

Amending an Approved Application

Should you wish to make an amendment to an approved study, you will need to submit an 'amendment request' for the consideration of the Chair of the UCL Research Ethics Committee. Applications can only be amended **after** ethical approval has been granted.

You will need to apply for an amendment approval if you wish to:

1. Add a new participant group;
2. Add a new research method;
3. Ask for additional data from your existing participants;
4. Remove a group of participants or a research method from the project, and have not yet commenced that part of the project;
5. Apply for an extension to your current ethical approval.

If you need to apply for an amendment approval, please complete the Amendment Approval Request Form on the next page.

When completing the form, please ensure you do the following:

- Clearly explain what the amendment you wish to make is, and the justification for making the change.
- Insert details of any ethical issues raised by the proposed amendments.
- Include all relevant information regarding the change so that the Chair can make an informed decision, and submit a copy of the sections of your application that have changed with all changes highlighted/underlined for clarity.
- You do not need to submit your original application in full again. However, if the changes you wish to make alters several sections of your application form, you are advised to submit this.

Please email a signed electronic copy to the REC Administrator: ethics@ucl.ac.uk

Amendment requests are generally considered within 5-7 days of submission.

Amendment Approval Request Form

1	Project ID Number: 8227/003	Name and Address of Principal Investigator: Prof Russell Viner UCL Institute of Child Health 30 Guilford St, Holborn, London WC1N 1EH r.viner@ucl.ac.uk
2	Project Title: You-COPE: Youth COVID Response Personal Experience: Tracking health and wellbeing amongst 16-24 year olds in the UK during and after the COVID-19 pandemic	
3	Type of Amendment/s (tick as appropriate) Research procedure/protocol (including research instruments) <input checked="" type="checkbox"/> Participant group <input type="checkbox"/> Sponsorship/collaborators <input type="checkbox"/> Extension to approval needed (extensions are given for one year) <input type="checkbox"/> Information Sheet/s <input checked="" type="checkbox"/> Consent form/s <input checked="" type="checkbox"/> Other recruitment documents <input checked="" type="checkbox"/> Principal researcher/medical supervisor* <input type="checkbox"/> Other <input type="checkbox"/> <i>*Additions to the research team other than the principal researcher, student supervisor and medical supervisor do not need to be submitted as amendments but a complete list should be available upon request *</i>	
4	<p>We propose an ethics amendment to the above study. The amendment specifically is as an add-on to the study, to collect more frequent data on well-being and also physical well-being measures by use of a digital app on phones of participants. We propose to only contact participants who are currently enrolled on the study who have indicated that they are content with the research team to contact them about related research. These participants will be contacted by the e-mail that they have provided for the study, and sent an information sheet on the add-on study. It will be clear that they do not have to take part if they do not wish to, and once they have downloaded the app they will be asked for consent to take part in this additional part of the study.</p> <p>Rationale:</p> <ul style="list-style-type: none"> - The app would allow more frequent (daily) brief questionnaires (using validated questionnaires) on mental health and well-being as young people emerge from lock-down, and future lock-downs. This will allow a more detailed, longitudinal understanding of how young people are being affected. - With young people's permission, the app will collect information on health behaviours in 3 specific domains– physical activity (measured step count on phone), sleep time (derived on phone) and screen time (not type of use, only daily total). - The app will allow more frequent study of mental health and physical health during potential localised lockdowns because of COVID-19. 	

- These new, more frequent mental health measures and additional health behaviour data can be linked to baseline data in the online survey.
- Young people will be asked for permission to collect health behaviour data from their phones pertaining to the last 6 months, to identify changes from before and throughout lock-down
- The above study (You-COPE) is currently active, recruiting and collecting survey data according to the approved protocol. At the end of the initial survey, participants are asked: : *“Please indicate below whether you might be willing for a member of our wider research team to get in touch with you via email about other related studies. This only indicates consent to be contacted and you will be under no obligation to take part.”* Young people who have been recruited to the current study, and have agreed to this above statement will be contact by e-mail to: 1) Ask if they would like to be involved with this additional way of studying the impact of COVID-19 on their lives and wellbeing using a digital app on their phone with an attached information leaflet; 2) explain that this will be for brief daily questionnaires and also to collect data that their phone on steps count, sleep time and screen time usage (but explicitly not what they had been watching). They will then be directed to links to download the app (through usual links for Android or Apple).
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Details of Amendments (provide full details of each amendment requested, state where the changes have been made and attach all amended and new documentation)

The proposed amendment is to deliver an app as an add-on to the current online study. The rationale for this is presented above. Specific details of the amendment are given below:

Consent for involvement:

- If young people decide to download the app, young people will be asked for consent to be involved with this amendment. After completed, consent forms will viewable to young people option within the options menu of the app, as well as a contact e-mail within the options of the menu. A PDF copy of the consent will be transferred encrypted associated with the e-mail to the data safe haven for the research team.
- It will be made clear that young people can withdraw from this aspect of the study at any time. There will be an option in the app menu to let the researchers know that they no longer want to be part. They will then be instructed to delete the app. Once young people have indicated on the app that they do not want to take part any more, the app will no longer collect data or prompt to collect data.

