**note to applicants: it is important for you to include all relevant information about your research in this application form as your ethical approval will be based on this form. Therefore anything not included will not be part of any ethical approval.**

**You should read the Ethics Application Guidelines and have them available as you complete this form.**

### APPLICATION FORM

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| **SECTION A APPLICATION FOR ETHICAL REVIEW: HIGH RISK** |

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| |  | | --- | | **A1** | | **Project Title:** Neural mechanisms of emotional learning | |
| Date of Submission: 29/01/18 | Proposed Data Collection Start Date: 01/02/18 |
| UCL Ethics Project ID Number: 12707/001 | Proposed Data Collection End Date: 01/01/19 |
| **Is this application for continuation of a research project that already has ethical approval? *For example, a preliminary/pilot study has been completed and this is an application for a follow-up project? If yes, please provide the information requested below.*** | |
| Project ID for the previous study: |  |

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| |  | | --- | | **A2** | | **Principal Researcher**  *Please note that a student – undergraduate, postgraduate or research postgraduate cannot be the Principal Researcher for Ethics purposes.* | |
| Full Name: Professor Ray Dolan | Position Held: Mary Kinross Chair of Neuropsychiatry |
| Name and Address of Department:  Max Planck UCL Centre for Computational  Psychiatry and Ageing Research, 10-12 Russell  Square, London, WC1B 5EH | Email: r.dolan@ucl.ac.uk |
| Telephone: 020 3108 7538 |
| Fax: 020 7813 1445 |
| **Declaration To be Signed by the Principal Researcher**   * I have met with and advised the student on the ethical aspects of this project design *(applicable only if the Principal Researcher is not also the Applicant).* * I understand that it is a UCL requirement for both students & staff researchers to undergo Disclosure and Barring Service (DBS) Checks when working in controlled or regulated activity with children, young people or vulnerable adults. The required DBS Check Disclosure Number(s) is: NA * I have obtained approval from the UCL Data Protection Officer stating that the research project is compliant with the Data Protection Act 1998. My Data Protection Registration Number is: TBC * I am satisfied that the research complies with current professional, departmental and university guidelines including UCL’s Risk Assessment Procedures and insurance arrangements. * I undertake to complete and submit the ‘Continuing Review Approval Form’ on an annual basis to the UCL Research Ethics Committee. * I will ensure that changes in approved research protocols are reported promptly and are not initiated without approval by the UCL Research Ethics Committee, except when necessary to eliminate apparent immediate hazards to the participant. * I will ensure that all adverse or unforeseen problems arising from the research project are reported in a timely fashion to the UCL Research Ethics Committee. * I will undertake to provide notification when the study is complete and if it fails to start or is abandoned. | |

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| |  | | --- | | **A3** | | **Applicant(s) Details** *(if Applicant is not the Principal Researcher e.g. student details):* | |
| Full Name: Dr Toby Wise | |
| Position Held: Postdoctoral Fellow | |
| Name and Address of Department: Max Planck UCL Centre for Computational  Psychiatry and Ageing Research, 10-12 Russell  Square, London, WC1B 5EH | Email: t.wise@ucl.ac.uk |
| Telephone: 020 3448 4411 |
| Fax: 020 7813 1420 |
| Full Name: Dr Gita Prabhu | |
| Position Held: Research Manager | |
| Name and Address of Department: Max Planck UCL Centre for Computational  Psychiatry and Ageing Research, 10-12 Russell  Square, London, WC1B 5EH | Email: g.prabhu@ucl.ac.uk |
| Telephone: 020 3448 4411 |
| Fax: 020 7813 1420 |

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| |  | | --- | | **A4** | | **Sponsor/ Other Organisations Involved and Funding** |
| 1. **Sponsor:**  **UCL**  **Other institution**   If your project is sponsored by an institution other than UCL please provide details:   1. **Other Organisations**: If your study involves another organisation, please provide details. *Evidence that the relevant authority has given permission should be attached or confirmation provided that this will be available upon request.* 2. **Funding:** What are the sources of funding for this study and will the study result in financial payment or payment in kind to the department or College? *If study is funded solely by UCL this should be stated, the section should not be left blank.* Wellcome Trust Fellowship to Dr Toby Wise |

