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

ADMINISTRATION OF INTERVIEWS AND/OR STANDARDISED QUESTIONNAIRES ON SENSITIVE AND/OR MEDICAL TOPICS, FOR TESTING AND/OR RECRUITMENT OF PARTICIPANTS

(Incorporating, but not limited to, 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 include the administration of interviews and/or standardised questionnaires exploring, for example, 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 cause distress.

Studies incorporating interviews or questionnaires asking about sensitive topics cannot be reviewed by the committee Secretariat, therefore this Approved Procedure is intended to cover studies where the only factors that might result in the need for more detailed ethical scrutiny (committee review) relate to the administration of such interviews and/or questionnaires. With appropriate safeguards, as described below, interviews/questionnaires under this Approved Procedure may be conducted face-to-face, by telephone or online (where contact details for the participant are obtained).

For the purpose of this procedure, relevant interviews are defined as "a conversation between researcher and participant where the researcher interacts with the participant on sensitive and/or medical topics that could cause distress and/or reveal criminal behaviour. It may include administration of psychological tests, either for the purpose of evaluating participants' relative intelligence or other capabilities or for the purpose of eliciting mental characteristics."

The following may be conducted under this procedure:

- Interviews and/or standardised questionnaires administered as part of the research
- Standardised questionnaires administered as part of the screening process in order to recruit a certain population of participants into a research study (for example, people responding to advertisements requesting participants with a history of depression).

This procedure **may not** be applied to:

- anonymous online studies that include questionnaires where responses could trigger the need for 'duty of care' follow-up, such as suicidal ideation (e.g. QIDS, PHQ-9 and SCID). If unsure, please contact your ethics committee to check.
- use of questionnaires on particularly sensitive topics (such as childhood abuse) to screen potential participants online (see also section 7.1)

- interviews conducted in a participant's home
- research that also involves deception
- research where participants are recruited through NHS services or as a consequence of their contact with NHS services
- research in which information is elicited from participants concerning their own participation in the abuse of children

Such studies would raise ethical issues beyond the scope of this Approved Procedure and require application for ethical review by committee.

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 '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.

Interviews (performed face to face or remotely). All staff administering sensitive interviews must be thoroughly trained in their use by an individual with an appropriate qualification (for example by a clinical psychologist or medical doctor). Interviewers should receive ongoing supervision by an experienced member of staff (either by someone with clinical training or, at the discretion of the PI, by non-clinical staff with significant experience in the use of interviews with the participant group under investigation). If possible, professional training in the use of specific structured clinical interviews, where used, 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 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 an interview (see Best Practice Guidance 08) and should be familiar with the CUREC guidelines and this Approved Procedure. A process 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 research, individuals administering face to face interviews should always have another experienced member of staff physically available (i.e. contactable and within the same building) who can be contacted in the event that a participant becomes distressed or appears to be at risk of serious harm. In the situation in which an undergraduate student is conducting an interview, an experienced member of the team must be present in the room for the first few interviews until they are confident that the student may conduct an interview alone. The experienced member should still be physically available (i.e. contactable and within the same building), so that they can speak directly to the participant if necessary.

For research involving graduate students or other members of staff as interviewers, supervision arrangements should be decided on a case by case basis and will vary according to the population being investigated and the degree of experience of members of staff/graduate students conducting the interviews. Where research includes discussion of sensitive topics, may induce distress or reveal information indicating risk, graduate students and new research staff must initially be

supervised/observed. It is the responsibility of the PI (or the supervisor in the case of graduate students) to ensure that adequate training and 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 completed in the presence of the researcher:
Most questionnaires are designed to be completed by participants with limited input from the researcher. However, researchers should be familiar with all questionnaires being administered so that they can answer any questions participants might have. Researchers should remain vigilant to any signs of distress if the questionnaires are being completed during a physical visit or by telephone.

Questionnaires completed remotely:
These should include triggers, where appropriate, to alert the researcher when a participant has scored for risk or above clinical cut-offs.
It is also recommended that researchers assess survey/questionnaire responses to ensure data quality (such as looking for 'straightlining' - where the same number or box is selected in answer to every question).

