosed to external parties. For example it would not be appropriate for a researcher to pass on to a General Practitioner information about a suicidal participant’s history of sexual abuse, only the information that has led the researcher to suspect that the participant is currently at serious risk.

4.5. In situations where a participant discloses information during interview that suggests ongoing distress and suicidal ideation of a less severe or imminent nature, the participant should be encouraged to seek advice from existing care-givers and/or their General Practitioner. Participants should also be given details of other local organisations offering support (e.g. Samaritans, MIND – see Box 3 on Page 8), if appropriate.

5. **Detection of Undiagnosed Psychiatric Problems**

5.1. Researchers should be extremely cautious in offering advice to individuals on the basis of responses to psychiatric screening interviews, informal clinical interviews, or self-report questionnaire responses, particularly as information may be obtained out of context and without a broader understanding of the individuals’ circumstances. However, on occasion, it would equally be unethical for a researcher to withhold information that could have serious implications for the individual. The question that researchers need to consider is whether drawing attention to, or discussing, a problem identified during psychiatric screening could help the individual gain access to services that might be of help or whether it is simply likely to produce alarm or distress.

5.2. If an interviewer suspects that a participant may have a serious psychiatric disorder (e.g. bipolar disorder) that is causing distress but which has not been diagnosed or treated, then advice should be sought from a senior researcher on the team. Those who are not clinically qualified should not offer advice directly to the participant in such circumstances. In such a case it may be helpful for a senior researcher to discuss the symptoms in more detail with the participant with a view to encouraging them to seek help.

5.3. Where participants report unusual psychological phenomena which are not a source of distress (for example benign obsessions or rituals) it would almost certainly be inappropriate for researchers to draw attention to them.

5.4. Researchers should not ‘diagnose’ participants or use diagnostic labels (e.g. ‘post-traumatic stress disorder’) to describe symptoms not described by the participants in these terms. Rather discussions should generally be based around the symptoms described by the participant, using their language. Where appropriate, participants should be told that it is possible to get help and treatment for symptoms of that type, either via their General Practitioner, or another agency. See Box 3 for helpful contacts. Again participants should generally be directed to their General Practitioner in the first instance.

6. **Studies Involving Brief Psychiatric Screening by Telephone**
6.1. Telephone screening has the benefit that individuals who will eventually be deemed ineligible to take part in a study are excluded at an early stage and are hence saved the time and effort of attending a face-to-face session. However it has the disadvantage that sensitive information may be elicited prior to obtaining written informed consent. Ideally screening conducted by telephone should be kept to a minimum.

6.2. Informed verbal consent should always be obtained explicitly before asking screening questions over the telephone. Any screening questions should be preceded by an explanation and a warning that their content is of a sensitive nature. In many cases it may be sufficient to provide information about exclusion criteria without requiring a response from participants (for example “this study is not suitable for people who have major problems with drugs or alcohol”). This allows ineligible individuals to ‘opt-out’ at an early stage without disclosing difficult information.

6.3. In cases where a research participant reveals over the telephone information that they are in significant distress or at risk of serious harm the same procedure should be followed as for individuals presenting with these problems in person (advising the individual to seek help from their GP or other existing sources of support, or in cases of acute risk, from the emergency services). It should be noted however that individuals contacting researchers by telephone may be anonymous and may not wish to disclose identifying information so action that can be taken may well be limited to the suggestion of sources of support and encouragement to seek this.

7. Recording Details of Serious Incidents

7.1. Research teams should develop a standard procedure for recording details of incidents where participants are judged to be at serious risk, including recording of information about the reasons for concern and a record of any action taken by the researcher (e.g. advice and information given, contacts made). Any incidents should be discussed with the senior researcher on the team and any contacts made with General Practitioners should generally be confirmed in writing. See Box 2 for a sample form.
Box 2. Sample Incident Report Form

<table>
<thead>
<tr>
<th>Incident Report Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Research Psychologist Involved: ________________________________</td>
</tr>
<tr>
<td>Participant ID Number: __________</td>
</tr>
<tr>
<td>Details of Incident: (e.g. reasons for concern)</td>
</tr>
<tr>
<td>Action Taken: (e.g. discussed with whom, who contacted, outcome, decisions?)</td>
</tr>
<tr>
<td>Patient’s General Practitioner Contacted by Researcher: Yes / No (By participant? Yes / No)</td>
</tr>
<tr>
<td>Duty General Practitioner Contacted by Researcher: Yes / No (By participant? Yes / No)</td>
</tr>
<tr>
<td>If Contacted by Researcher: Name and Address of General Practitioner:</td>
</tr>
<tr>
<td>Letter sent to GP to confirm details of contact? Yes / No</td>
</tr>
<tr>
<td>Letter attached? Yes / No</td>
</tr>
<tr>
<td>Signed (Research Psychologist): Date:</td>
</tr>
</tbody>
</table>

8. Research on Student Volunteers

8.1. The same procedures as those outlined above should be adopted when responding to information indicating serious distress or risk of harm in student participants. No disclosure of information should be made to third parties except in circumstances in which an individual is judged to be at serious and immediate risk. Again, every effort should be made to encourage the student to seek help independently from the appropriate sources (which may include but not be limited to University facilities) and information should only be disclosed to someone in a capacity to arrange care. It would not be appropriate to pass on confidential information to officials at a student’s college without the student’s consent unless it was judged that this would be essential to ensure the student’s safety.

9. Role of Researchers in Relation to Service Providers
9.1. Researchers should be careful not to act in ways that may cut across service providers (such as general practitioners, community mental health teams) who have a professional role in assessing and managing psychiatric distress.

Box 3. Useful Contacts (note that details may change so numbers should be checked before distribution to participants)

Oxfordshire Mind Mental Health Info line
01865 247788

Nightline – Oxford University Listening Service for Students, 0th week to 9th week
01865 270270

Samaritans
Drop in at 60, Magdalen Road, Oxford.
Phone (01865) 722122 or 116 123 (this number is free), 8:00am to 10:00pm

NHS 111 – when it’s less urgent than 999 But you need medical help quickly