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| 1. **I have discussed this project with the principal researcher who is suitably qualified to carry out this research and I approve it.**   **I am satisfied that *[please highlight as appropriate]:***   1. **Data Protection registration:**  * **has been initiated**  1. **a risk assessment:**  * **has been satisfactorily completed**  1. **appropriate insurance arrangements are in place and appropriate sponsorship [funding] has been approved and is in place to complete the study.**  **Yes**  **No** 2. **a Disclosure and Barring Service check(s):**  * **is not required**   *Links to details of UCL's policies on the above can be found at:* [*http://ethics.grad.ucl.ac.uk/procedures.php*](http://ethics.grad.ucl.ac.uk/procedures.php)  **\*\*If any of the above checks are not required please clarify why below.**  DBS is not required as the study only involves adult participants aged 18 and above. |
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| **SECTION B DETAILS OF THE PROJECT** |

**\*\*It is essential that Sections B1 and B2 are completed in simple understandable lay language that a non-expert could understand or you risk your project being rejected**

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| |  | | --- | | **B1** | | **Please provide a brief summary of the project in simple lay person’s prose outlining the intended value of the project, giving necessary scientific background.**  *(max 500 words)***.**  Humans typically learn rapidly about positive and negative outcomes in their environment, allowing the formation of an accurate picture of the presence of rewards and punishments. However, alterations in these learning processes have been shown to relate to traits relevant to psychiatric illness, and some pathological differences in these learning processes appear to be important in mental health problems such as anxiety.  Although there is an extensive literature on the neural systems underlying these learning processes, and how they might be altered in psychiatric illness, emerging research raises the possibility that the neural processes responsible for this learning behaviour may be more complex than previously thought. In particular, it has been proposed that learning may depend on “offline” as much as “online” processing; that is to say that how we process the outcomes of our behaviour after receiving a reward or punishment may be as important as the experience of receiving the outcome itself. This is thought to depend on our ability to “replay” events after they have happened, which allows us to continue to learn from them even when resting or sleeping.  A parallel line of research in rodents has indicated that the brain tends to replay experiences after they occur, and while the animal is at rest. This replay process could therefore underlie our ability to learn from experiences “offline”. Recently, work from our group has demonstrated that it is possible to identify a similar replay process in humans using magnetoencephalography.  The aim of this project will be to use these newly developed methods to examine neural replay during tasks where subjects learn from rewards and punishments to investigate whether replay of these experiences during rest occurs, and whether it relates to subjects’ ability to learn from these experiences.  Additionally, it is well known that many psychiatric disorders such as depression and anxiety are associated with a tendency to “replay” negative experiences, which exacerbates symptoms. We also wish therefore to examine whether subjects’ tendency to neurally replay experiences in our tasks is associated with their reported tendency to worry about or ruminate over everyday events.  This project will give us a greater understanding of the neural mechanisms underlying emotional learning, and will give us an insight into how these problems might relate to mental health problems. This will pave the way for future research investigating these processes in clinical populations. |