3. METHODS FOR RECRUITING PARTICIPANTS

3.1 Studies that will use interviews/questionnaires for recruitment/screening of those who have expressed an interest

If questionnaire screening (either online or paper based) is being used to select participants before recruitment into the research, participants should receive the full information sheet and be asked to provide consent for the screening process (e.g. filling in the questionnaire, the researchers analysing the questionnaire and potentially contacting the participant on the basis of the score) before completion of the questionnaire.

Questionnaires may be widely distributed using methods based on 'opt-in' (i.e. respondents actively choose to reply) and providing appropriate permission is received. In the case of student participants, this may include advertisement in-person (e.g. at the end of a lecture or talk, with prior permission of the organiser), or online; college pigeon holes (with prior permission of the College); via email lists (e.g. psychological or other societies, with prior permission of the organisation) or research databases (e.g. Department of Psychology's Research Participation Scheme, with prior permission of the Department). Other groups of participants may be recruited by similar methods of advertisement at appropriate occasions and locations. Where an initial direct approach is made in person, it must be stressed that there is no obligation to take part and that potential participants may take time to go away and consider participation.

Questionnaires should be accompanied by a brief paragraph explaining that respondents may, or may not, be approached again and invited to take part in further research and that all replies will be treated as confidential and held in accordance with the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and research codes of conduct. Contact details of the participant must be provided before the screening questionnaire is accessed.

All questionnaires collected in this way will be treated as confidential and stored securely according to the UK General Data Protection Regulation (UK GDPR), the Data Protection Act 2018, and research codes of conduct (see 3). They will be pseudoanonymised by the research team at the point of receipt, i.e. personal identification removed from the document and replaced by a code, which is linked to personal identifiers in a file stored separately from the questionnaires.

All completed questionnaires from people who are not subsequently included as research participants should be destroyed as soon as possible.

Participants may be offered some minimal financial incentive to return completed questionnaires, such as entry into a prize draw.

3.2 Studies that will not use interviews/questionnaires for recruitment screening

Potential participants may be identified by poster or online adverts, social media, word-of-mouth and e-mail postings to departmental and college mailing lists, which will contain the contact details of the researcher who will send further information sheets to interested participants. Contact details of researchers will be detailed in individual adverts and Information Sheets.

3.3 Recontacting participants of previous studies

Participants who previously gave consent for their details to be retained on a database for the purpose of being notified about future studies may be approached only by using the contact details they provided. Participants should be reminded of their first response by way of explanation for the second approach. The information sheet relevant to the new research should be provided at this point and other procedures followed in the usual way.

4. INFORMATION PROVIDED TO PARTICIPANTS

The information provided should be appropriate to your specific research and presented in an accessible way. If there is not enough information, potential participants might not be able to make an informed decision. On the other hand, if the information sheet is too long or unclear (e.g. through using overly-technical language) they might not read it properly or it could deter them from taking part. 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.

Please refer to, and use, the **Participant Information Sheet template** for research conducted in-person, or the **Template Information sheet for online research.**

5. CONSENT OF PARTICIPANTS

Informed consent will be sought from all participants prior to the commencement of research activity, including screening. The procedure by which informed consent is sought will depend on the nature of the research. Generally, research involving face-to-face interviews or questionnaires should obtain written informed consent. Written consent will be obtained from all participants on the day of the first session, following a suitable (at least 24 hour) period during which they will have had an opportunity to read the Information Sheet and discuss their participation with others and with the researchers. An experienced researcher will answer all and any questions before consent is obtained. Consent will be taken by a member of the research team who has appropriate training, as confirmed by the Principal Investigator. Participants will be reminded that they are able to change their mind and withdraw from the study at any point without penalty.

Please refer to, and use the **Written Consent Form template** for in-person research.

If online questionnaire screening is being used to select participants before recruitment, consent can be documented by asking the participant to click an online box. A suitable statement should be used, such as "I have read the information sheet for this research and agree to completing screening questions with a view to taking part. I understand that completion of the questions does not oblige me to take part in the research if I am eligible'

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).

In cases where the researcher has any doubts over the capacity of the participant 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 research should cease and the researcher should act to ensure the safety of the participant.

Please also see CUREC's guidance on the informed consent process.

6. COMPENSATION

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'.

