NEGATIVE MOOD INDUCTION IN PARTICIPANTS WITH OR WITHOUT A HISTORY OF DEPRESSION

1. SCOPE

The negative mood induction procedure has been used widely to examine the effects of mood change on cognitive processing. This Approved Procedure is designed to cover the use of a negative mood induction procedure in studies of both participants with and participants without a history of depression. Because a negative mood induction might occasionally "*induce anxiety, stress or another harmful psychological state in participants that might persist beyond the duration of the test/interview*" this would usually result in the researcher completing a full CUREC 2 application (unless instead their department has started using Worktribe Ethics to apply for ethics review). This Approved Procedure is intended to cover **only studies in which participants have been screened to ensure an absence of currently significant depressive symptoms or suicidal ideation** (as described below). Participants with previous symptoms of depression can be recruited.

Note this procedure does not cover studies in which deception is used during the induction of negative mood, such as occurs with failure tasks in which participants are asked to complete a difficult or impossible task and are then given feedback indicating that their performance was substandard. Such studies should be submitted for ethics review as a full CUREC 2 or CUREC 3 application if your department is not yet using Worktribe Ethics (in which case, this should be used instead).

In a typical study, participants are informed that the purpose of the mood induction procedure is to induce a sad mood and that in order to do this they will be asked to perform a task designed to induce a lower mood such as listening to sad music, watching sad films, reading cards containing sad (Velten) statements (negative statements such as "There are things about me that I don't like") or focussing on difficulties they have experienced in their life (or some combination of these). The researcher should remain present in the room throughout the procedure.

If several cognitive tasks are to be administered following induction of sad mood, then mood boosters (i.e. further "doses" of the mood induction procedure) may be given between tasks. These are necessary because induced mood is transient and mood induction boosters are needed to sustain the mood during completion of the post-induction cognitive tasks.

Participants should be asked to rate their mood (e.g. happiness and despondency) periodically on visual analogue scales or similar measures, prior to, during and following the mood induction procedure enabling interviewers to detect participants whose mood changes as a result of the mood induction and whose sad mood is persisting at the end of the session.

2. TRAINING OF RESEARCH STAFF

All researchers should be trained in the use of the mood induction procedure.

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 Oxfordshire Safeguarding Children Board's 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.

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.
Potential participants will be identified by one of the methods outlined on the CUREC application. When a potential participant registers interest, further information (prepared using the associated template information sheet) will be sent, together with details as to how to confirm they would like to take part.

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.
In addition to the standard information included for all studies, those studies using mood induction procedures must include a description of the mood induction procedure itself, its intended outcome and a statement concerning the possibility of inducing a negative mood. An example of the description of the mood induction procedure that can be included in the Participant Information Sheet is included in section 7.2 below.

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 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. Vulnerable populations or participants who are unable to provide informed consent in English are not covered by this Approved Procedure.

Copies of the signed consent forms will be provided to the participants along with the information sheet. The originals will be kept in the files of the researchers.

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

6. COMPENSATION

Compensation (either financial or in kind) may be offered to participants for their time and travel expenses. Some studies (for example, those investigating reward processing) may offer a performance-related reward. Individual proposals will detail the value (if any) of compensation to be offered. Compensation is limited to the time and inconvenience incurred as well as reasonable travel expenses and will in no circumstances consist of course credits for student participants.

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. If reimbursement values are included, 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

7.1 Risks to participants

The negative mood induction procedure results in a transient increase in sad mood.
Individuals who are experiencing current psychological distress or suicidal ideation should not complete the sad mood induction procedure, so adequate screening must be in place.
Occasionally sad mood may still be present to some degree at the end of the formal session.

7.2 Safeguards

Participants should be provided with information about the mood induction in the information sheet. The fact that the mood induction procedure is under participants' own control should be emphasised - participants have to actively engage in the induction procedure in order for it to have an effect. Participants who feel uncomfortable and do not want to get into a sad mood are unlikely to do so. For instance, the information sheet could be worded as follows:

"In order to assess the effect that your mood has on your thinking, at some point during the session you will be asked to bring to mind some sad thoughts while listening to music for a few minutes. To help you get into a sad mood you will also be asked to read some cards that contain statements describing the kinds of thoughts and feelings people have when in a sad mood. This procedure is called 'mood induction' and would be under your own control the whole time."

The procedure should be discussed so that all participants have been made aware of, and given informed consent to participate, in this aspect of the session.

- Participants must be screened for depressive symptoms or suicidal ideation. This can be done using standardised scales or clinical/semi-structured interviews as appropriate. The purpose of this process is to ensure that currently depressed and/or high risk individuals do not complete the mood induction.

Researchers should consult the IDREC Best Practice Guidance 08 on how to respond if screening identifies participants in significant distress.
Researchers must explicitly ask participants if their mood has returned to normal following completion of any tasks, and should fully debrief participants. During debriefing participants should be given an opportunity to discuss their experiences. This procedure, in itself, almost always has the effect of eradicating any persisting sad mood since it allows participants to step back from their experience of the mood induction and view it objectively.
If any sad mood persists participants can be given a positive mood induction (positive Velten statements and positive music). In practice this is very rarely, if ever, necessary.

8. MONITORING AND REPORTING OF ADVERSE OR UNFORESEEN EVENTS

In the rare circumstances in which a participant shows signs of excessive sadness or distress during the mood induction the researcher should respond by immediately terminating the mood induction procedure.
Any adverse reactions to the mood induction procedure (e.g. if a participant becomes distressed) should be reported to the senior investigator.

9. 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 (e.g. questionnaires) must be labelled with a code number rather than a name or initials, and accessed via a password- and firewall-protected server.

The keys linking personal details to the codes used to label other research data (if used) 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).

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.

10. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
2.0	Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
3.0	Revision to include procedures other than music-based mood induction	2.0
3.1	Hyperlinks updated for new CUREC website	3.0
3.2	Removed reference to sections of the old CUREC 1 checklist	3.1
3.3	Updated to increase accessibility	3.2
4.0	Reviewed procedure with minor changes. Addition of new sections on compensation and data management (text approved by CUREC Nov 2021). Revision to sections on recruitment, provision of information to participants, and consent from participants – to reflect other Approved procedures.	3.3
4.1	Added reference to Worktribe	4.0