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| |  | | --- | | **B2** | | **Briefly characterise in simple lay person’s prose the research protocol, type of procedure and/or research methodology (e.g. observational, survey research, experimental). Give details of any samples or measurements to be taken** *(max 500 words).*  Healthy adult volunteers aged 18-65 will be recruited and asked for informed consent to participate after being fully informed about all aspects of the study in advance.  Participants will play games in which they learn associations between sequences of visual stimuli and rewarding or punishing outcomes. These associations may be unclear or change over time to make the task more challenging. Rewarding outcomes will take the form of monetary wins (which will be translated into bonus payments at the end of the experiment), while punishing outcomes will be either monetary losses or mild cutaneous electric shocks. Participants’ task will be to learn to choose sequences of stimuli that maximise reward and/or minimise punishment. Subjects will also be asked to fill out published, standardised questionnaires measuring traits that are relevant to mental health problems.  The study will take place over one or two sessions (the necessity of the second session will be determined based on pilot data): In the first session, subjects will first play the games outside the scanner until they have learnt how to choose different sequences of stimuli, without receiving any rewarding or punishing outcomes. We expect this to take no longer than one hour. Once they have reached a predetermined performance threshold, subjects will enter the scanner. Once in the scanner, subjects will first passively view sequences of images; neural responses to these images will be used in the analysis phase. Subjects will then play the game they had previously practiced with the addition of rewarding and punishing outcomes. Scanning is expected to last approximately 1 ½ hours, but will take no longer than 2 hours. After scanning, subjects will complete questionnaires which will take up to 30 minutes. These will be either paper copies or delivered electronically through a secure online UCL server. Finally, subjects may return for a second session within two weeks where they will replay the game outside the scanner. This session will take up to one hour, and will be used to evaluate how well subjects remember what they learnt in the previous session.  The experiment will be conducted in testing rooms and the MEG facility at the Wellcome Centre for Human Neuroimaging, with scanning conducted using the MEG scanner at this facility. Participants will be comfortably seated in the shielded MEG room while the task is projected to a screen in front of them. The subjects will see visual stimuli and will be required to give responses by using a button-box. Depending on requirements identified in pilot experiments, physiological measures may be recorded during the MEG session. These may include EOG (to correct for artefacts caused by blinking and eye-movements), EEG (to improve the sensitivity of MEG and for better source localisation), EMG (to record muscle activity in the hand) or eye-tracking (to record eye-movements and pupil size during the MEG-scanning session). We will ensure that participants are as comfortable as possible before starting, and it will be emphasised that they are free to stop the session at any point, without having to provide a reason why. They can communicate with the researchers via a microphone and intercom at all times.  Where mild electric shocks are involved, we will ensure that subjectively identical pain levels are given to each participant. One small electrode will be placed on the back of the hand, through which a brief current can be delivered to cause a brief, painful sensation that increases in intensity as the current amplitude is increased. We will use a strict procedure for this that has been validated in previous behavioural and neuroimaging studies of our group at UCL (e.g., Seymour et al., 2012, J Neurosci; Crockett et al., 2014, Proc Natl Acad Sci USA; Winston et al., 2014, J Neurosci), administering stimuli in small steps of ascending intensity. Participants rate each stimulus on a scale, and explicitly indicate when they are approaching their tolerance level. They are asked on each occasion whether they are happy to move on to try the next increment. Stimuli are not administered above the participant’s tolerance level. A level will be chosen for the experiment that corresponds to 8/10 or less on the rating scale (where 10/10 = intolerance). The electrical stimuli are completely harmless, and are widely used in the study of pain and processing of aversive events. We will follow the procedures used in previous approved projects from our group (UCL Project IDs 3953/001, 4418/001, 9787/001).  We will also run a behavioural pilot experiments (with up to 40 subjects) with variants of the task described here to optimise the task design prior to commencing scanning. These will be identical in format to the real task, and subjects will receive performance-dependent pay and mild electric shocks. Subjects may also be asked to complete questionnaires in these sessions. These sessions will take no more than 1 ½ hours.  The questionnaires used are as follows:  State-Trait Anxiety Inventory (Speilberger, C. D., et al. (1970) Mind Garden)  Beck Depression Inventory (Beck, A. T., et al. (1961) Arch Gen Psychiatry)  State-Trait Inventory for Cognitive and Somatic Anxiety and Intolerance of Uncertainty Scale (Grös, D. F., et al. (2007). Psychological assessment)  Intolerance of Uncertainty Scale (Buhr, K and Dugas, M.J. (2002)  Behaviour research and therapy)  Quick Inventory of Depressive Symptomatology Self-Report (Rush, A.J., Trivedi, M.H., Ibrahim, H.M., Carmody, T.J., Arnow, B., Klein, D.N., Markowitz, J.C., Ninan, P.T., Kornstein, S., Manber, R. and Thase, M.E. (2003), Biological Psychiatry)  Ruminative Response Scale (Treynor, W., Gonzalez, R. and Nolen-Hoeksema, S. (2003). Cognitive therapy and research)  Penn State Worry Questionnare (Meyer, T. J., Miller, M. L., Metzger, R. L., & Borkovec, T. D. (1990). Behaviour research and therapy) |
| *Attach any questionnaires, psychological tests, etc.* *(a standardised questionnaire does not need to be attached, but please provide the name and details of the questionnaire together with a published reference to its prior usage).* |

