HANDLING DISTRESS OR MENTAL HEALTH PROBLEMS IN PARTICIPANTS IN CUREC-APPROVED RESEARCH

Several research groups in the University (e.g., in the Departments of Psychiatry, Experimental Psychology and Clinical Psychology) conduct research that involves psychiatric or psychological screening and assessment of distress or symptoms in participants recruited from the community. This includes studies involving student volunteers as research participants. Such assessments 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, 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.

Moreover, CUREC requires that studies using research methods that either *expose participants to psychological stressors beyond those of their everyday life* or which *may induce anxiety, stress or other negative mental states with the potential to persist beyond the duration of the test or interview* submit a CUREC 2 or CUREC 3 application for ethics review.

However, researchers conducting a range of other studies may be concerned about how to proceed when information about *pre-existing* or previously unknown distress or mental health problem comes to light during the research incidentally. Additionally, research interview topics may unexpectedly provoke distress.

This document provides guidance on identifying and addressing the ethical issues associated with research where there is a possibility that individuals will be recruited who have high levels of pre-existing distress or where distress may be unexpectedly triggered by the research, and may include individuals who pose a threat or danger to themselves.

1. Recruitment and informed consent

1.1. As in all studies, information for the participants (such as recruitment material and participant information sheets) should be designed to ensure that individuals have an accurate idea of what the research will entail. The amount of information to provide at this stage will depend on the topic and on what participants are being asked to do. To help inform participants' decisions about taking part, it is good practice to be explicit from an early stage of the recruitment process about any aspects of the research that may cause distress.

1.2. Information for the participants should explain that they can avoid any questions they do not want to answer and that they are free to provide as much or as little information as they like. This

will reduce the likelihood that participants end up disclosing information they are uncomfortable sharing with other people or which triggers uncomfortable feelings.

1.3. It is important that participants understand the remit of the researchers in the context of the research being conducted, particularly if the researchers have a professional qualification in a related area. Researchers may provide information about relevant sources of support, but it is not usually appropriate for the researchers themselves to provide, for example, legal advice or medical care, even if they are qualified to do so. Student researchers in this situation are advised to discuss this with their supervisors in advance and clarify the boundaries of their roles. Being clear about the remit of the researcher(s) will also reduce the likelihood that individuals contact the research team because they are primarily seeking access to treatment or clinical assessment which is not the aim of the study.

1.4. 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 stressful experiences. If the research includes questions about past traumatic experiences or past abuse, or completion of psychological or psychiatric symptom scales including questions about thoughts of self-harm/ending one's life (e.g., BDI, PHQ-9), then this should be stated explicitly in the information sheet to participants. This will enable individuals who would find such questions too 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 can obtain a good rapport with research participants and deal sensitively with the disclosure of personal information. Researchers should remain vigilant for signs of distress or discomfort during psychiatric interviews and should, if appropriate, confirm the participant's right to decline to answer questions or to terminate the interview.

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 information suggesting the presence of an undiagnosed psychiatric disorder, or information that implies a risk to the individual.

2.5. Researchers may sometimes wish to use an unstructured clinical interview or open questions to screen or question an individual about their psychiatric history or any distressing thoughts or feelings. These may be relatively brief and designed, for example, to exclude potential participants who have ever received psychiatric or psychological treatment. 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.

2.6. If the interviews or questionnaires are conducted online rather than in-person, the research team will need to be aware that it may be harder to spot signs of distress and therefore take steps to mitigate this. Measures will need to be put in place to ensure data are kept secure.

3. Dealing with Participants in Acute Distress

3.1. It may become apparent during a research session that an individual is experiencing 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. Whenever a participant appears to be acutely distressed, researchers should offer to bring the study session to a close. They should sensitively ask questions to ascertain whether 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 <u>not</u> currently receiving support then the researcher could encourage them to contact University or college welfare services (e.g. University Counselling Service), psychological services (e.g. Talking Space Plus) or their General Practitioner (particularly if there is any concern that they may be at risk of harm to themselves or others).

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 an 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) it is good practice to include a clause in the consent form to clearly indicate the limits of

confidentiality to the participant, 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. Whilst a researcher would be expected 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, having such a statement would make it clear to the participant that this could occur.

4.3. In all circumstances, the researcher should only breach confidentiality as a last resort and should keep the participant informed of their actions throughout (e.g., whom 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, but 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 the 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 sources of support or their General Practitioner. Participants should also be given details of other local organisations offering support (e.g., Samaritans, MIND, Nightline, Safe Haven – see Appendix), as appropriate.

