**UCL RESEARCH ETHICS COMMITTEE**

# Amendment Request Form

Please complete this form to make any amendments to an already approved study. Carefully read the information below to check that your planned changes are covered by this form. Once completed, submit your application to [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk) for consideration by the UCL REC.

**Changes Covered by an Amendment Request:**

Amendments can cover a range of small changes as long as these are in line with and do not significantly deviate from the original approval. For example:

* Adding a new participant group or adding to participant numbers
* Asking for additional data from existing participants
* Adding or removing a group of participants or a research method from the project
* Applying for an extension to your current ethical approval – Studies can run for 5 years, after which a new ethics application must be submitted.

**Changes NOT Covered by an Amendment Request:**

Significant changes to your study are not covered by Amendment Requests and should be submitted as a new Ethics Application. Changes not covered by an amendment are, for example: substantial changes to the study aims or methodology, addition of an overseas location or any changes where the risks and ethical issues are vastly increased.

**Extensions:**

An extension after the end date for your study’s ethical approval is not possible and you will need to submit a new Ethics Application. Further, you will need to confirm that no data collection has taken place since the end date as collecting data without valid ethical approval could amount to research misconduct and may lead to disciplinary action. The total duration of a project, including any extensions, cannot normally exceed six years.

**Your Application Must Include:**

* A clear explanation of what the amendment you wish to make is and the justification for making the change.
* Details of all the ethical issues raised by the proposed amendments. This section must not be left blank.
* An updated version of your latest Ethics Application form, that includes all previous amendments, with your proposed amendments highlighted. This allows the reviewer to clearly see the changes and their effects and ensures the REC has an up-to-date overview of the study.
* All other updated documents, such as Participant Information Sheets, Consent Forms and recruitment adverts, similarly highlighted to reflect all changes.

If any of the above points are missing, your application will not be reviewed and will be sent back to you.

**Review Process:**

Amendment Requests are reviewed by the original ethics reviewer, when possible. The time taken to review is dependent on the level of detail provided, the quality of the application and the availability of reviewers. As such, more complicated amendments are likely to take longer than simple, small changes.