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| |  | | --- | | **B6** | | **Please outline any ethical issues that might arise from the proposed study and how they are be addressed.** *Please note that all research projects have some ethical considerations so do not leave this section blank.*  We do not foresee any significant issues arising from this proposal. The primary issue is the use of mild electric shocks, as these can cause pain and distress. For these reasons, we take steps to minimise physical or psychological harm. Firstly, subjects are given time to read the information about the study and to discuss the methods used with the experimenter. Secondly, they are gradually introduced to the stimuli during the thresholding procedure. In this procedure, the initial shocks are at a very low intensity and are slowly raised. Importantly, shocks are never administered above subjects’ personal tolerance level. Subjects always have control over this procedure, and it is made clear to subjects that they can elect to stop the procedure at any point should they find it too painful. Lastly, the level of stimulation used in the task itself will never be at their maximum tolerance level, and will be at a level that has been well tolerated by subjects in previous studies using identical stimuli. Note again that electrical stimuli are completely harmless, and have been used for many years in experiments assessing sensation, pain processing, and aversive learning (e.g. in previous projects from our group: UCL Project IDs 3953/001, 4418/001, 9787/001). |

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| **SECTION C DETAILS OF PARTICIPANTS** |

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| |  | | --- | | **C1** | | **Participants to be studied**   |  |  | | --- | --- | | **C1a. Number of volunteers:** | 100 | | Upper age limit: | 65 | | Lower age limit: | 18 |   **C1b. Please justify the age range and sample size:**  40 participants for piloting and 60 for the experiment. We have restricted the range to minimise issues surrounding developmental and age-related changes in neural processing. The sample size will provide adequate power to detect the effects we are interested in.  Exclusion criteria will include the following:  - People with substantial present neurological or psychiatric diagnosis  - People with a cardiac or endocrine disorder  - Standard MEG exclusions according to departmental policy (e.g. pregnancy) |

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| |  | | --- | | **C5** | | **Recruitment**  (i) Describe how potential participants will be identified:  Participants will be identified by either their response to an advertisement in the general community or from the UCL participant pool. Advertisement will be distributed electronically or via posters, leaflets or flyers. Participants may also be identified through the existing Neuroscience in Psychiatry Network (NSPN) database, the ‘2k cohort’ of the U-Change project. Those listed in the 2k database have consented to be informed of future research studies by the NSPN team.  (ii) Describe how potential participants will be approached:  Screening  Potential participants will be approached for screening and recruitment using the most convenient method for subjects, this includes post, telephone, email or a secure web-based system. An information sheet will be provided, describing what to expect during the study. Screening of participants will prevent unnecessary journeys to the assessment centre for those who are not suitable. This includes for example WTCN participants MEG safety criteria (such as checking that subjects do not have any metal implants) and relevant medical history. Our research aims at gaining better insight into affective disorders such as depression or anxiety. Thus, in some cases, the suitability of potential participants will be assessed via responses to a short standardised published questionnaire (see above) assessing mood and feelings.  This questionnaire will take no more than 5 minutes to complete. For questionnaires and safety questions given prior to attendance at an assessment day, participants will have received an information sheet for the study beforehand and have had a chance to ask questions via telephone or email. Information to the participant will be sent via an email. Screening questionnaires will be completed online and hosted on secure UCL servers at the WTCN. Subjects will complete these questionnaires using an anonymous ID so that no personal identifiable data is recorded.  Follow-up  Subjects may be invited to take part in a follow-up session up to two weeks after the first session where they will complete further computer tasks. If this is the case, subjects will be informed at the first session and asked if they wish to participate in the second session.  Participants from the NSPN database will be contacted by the NSPN study team (via telephone, email or post), inviting them to participate. Prospective participants will similarly receive a detailed information sheet, describing what to expect during the study.  (iii) Describe how participants will be recruited:  Time will be given to participants to decide whether they would like to participate. During this time, we will provide answers to any questions participants may have. Participants will be recruited for the study if they meet the appropriate criteria to take part.  *Attach recruitment emails/adverts/webpages. A data protection disclaimer should be included in the text of such literature.* |

