RECRUITMENT AND TESTING OF PARTICIPANTS SELECTED TO SCORE HIGHLY ON MEASURES INDICATING SLIGHTLY HIGHER THAN AVERAGE VULNERABILITY TO PSYCHOLOGICAL DISORDERS

1. SCOPE

Research conducted within the University frequently involves the recruitment and testing of selected participants, such as those scoring highly on measures of trait anxiety, depression, or dysphoria.

Recruitment typically involves widespread administration of personality questionnaires followed by selective approach only to those scoring at particularly high levels. Frequently a control group, comprising those scoring low on the same selection measure, will be recruited.

This approved procedure is intended to cover any studies involving procedures where the higher than average vulnerability of the population gives rise to additional ethical considerations. These additional ethical issues can be summarised as follows:

1. Identification of individuals scoring within a clinical range on one or more measure
2. Enhanced risk of distress during study procedures, due to pre-existing vulnerability

This approved procedure covers testing involving any of the following: personality, mood state or clinical screening questionnaires; computerised cognitive tasks involving positive, negative and neutral material such as words, text, faces or more complex pictures; behavioural tasks such as sorting, counting or arranging objects.

It also covers the administration of mild stressors (e.g. difficult anagram tasks; performing a short speech), mood induction (e.g. listening to sad music) and ‘cognitive modification’ paradigms (where participants have to generate negative interpretations or attend to negative information).

This approved procedure does not cover those recruited as having a clinical condition (e.g. via poster or advertisement specifying the condition of interest; see CUREC_AP_IDREC_04) nor clinical patients within the NHS. Neither does it cover the use of invasive procedures.

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.
Researchers (including students) should be trained by their supervisors in the research methods and procedures appropriate to their study, including the sensitive use of clinical screening questionnaires and personality trait inventories. They should either be supervised by a clinically qualified professional or have access to one through the contacts of their supervisor.

All students are to acquaint themselves with, and follow, the British Psychological Society Code of Conduct and the University of Oxford data protection and academic integrity guidelines https://compliance.web.ox.ac.uk/data-protection-policy.

3. METHODS FOR RECRUITING PARTICIPANTS
Participants are recruited selectively based on their responses on personality trait or other questionnaires indicating above average vulnerability to psychological disorders.

3.1 Initial Approach
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 (e.g. at the end of a lecture or talk, with prior permission of the organiser); college pigeon holes (with prior permission of the College); 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 in appropriate occasions and locations.

Questionnaires should be accompanied by a brief paragraph explaining that respondents may, or may not, be approached again and invited to take part in a further study and that all replies will be treated as confidential and held in accordance with the General Data Protection Regulation (GDPR) and research codes of conduct. The following phrase, or similar, should appear alongside sections requesting the completion of contact details:
‘OPTIONAL: Please only provide contact details if you are willing to be approached again about participation in further research’.

All questionnaires collected in this way will be treated as confidential and stored securely according to the General Data Protection Regulation (GDPR) and research codes of conduct (see 3). They will be anonymised 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 that are not to be used in a research study 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 Second Approach
Participants may be approached again only by using the contact details given. Participants should be reminded of their first response by way of explanation for the second approach. The information sheet relevant to the study should be provided at this point and other procedures followed in the usual way.

4. INFORMATION PROVIDED TO PARTICIPANTS

Details provided to participants should follow the proforma and guidelines provided by CUREC in the usual way. The current guidance for the Participant Information Sheet can be found at [http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#collapse1-2](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent#collapse1-2).