**Amendment Request Form**

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| **1** | **Ethics ID Number:** 24867/001 |
| **2** | **Project Title:** Social Emotions |
| **3** | **Name of PI:** Prof Argyris Stringaris |
| **4** | **Name of Researcher(s) \*for student projects:** Dr Georgina Krebs, Dr Isobel Ridler, Dr Marjan Biria, Dr Madeleine Payne, Miranda Copps and Johannes Keil |
| **5** | **Faculty and Department:** Department of Psychiatry, Department of Psychology and Language Sciences |
| **6** | **Type of Research:**   |  |  |  |  | | --- | --- | --- | --- | | Undergraduate |  | Staff |  | | Postgraduate Research |  | Postgraduate Taught |  | |
| **7** | **Date of Original Ethics Approval:** 24/04/2023 |
| **8** | **Amendment start date:** 23/09/2024  *(List any requests for an accelerated review, due to funding reasons for example, and when the proposed changes are likely to be implemented).* |
| **9** | **Has this study been amended before:**Yes      No     **If yes, how many amendment requests have been submitted prior to this one?**  *(Please briefly describe all previous amendments and when they were approved).*   * Amendment 1 (approved on 27/06/2023): reduce age range from 16 to 14, requested to collect audio and video recording from online participants as well, changed study title, additional research platforms. * Amendment 2 (approved on 20/11/2023): remove some exclusion criteria, increase sample size, some other minor changes regarding the language we had used, removed 48h time window between reading info sheet and participating to give participants as much time as they need. * Amendment 3 (approved on 24/07/2024): increase age group to 65 years, requested additional platforms for testing adolescents, requested additional methods of compensation (bank transfer, student credits), development of hunger-induced mood questionnaire, inclusion of additional anxiety and anger scales * Amendment 4 (approved on 13/11/2024): change from opt-out to opt-in parental consent; requested additional questionnaires for measuring symptoms of autism, self-focused attention and eating behaviours; reintroduction of a screening step via Redcap. |
| **10** | **Type of Amendment:***(Tick all that apply)*    Extension to approval (for 1 year)   Data management/storage, retention and destruction    Research method/protocol    Location of research / research site / data source  Participant group   Sponsorship/Collaborators   Information Sheet(s)/Consent Form(s)   Consent method  Data collection method  Publication and sharing  Recruitment Documents    Principal Investigator\*    Update to research instruments/tools  Other (Please specify in section 11)      \* To Note: *Additions to the research team, other than the Principal Investigator, the Student Supervisor and the Medical Supervisor, do not need to be submitted as an Amendment. An updated list can be emailed to*[*ethics@ucl.ac.uk*](mailto:ethics@ucl.ac.uk)*to keep on record.* |
| **11** | **Details of Amendment(s):**  *(Describe the amendment(s) to be made to the project, in accessible language. Include any changes to be made to the data management aspects of the study. Also, indicate which sections these amendments change in your updated Ethics Application form which must be included as part of your application).*   1. To add the following questionnaires [Section B2]. Some explanation for these measures has been added to Section B1. We would like to add:  * The option for participants to indicate their choice between different items of the questionnaire (typically symptoms) that they have indicated as applying to them. * Option to ask participants whether they consider themselves as suffering depression or anxiety (‘do you suffer from depression?’ and ‘do you suffer from anxiety?’), and (intended) help-seeking (‘If you have been bothered by the previously mentioned symptoms, have you sought, or considered seeking, help for them?’) * A questionnaire that asks about the severity, impact, frequency, and perceived controllability and likelihood to change of specific symptoms. [appended] * A choice-task based on items from these questionnaires, where participants choose between hypothetical ‘treatment packages’, based on a range of attributes like cost and wait-time. [appended] * ‘User experience’ questionnaires for the choice tasks [appended] * A shortened and adapted version of the decisional conflict scale (O’Connor, 1995) [appended] * Questions to record participants’ gender, level of education, ethnicity and past psychotherapy utilisation (type, purpose, duration)  1. Adapt screening to sample participants with higher levels of depression. |
| **12** | **Justification:**  *(Provide a brief explanation of why these changes are required and why they are needed now).*   1. **Addition of questionnaires:** The Social Emotions project is part of a larger Wellcome-funded project investigating the ‘active’ ingredients of therapy for (social) anxiety. So far, our preliminary study results have suggested that manipulation of social emotions can have an impact on outcomes such as mood and anxiety. To ensure effective knowledge utilisation, we now seek to include a few more questionnaire measures to understand participants’ priorities for interventions on (social) emotion in our protocols. We will do this by including a pairwise choice questionnaire that measures: 2. which symptoms are most important for participants with elevated levels of anxiety- or mood-related distress. 3. how much participants want these symptoms to be addressed by interventions.   To achieve this aim, we include a choice task between symptoms or hypothetical treatments that vary, e.g., in focus on certain symptoms, cost or wait-time. Finally, we seek participants’ input on how they perceive this method of measuring their preferences using a series of questions (e.g., about usefulness, legibility, ease of use, length), as well as how conflicted they felt about their choices during the choice task. This involves showing them the results of the questionnaire, presented as the ‘top-5 symptoms you would like to go away’ according to our questionnaire. To understand whether different groups have different priorities, we would also like to include questions on education, ethnicity, sex/gender and age, and past therapy utilisation. To keep the study sessions to the appropriate time length (1.5 hours), we will only use a selection of questionnaires from our list in any single study.   1. **Addition of screening step:** We already have been granted permission to pre-screen participants with higher levels on social anxiety. Since social anxiety and depression frequently happen together, we would like to slightly extend our scope to young people who also have depression. We also plan to ask about participants’ own illness conceptualisation (“Do you suffer from depression/anxiety?) and reported help-seeking (e.g., “Have you considered seeking help for depression/anxiety”) as alternative indicators of distress. Since we only plan to pre-screen participants aged 16 years or above, this minor extension does not change the ethical considerations involved**.** |
| **13** | **Ethical Considerations:**  *(Explain all new ethical issues raised by the amendment and how these will be addressed. This section must NOT be left blank).*  **Sampling participants with probable distress from depression.**  Your committee has already granted us permission to recruit participants with elevated levels of social anxiety, expanding to depression is a minor addition. In addition, you have already approved our study to ask questions about depression. We will follow the same—previously approved—safety protocol (a) by providing the research team’s contact details and guidance on how to access mental health support (e.g., via charities, NHS or university services) in information sheets and (b) again, including that information at the end of the experiment. Similarly, any in-person testing sessions, we will follow a validated risk management procedure (STORM) as previously approved.  **Potential distress from answering mental health questionnaires during screening:**  There is no change to this, as we are using the same questionnaires as before, with the addition of the preference questionnaires.  **Misconstruing presented information as medical advice.**  We will ensure that any statements we make about the hypothetical therapies we use in the questionnaires, or about the participants’ preference questionnaire results are not misconstrued as clinical advice. To this end, we have amended the PIS to specifically mention that they may see some hypothetical scenarios involving therapy and results of their preference questionnaire, but that this is part of a research study, may not be accurate and does not constitute any form of medical advice. This information will be reiterated at the end of the experiment. |
| **14** | **Attachments:**  *(List which attachments have been included. To Note: ALL Amendment Requests must be accompanied by an updated and highlighted version of your latest Ethics Application and supporting documentation that include all previously approved amendments, as appropriate, except for solely extension requests).*  **Updated study documents:**   * Ethics application form   **New study documents:**   * + PIS and consent form for participants participating in an arm of the study that involves screening for likely distress from low mood/anxiety as well as the choice task   + Overview of forced-choice items and questions asked during the study-evaluation part. |
|  | **Declaration:**   * I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it. * I confirm that this amendment does not fundamentally change the study. * I confirm that all relevant data protection arrangements are still in place for the duration of this amendment. * I consider that it would be reasonable for the proposed amendments to be implemented.   **Principal Investigator Name\*:** Professor Argyris Stringaris  **Principal Investigator Signature:**  **Date:** 20/09/2024  *\* To Note: The named Principal Investigator must sign this form. Applications submitted without this section having been completed by the PI will be returned to the applicant.* |

*Last updated February 2021*