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| |  | | --- | | **C7** | | **CONSENT**  **Please describe the process you will use when seeking and obtaining consent.**  Participants will be given the information sheet and consent form to read, but will also have the study explained to them by the researchers. The participant is encouraged to ask questions. At each stage of the study the procedure they are about to take part in will be thoroughly explained. Care is taken to emphasis to participants that their involvement is voluntary and they are free to withdraw from the study at any point without giving a reason.  *A copy of your participant information sheet(s) and consent form(s) must be attached to this application. For your convenience proformas are provided in Appendix I. These should be filled in and modified as necessary.*  In cases where it is not proposed to obtain the participants informed consent, please explain why below.  N/A |

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| |  | | --- | | **C10** | | **Information Sheets And Consent Forms: Appendix I**  **A poorly written Information Sheet(s) and Consent Form(s) that lack clarity and simplicity frequently delay ethics approval of research projects.** The wording and content of the Information Sheet and Consent Form must be appropriate to the age and educational level of the research participants and clearly state in simple non-technical language what the participant is agreeing to. Use the active voice e.g. “we will book” rather than “bookings will be made”. Refer to participants as “you” and yourself as “I” or “we”. An appropriate translation of the Forms should be provided where the first language of the participants is not English. If you have different participant groups you should provide Information Sheets and Consent Forms as appropriate (e.g. one for children and one for parents/guardians) using the templates provided in Appendix I. Where children are of a reading age, a written Information Sheet should be provided. When participants cannot read or the use of forms would be inappropriate, a description of the verbal information to be provided should be given. Where possible please ensure that you trial the forms on an age-appropriate person before you submit your application. |

**RISD BENEFITS to**

**the researcher and the researched**

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| **SECTION D: DATA STORAGE AND SECURITY** |

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| |  | | --- | | **D1** | | **Will the research involve the collection and/or use of personal data?**  **Yes**  **No**  **If yes, is the research collecting or using:**   * **sensitive personal data as defined by the UK Data Protection Act (racial or ethnic origin / political opinions / religious beliefs / trade union membership / physical or mental health / sexual life / commission of offences or alleged offences), and/or** * **data which might be considered sensitive in some countries, cultures or contexts?**   **If yes, state whether explicit consent will be sought for its use and what data management measures are in place to adequately manage and protect the data.**  Explicit consent will be sought for the use of personal data, which is only used to contact participants. This data, and codes to link it with non-identifiable data, will be stored on secure UCL servers or in locked cabinets and never released beyond the researchers working on the project. |
| |  | | --- | | **D2** | | **During the Project (including the write up and dissemination period)**  **State what types of data will be generated from this project** (i.e. transcripts, videos, photos, audio tapes, field notes, etc).  Data generated from this project will include answers to questionnaires, behavioural responses during the tasks (including subjects’ choices and reaction times), and brain activity data measured using MEG.  **How will data be stored, including where and for how long?** This includes all hard copy and electronic data on laptops, share drives, usb/mobile devices.  Personal identifiable data will be stored on UCL servers or in locked cabinets. Electronic PID data will be deleted once the anonymised data has been made public and consent forms will be kept for 5 years. Non-identifiable data will be stored on UCL servers, researchers’ laptops, or on cloud storage services.  **Who will have access to the data, including advisory groups and during transcription?**  Identifiable data will only be accessed by UCL researchers working on the study. |