In some cases (e.g. when using unpleasant pictures) it will be appropriate to show participants examples of stimuli to be used prior to taking written consent. Specific points of information to be added to the information sheet for studies falling under this approved procedure are:

- The basis on which participants have been invited to take part (e.g. ‘You have been selected based on your responses to a screening questionnaire designed to assess your personality’)
- Where negative materials (e.g. words, text, faces, pictures) are to be included this should be explicitly stated (e.g. ‘during this experiment you will be asked to read positive, negative and neutral words, such as ‘happy’, ‘death’ and ‘book’)
- Details of each task to be undertaken should be given, paying particular attention to any potentially stressful procedures (e.g. ‘You will be asked to listen to music that some people may find sad’; ‘You will be asked to give a 5 minute speech’; ‘You will be asked to solve some difficult anagrams’)
- Where personality questionnaires or other personal information is requested (e.g. about past or current psychological disorders or treatment), the nature of the questions to be asked should be made explicit (e.g. ‘Some questions will ask about your past and current psychological wellbeing’ or ‘You will be asked about how you have been feeling over the past week and how you feel in general’)
- The right to decline answering any question should be stated.
- The limits of confidentiality should be stated (i.e. that confidentiality may be breached in the rare case that the experimenter becomes aware of a serious risk of harm to self or others)

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.

Please refer to the Information Sheet associated with this Approved Procedure.

5. CONSENT OF PARTICIPANTS

Written informed consent must be obtained from all participants using the Consent Form associated with this approved procedure. Consent will be obtained for each study by a researcher trained in taking informed consent.

Participants will sign, print and date their names. The researchers who secure the consent will also sign, print and date their name.
6. **FINANCIAL AND OTHER REWARDS TO PARTICIPANTS**

Financial incentives, if available, should be in line with the usual local hourly rate and information about whether or not any payment is offered should be included in the information sheet in the usual way.

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

7.1. **Risks to participants**

1. **Distress.** Participants recruited on the basis of high levels of vulnerability may be very slightly more prone to becoming distressed when processing negative material, undertaking slightly stressful tasks, or answering personal questions.

*Safeguards:* Additional care is needed to fully inform participants about the nature of such tasks as covered under point 5 above. Participants should be routinely asked at the start of testing to inform the researcher if they experience any discomfort or undue distress. Researchers should remain vigilant to signs of this. Where suspected, the possibility to withdraw from a task, questions, or if necessary the whole study, should be reiterated. In the extremely rare event that considerable distress is seen, the researcher should draw the session to a close, following Best Practice Guidance 01.

2. **Individuals scoring within a clinical range.** 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 individuals in a typical study. However, the recruitment of adults at risk renders it more likely that researchers will encounter this than in unselected populations.

*Safeguards:* Where spontaneous comments or questionnaire responses reveal clinically significant levels of symptomatology the researcher may wish to consider passing the attached letter to the participant at the end of the session, or sending it afterwards. Individual judgement should be used in determining when this would and would not be appropriate and researchers should take into account the specific clinical thresholds appropriate to the questionnaires used in their study. A less experienced researcher may need to consult their supervisor before sending the letter to a participant.

As a general safeguard (i.e. relevant to 1 and 2 above) researchers should routinely conduct a short debriefing at the end of testing. This should include i) asking how participants are feeling and ii) an opportunity to ask questions.

7.2. **Risks to Researchers**

While there are no specific risks to researchers, the rare occasions outlined above can be stressful for researchers, particularly those with less experience. 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 study 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.
8. MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS
While researchers may not always remain in the same room as participants, they should always be within easy reach of the participant’s location. During any potentially stressful procedures (see above) they should remain in direct contact with participants and monitor their response.

Any undue distress occurring during a procedure should be reported to the supervisor/ a senior investigator at the time, allowing accurate monitoring to take place and support provided as necessary.

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
These have been addressed in sections 5 and 8.

11. DATA PROTECTION ISSUES
As stated under 4, all questionnaires collected at first recruitment should be treated as confidential and stored securely according to data protection guidelines and research codes of conduct (see 3). All completed questionnaires gathered at first recruitment, which are not to be used in a subsequent research study, should be destroyed as soon as possible.

Recruitment questionnaires and all other data (which should be anonymised at the point of collection) are to be stored securely in accordance with the General Data Protection Regulation (GDPR), as stated above.

12. FURTHER INFORMATION
Procedures outlined above are based upon those previously submitted and approved by the University of Cambridge.
13. CHANGE HISTORY

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