Consideration should be given to how and when participants are told about any recompense. Participant information sheets and recruitment materials should state that recompense will be made so that potential participants are not discouraged from participating by the associated costs. As a general rule, recruitment material should not state the value. However, if this is necessary (e.g. it is a requirement of a third-party recruiter), advertisements must not emphasise the value of the payment (for example, through the use of formatting). Further guidance is available within CUREC's Best Practice Guidance 05 on Payments and incentives in research.

7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE THEM

7.1 Risks to participants

General Approach. Participants should be thoroughly informed about the nature of any tasks before consenting to take part (e.g. by clearly describing in the PIS what will be asked of them). Additionally participants' right to withdraw from the research at any time should be emphasised at the start of the research, 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 session to a close and ensure the safety of the participant (see Best Practice Guidance 08).

Nature of interviews/questionnaires: While questionnaires asking about particularly sensitive topics (such as childhood abuse, suicidal ideation) may be used in activity where a researcher is interacting with a participant (e.g. face-to-face meeting, telephone screening), such questionnaires may not be used online under this procedure.

Participants who become distressed during the research: Participants recruited on the basis of high levels of vulnerability may be somewhat more prone than people in unselected groups to becoming

distressed when processing negative material, undertaking slightly stressful tasks, or answering personal questions. In instances where the person conducting the interview is not clinically qualified, potential 'red flag' answers should be identified and discussed with the PI/delegated experienced researcher prior to interviews as part of the training procedure.

Participants scoring within a clinical range on a questionnaire or following an interview: While researchers should be careful not to suggest the presence or absence of diagnosable conditions, there is a duty of care to ensure that participants whose responses might indicate clinically significant levels of symptomatology are aware of the help that is available to them should they wish to use it. There would not normally be more than one or two such participants in a typical study. However, the recruitment of adults at risk renders it more likely that researchers will encounter this than in unselected populations.

Where spontaneous comments or questionnaire responses during the session reveal clinically significant levels of symptomatology in a participant, the researcher must consult with the PI/delegated experienced researcher. Individual judgement should be used in determining whether a medical referral would be appropriate, and researchers should take into account the specific clinical thresholds appropriate to the questionnaires used. Any such referral may only be discussed with a participant after informing and getting approval from the PI or delegated experienced researcher.

Monitoring and responding to information collected: Where studies are collecting information relevant to risk to participants (e.g. measures of suicidal ideation) the research group should have a clear policy for how the information will be reviewed and responded to during the study. 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 visit. 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. It is for this reason that this procedure is not applicable to anonymous online studies in which such information is gathered. Online/remote questionnaires including this information may only be utilised where contact details for the participant are obtained in advance and the online set-up should include triggers, where appropriate, to alert the researcher when a participant has scored for risk or above clinical cut-offs. An experienced researcher should then contact the participant to provide advice/support.

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). Criminal activity related to drug use only should generally not be revealed unless under court order. 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

Researchers should discuss risks with their supervisor/PI and, if appropriate, put a risk assessment in place for the study. Interviewing participants 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. All researchers working with selected populations should have the opportunity for regular debriefing with their supervisor, either on demand or routinely as appropriate to the situation and setting. If the supervisor is unavailable at any time during a testing period then suitable alternative arrangements for accessing support if needed should be made. 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 interviews. It is best practice for interviews to be conducted only when another member of the research team is in the building and is available to be contacted (in person or by telephone) for advice. If the particular research poses a real risk of this, then there should always be two researchers present in the interview room.

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 Principal Investigator informed. A record of the incident and the actions of the interviewer to ensure the participant's safety should be recorded and a summary sent to the Ethics Committee who approved the research.

9. COMMUNICATION OF RESULTS

In line with the General Data Protection Regulation (GDPR), and the Data Protection Act 2018, participants 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 session. In these cases researchers have a responsibility to ensure the safety of the participant, terminating the 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 of 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. Similarly, it should be mentioned, where appropriate, that there may be an obligation to breach confidentiality under certain conditions described in law and professional guidelines (these conditions are to be detailed in the application and PIS with appropriate references).