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| |  | | --- | | **D4** | | **After the Project**  **What data will be stored and how will you keep it secure?**  Personal data (names, contact details, and codes linking this information to non-identifiable data) will be stored for up to 5 years on UCL secure servers or in locked filing cabinets. All other (non-identifiable) data from the study will be kept indefinitely and may be openly shared.  **Where will the data be stored and who will have access?**  Personal identifiable data will be stored on UCL servers or in locked cabinets until the project is completed, with access only available to the UCL researchers working on the study. Non- personal data will be made publicly available online after completion of the study.  **Will the data be securely deleted?**  **If yes,** please state when will this occur:  Personal data will be securely deleted after 5 years. |

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| |  | | --- | | **D5** | | **Will the data be archived for use by other researchers?  Yes  No**  If **Yes**, please describe provide further details including whether researchers outside the EEA will be given access.  Data shared on pubic repositories will be publicly accessible. These data will be anonymised with no personally identifiable information. |

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| **SECTION E: DETAILS OF RISKS AND BENEFITS to the researcher and the researched** |

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| |  | | --- | | **E1** | | **Please state briefly any precautions being taken to protect the health and safety of researchers and others associated with the project (as distinct from the research participants).**  There are potential hazards regarding electrical safety when using computers and the MEG scanner. All equipment used fulfils departmental safety guidelines. All staff undergo WTCN safety course prior to using the testing rooms and safety equipment, which includes explanation of the department's SOPs and showing the locations of the panic alarms (located in all testing rooms and scanning suites). There are always two members of the research team/WTCN staff present for scanning. Researchers are also required to attend an induction which includes the fire evacuation process. Researchers will have attended a neuroimaging safety course and all precautions necessary for operating near high-field magnets will be taken. Lastly researchers will be training according to departmental guidelines in using the electrical stimulation equipment. |

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| |  | | --- | | **E2** | | **Will these participants participate in any activities that may be potentially stressful or harmful in connection with this research?  Yes  No**  If **Yes**, please describe the nature of the risk or stress and how you will minimise and monitor it.  The electric shocks might cause mild pain, however, studies using identical procedures demonstrate that subjects are very rarely distressed by the stimuli at all. Nevertheless, should this be the case, we would stop the experiment for that participant. Moreover, by using the thresholding procedure we ensure that participants are not exposed to stimuli above their personally defined tolerance level, and subjects may stop the task at any time should they find the stimuli too harmful. We will take every step to minimize any potential distress.  The scanner is in an enclosed space and participants could feel claustrophobic. Participants are informed of this in the information sheet, verbally when they first express an interest in taking part, and they also see the scanner before taking part. Participants are shown the panic alarm before scanning starts and are shown how to activate the alarm prior to scanning to make sure it is operational. They are informed that at any point of testing if they wish to come out of the scanner they can do so by pressing the alarm.  If electrodes are used, they will be placed on the skin of the arms and/or face and the skin is rubbed gently prior to putting on the electrodes. Participants may find this slightly uncomfortable and they do not have to proceed if they do not want the electrodes applied. Lastly, the participants may get tired playing the tasks and we will provide breaks during the sessions as required. |

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| |  | | --- | | **E3** | | **Will group or individual interviews/questionnaires raise any topics or issues that might be sensitive, embarrassing or upsetting for participants?**  If **Yes,** please explain how you will deal with this.  Yes. It is necessary to enquire about the medical history of any participants as any previous operations or procedures may be a contraindication to scanning. Also, as our study is a test psychological functioning, any previous psychiatric problems may be part of exclusion criteria. We will also ask women about the possibility of pregnancy.  Participants will read and be informed of the need and reasons for these questions before arrival, and can choose to withdraw if they feel any discomfort. All information given will be treated in strict confidence by the research group, and only directly relevant questions will be asked.  Some of the questionnaires touch on emotionally sensitive topics and may be considered embarrassing. We address this concern in several ways. First, participants will always be notified in advance when potentially sensitive questions will be raised, and informed that their participation is optional and they are free to withdraw from the experiment at any time without penalty. Second, participants' will be informed that their responses will be fully anonymised. Participants' data will be linked with a unique ID number, and the link between participants' personal details and the ID numbers will be stored securely in accordance with the Data Protection Act 1998 and General Data Protection Regulation.  An additional potential concern is the nature of some questions that appear in the questionnaires used, particularly in those that ask questions about suicidality such as the BDI-II. We have carefully selected self-report measures that have been designed for and extensively validated in unsupervised, self-report settings without issues. Historically, one potential concern has been that asking about suicide may induce or increase suicidal thinking and/or the likelihood of acting on these thoughts. This assumption is not supported by empirical evidence (see below) or the clinical experience clinicians working in our group. A recent review of 13 studies (Dazzi et al, 2014), found no evidence to support this and rather that asking about suicide and related behaviours may reduce suicidal ideation especially if it promotes treatment seeking. |
| |  | | --- | | **E4** | | **Please describe any expected benefits to the participant.**  There are no direct benefits to participants. However, by taking part in this study participants will help understand how the brain works and may contribute to the improvement of diagnosis and treatment of mental disorders associated with problems in emotional processing such as depression or anxiety. |