5. Detection of Undiagnosed Psychiatric Problems

5.1. Researchers should be extremely cautious in offering advice to individuals based on their responses to psychiatric screening interviews, informal clinical interviews, or self-report questionnaires, particularly as information may be obtained out of context and without a broader understanding of the individual's 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 a researcher 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 experiences or behaviours, which are not a source of distress (for example benign rituals or superstitious thoughts) 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 understood by the participants in these terms. Rather,

discussions should generally be based on the experiences described by the participant, using their language. Where appropriate, participants should be told that it is possible to get help and treatment for distressing experiences of that type, either via their General Practitioner, or another agency. See the Appendix for helpful contacts. For issues surrounding psychiatric diagnosis, 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 of a sensitive nature should be preceded by an explanation and a relevant warning. 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. Furthermore, as mental health problems can be of variable severity, information provided to participants should make clear what constitutes exclusion (e.g. anxiety/depression if required treatment with more than one drug or psychiatric input; any mental health problem including that treated with brief psychological intervention).

6.3. In cases where a research participant reveals over the telephone 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 the 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

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 by e-mail or letter.

7.1. The University uses an online Incident Reporting and Investigation System (IRIS) to record, review and investigate health, safety and environmental incidents that take place at the University. The use of this system allows for a swift, managed response to any incidents allowing the University to comply with its legal and moral obligations towards its staff, students, and visitors. Please see the safety office's web pages for details. Researchers should check whether their department expects

incidents such as those described in this guidance to be reported on IRIS. See Box 1 for a sample form which may be adopted in the absence of a departmental incident reporting procedure.

Box 1. Sample Incident Report Form

Incident Report Form

Name of Research Psychologist Involved: _____

Participant ID Number: _____

Details of Incident: (e.g. reasons for concern)

Action Taken: (e.g. discussed with whom, who contacted, outcome, decisions?)

Patient's General Practitioner Contacted by Researcher: Yes / No (By participant? Yes / No)

Duty General Practitioner Contacted by Researcher: Yes / No (By participant? Yes / No)

If Contacted by Researcher: Name and Address of General Practitioner:

Letter/e-mail sent to GP to confirm details of contact? Yes / No

Letter/e-mail attached? Yes / No

Signed (Research Psychologist): Date:

8. Research on Student Participants

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 is not limited to university services), and information should only be disclosed to someone who can arrange care and support. 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, and community mental health teams) who have a professional role in assessing and managing mental health problems.

10. Looking after the research team

10.1. Research relating to mental health problems and distressing thoughts or feelings may affect the people conducting the research. The Principal Investigator is responsible for ensuring that members of the research team receive suitable training and support throughout and that steps are taken to minimise the risk of distress to the research team and others involved in conducting the research. Opportunities for debriefing with more senior researchers should be provided following any incidents likely to cause, or identified by the researcher as causing, distress.

10.2. The Social Sciences Division provides training[1] and resources[2] on vicarious trauma.

[1] https://www.socsci.ox.ac.uk/event/vicarious-secondary-trauma-workshop
[2] https://socsci.web.ox.ac.uk/files/secondarytraumaforresearchersandsupervisorsjan17pdf

APPENDIX: Useful Contacts (note that details may change so numbers should be checked before distribution to participants)

Dial 999 if your life, or the life of someone you know, is at immediate risk.

NHS 111 – when it's less urgent than 999 but you need medical help quickly.

Contact your General Practitioner (GP) if you are experiencing mental health problems and are not known to local mental health services.

Oxfordshire Mind Mental Health Info line

Phone: 01865 247788

Text: 07451 277973

Email: info@oxfordshiremind.org.uk

Oxfordshire Safe Haven - a safe and welcoming place for adults in a mental health crisis

Phone: 01865 903 037

Email: osh@oxfordshiremind.org.uk

https://www.oxfordshiremind.org.uk/support-for-you/safe-haven/

Nightline – Oxford University Listening Service for Students 8pm to 8am, 0th week to 9th week

Phone: 01865 270270

Skype: oxfordnightline

Chat now via im

Samaritans

Drop in at 60 Magdalen Road, Oxford, OX4 1RB.

Phone (0330) 0945717 or 116 123 (this number is free)

Email: jo@samaritans.org