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

11. DATA MANAGEMENT AND PROTECTION

The research must be conducted in accordance with the Research Data Policy researchdata.ox.ac.uk/university-oxford-data-management-policy; CUREC's Best Practice Guidance 09 on Data collection, protection and management; and Research Data Oxford's guidance on data backup, storage and security.

Participants' informed consent must be obtained for participation in the study, which includes the collection, storage and retention of all data related to the study. Directly identifiable personal information held by the research team (such as contact details, consent forms and screening forms, which include name or other identifiers) must be held securely - either in paper format in lockable filing cabinets with access only by the University researchers, or in a password-protected database, on an encrypted machine or on a protected server. These should be servers provided by the University where the risks and access have been professionally managed. Other servers will require security assessment by University Information Security. Other research data must be labelled with a code number rather than a name or initials, and accessed via a password- and firewall-protected server. You should reflect on, describe, and justify in your application, what you would do with information provided about any illegal activity or something that may endanger the personal safety of participants, researchers, or third parties.

The keys linking personal details to the codes used to label other research data may be kept in paper format in lockable filing cabinets with access only by the researchers, or in a password protected spreadsheet on University approved servers. The keys should be kept separately from other study data. Such keys should be destroyed as soon as no longer needed, as should other personal data (with due regard to University and other guidelines on data retention, e.g. of consent forms).

In cases where participants are audio/video-recorded it will be made clear to participants that a) they have the right to decline recording, b) that recordings will be labelled only by a number code (but will remain identifiable due to their nature) and that c) audio recordings will only be available to the research team. Participants should ideally not be identifiable in any publications arising from information collected. Any video or audio material on which participants are potentially identifiable (images and/or voice recordings) must be kept securely (ideally encrypted) in a locked cabinet or on a password-protected desktop computer. The material may not be stored on laptops or websites, or shared with anyone outside the research team. Once an anonymous transcription has been produced, the original should be destroyed, unless retention can be justified. Note that there is an exception to the above where audio/video is an output of the research, in which case participants must receive full detail as to what the recording will be used for and give explicit consent for use/retention.

If researchers do intend to divulge results and/or personal information to anyone outside the research team, this must be made clear at the outset in the information sheet.

Contact details may be retained after the end of the research where the participant agrees to be contacted for future studies. These should be held separately from the study data, and a copy of the consent form retained as evidence of agreement to be contacted. For participants who do not wish to be contacted in the future, contact details will be destroyed as soon as possible after completion of their research participation. Personal and research data may be viewed by regulatory bodies and designated individuals within the University of Oxford for the purposes of monitoring and auditing the research with the written consent of the participant.

Anonymised data may be shared with other research institutions, including researchers outside of the UK and the EU, for use in other and future research studies. For detail on anonymisation, please refer to the Information Commissioner's Office (ICO) Code of Practice –'Anonymisation: managing data protection risk', especially Appendix 2 and Annex 1.

Where data has been anonymised (all identifying information removed, including any linkage document), there is no limit as to how long this may be retained by the researchers. However, the period of retention should be stated on participant information.

Sharing of Data

Research teams will be encouraged to make their data available for reuse and validation. In all cases, the data will be shared as openly as possible and as closed as necessary in order to protect the privacy of participants. Online repositories will be assessed by research teams for their appropriateness with regard to:

- the required treatment and de-identification of unique brain and biometric data in line with UK GDPR;
- control of how the data are accessed and re-used, including terms to protect the ongoing privacy of participants;
- required attribution of the data to the originating research team, the University and funding bodies;
- management of data withdrawal requests made by participants.

12. REFERENCES

General Medical Council (GMC) - Confidentiality: Good practice in handling patient information

13. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
1.0	This is a new Approved Procedure, combining retired Approved Procedures 04 and 09	N/A
1.1	Revised for accessibility purposes	1.0
1.2	Updated hyperlinks	1.1
2.0	Allowed low-risk questionnaires to be used in anonymous online studies, but explicity excluded those involving questions on suicidal ideation. Administrative revisions. Complete update of data management section – text approved by CUREC Nov 2021	1.2
2.1	Reference to Worktribe added	2.0
3.0	Clarified statements about illegal activity disclosure in sections 7.1 and 11 Clarified information about breaching confidentiality Removed reference to old MS Word application forms	2.1