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| |  | | --- | | **E5** | | **Specify whether the following procedures are involved:**  **Any invasive procedure(s)**  **Yes**  **No**  **Physical contact**  **Yes**  **No**  **Any procedure(s) that may cause mental distress**  **Yes**  **No**    Please state briefly any precautions being taken to protect the health and safety of the research participants.  Minimal physical contact is required to place electrodes on the hands and fingers of participants. Moreover, electric shocks cause mild pain, however, other studies using identical stimuli indicate that participants are very rarely distressed by the stimuli. If this is the case we will stop the experiment for that participant immediately. We will take every step to minimize any potential distress. Participants are introduced to the stimuli prior to the interactive part of the experiment by means of the thresholding procedure. The initial stimuli are extremely low, and subjects are allowed to get used to the set up and stimuli in a controlled and comfortable environment. During the thresholding procedure the amplitude of the stimuli is increased only in very small increments, and stimuli are not administered above the subject's tolerance level. Subjects are explicitly required to indicate when they feel they are approaching their tolerance level, and always have control over the procedure, by indicating on each occasion whether they are happy to move on to try the next increment. The level of stimulation used during the experiment will below the tolerance level, and at a level which has been well-tolerated by subjects in previous experiments using identical stimulus patterns (e.g., Seymour et al., 2012, J Neurosci; Crockett et al., 2014, Proc Natl Acad Sci USA; Winston et al., 2014, J Neurosci). Additionally, by ensuring that participants are fully informed of the experimental procedure, and emphasizing their right and ability to withdraw at any time, we aim to minimize these concerns.  All researchers and research assistants must have attended the WTCN Safety course and induction. This covers safety of the participants when scanning, cardiac arrest procedures, fire evacuation procedures and departmental SOPs. There are always two members of the research team/WTCN staff present for scanning, to assist participants if there is an incident. Physical contact with participants would only be to safely guide them in and out of the scanner and to place surface electrodes onto their skin. |

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| |  | | --- | | **E8** | | **Are you using a medical device in the UK that is CE-marked and is being used within its product indication?** **Yes**  **No**  If **Yes**, please complete Appendix IV. | |
| **CHECKLIST** | |

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| **Documents to be Attached to Application Form (if applicable) Tick if attached** |
| **Section B: Details of the Project**   * Questionnaire(s) / Psychological Tests * Relevant correspondence relating to involvement of collaborating  department/s and agreed participation in the research i.e. approval letters   to gatekeepers seeking permission to do research on their premises/  in their company etc. |
| **Section C: Details of Participants**   * + Parental/guardian consent form for research involving participants under 18   + Participant/s information sheet   + Participant/s consent form/s   + Advertisement |
| **Appendix I: Information Sheet(s) and Consent Form(s)** |
| **Appendix II: Research Involving the Use of Drugs**   * Relevant correspondence relating to agreed arrangements for dispensing   with the pharmacy   * Written confirmation from the manufacturer that the drug/substance has   has been manufactured to GMP     * Proposed volunteer contract * Full declaration of financial or direct interest * Copies of certificates: CTA etc…     **Appendix III: Use of Non-Ionising Radiation**  **Appendix IV: Use of Medical Devices** |

Updated 17.10.2017