Data collected by the app:

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A. Daily questionnaire data collection:

i) Questions relating to COVID infection and lockdown situation

1. Is the area where you are living under lockdown restrictions today? YES/NO

ii) (Office of national statistics (ONS) brief well-being scale)

2. Overall, how satisfied are you with your life **today**?

(numeric scale 0 -10, 0 labelled “not at all” and 10 labelled “completely”)

3. Overall, to what extent do you feel that the things you have done in your life **today** are worthwhile?

(Numeric scale as above)

4. Overall, how happy did you feel yesterday? (Numeric scale as above)

5. Overall, how anxious did you feel yesterday? (Numeric scales as above)

iii) Questions from PHQ-2 and GAD-2 (validated mental health questionnaire for age group studied)

Please rate the following statements about you today:

(4 options for each of the questions 6-9 below : never, sometimes, often, always)

6. Little interest or pleasure in doing things

7. Feeling down, depressed or hopeless

8. Feeling nervous, anxious or on edge

9. Not being able to stop or control worrying

B. Additional Fortnightly questionnaire data collection (added in addition to the above but only fortnightly)

1. Have you had Coronavirus (COVID-19)?

OPTIONS:

- Yes and had a positive test and now better
- Yes and had a positive and still unwell
- Not had a test but think I had it and now better

- Not had a test but think I have it and still unwell
- Not that I know of / No

(Warwick-Edinburgh Wellbeing Scale; WEMWEBS)

We are going to ask some questions about your feelings and thoughts over the last two weeks. Please select the box that best describes your experience of each over the last 2 weeks.

5 options for each: none of these, rarely, some of the time, often, all of the time)

2. I've been feeling optimistic about the future
3. I've been feeling useful
4. I've been feeling relaxed
5. I've been dealing with problems well
6. I've been thinking clearly
7. I've been feeling close to other people
8. I've been able to make up my own mind about things

C. Daily health behaviour data collected (at end of each day for full 24 hours)

- i) Step counts
- ii) Sleep time (where able to be derived on phone as a standard metric)
- iii) Total screen time – not what phone has been used for

At first day data collection, data for previous 6 months for i-iii health behaviours will be collected. This data will only be able to be collected if the young person has had their phone during this time period, or have not reset the measurements. Retrospective data will allow identification of change through the lockdown and also prior to COVID data for comparison with prospective data.

Final screen (after completing the questions) – same as the online survey.

“Thank you for completing today’s questions. We would be grateful if you could complete them again tomorrow. However you can choose not to answer questions on any day or stop using the app for any time. If you want to stop using the app altogether and no longer take part in this part of the study then please let us know in the “I no

longer want to take part” option in the app menu. If you have any concerns or have any further questions regarding this research, please email youcope@ucl.ac.uk. For more information on Coronavirus, please visit <https://www.gov.uk/coronavirus>

If you are concerned about your mental health it may be useful to talk to a family member or a friend. There is also a range of support available, and we would encourage you to contact one of the following:

- *Samaritans*: a free, 24-hour confidential listening and support service for people experiencing feelings of distress (call 116 123).
- *Papyrus Hopeline*: Provides information and support for anyone under 35 who is struggling with suicidal feelings, or anyone concerned about a young person who might be struggling, open weekdays 10am-10pm and weekends 2pm-10pm (call 0800 068 4141 or text 07786 209 697).
- *NHS*: If you feel like you need support with your mental health you can discuss this with your GP. If you feel at risk of harming yourself, please discuss this with your GP, call NHS 111 or go to a hospital A&E department.
- *Young Minds*: Please visit www.youngminds.org.uk for a list of other resources and services.

Your answers have been collected and you can now close the app now.”

Prompts and data entry:

- If young people have allowed for notifications from the app on the phone, they will receive reminders to complete the questionnaires, 3 times spaced out throughout the day .
- Young people can choose not to enter data on any day if they choose not to.

Ethical Considerations (insert details of any ethical issues raised by the proposed amendment/s)

- As outlined above, we will only contact participants who have agreed to further contact. Consent will be asked for this add-on once the app is downloaded.
- The psychology and wellbeing questions are validated questionnaires for the age group studied

App design process

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The app is ready to be used. It has been designed by Red Ninja (<http://www.redninja.co.uk>), a tech company which has extensive experience of providing electronic apps in healthcare. It has been designed using the input of two young people who have provided the following feedback, here are their feedbacks:

Young person 1:

After using for about a week, I can report I'm very comfortable with the You-COPE app. The daily survey does not take long to complete so doesn't feel like an imposition. I also felt comfortable answering the questions it asked. I am happy for the app to collect data about my steps, sleep and screen time usage- it doesn't feel like an invasion of privacy to me.

Young person 2:

Great app, thought the questions were very concise and direct. Only problem I have is that the data won't be accurate as it's not my Android it's my mums so the screen time, step count and hours slept would most likely be much higher

We have taken on board to point that young people might use someone else's phone. We have made it clear that we would like them to use their own phone in the information sheet. Data show that 96% of 16-24 year olds have their own smart phone. In a situation where the young person did not have their own phone they would be able to opt out of sharing the health data, so we wouldn't see this being an issue for most young people.

Data transfer process and data safety

The flow of data is secure and has been designed with Trevor Peacock, UCL's Head of Information Governance and Research, and also Tim Machin, head of IT for the Faculty of Population Health Sciences – they are both in agreement that the following path and protocol is appropriate in meeting governance requirements, and that reasonable steps have been taken to protect the data.

- Young people will be asked to download the app, and will be invited to do so by e-mail using the e-mail address they provided in the ongoing You-COPE online mental health survey study. If they wish to be involved with this add-on, they can then download the app (there is an app which works on Apple and Android from relevant online stores). The young people will be asked to consent for their involvement with the app in a new consent form, and a new information sheet will be provided in the e-mail about this add-on to the online study. The information sheet will also be available in the option menu of the app. Young people will register to use the app using their e-mail address, these will be the only potentially identifiable data on young people.
- On the first data extraction, in addition to the questionnaires below the following data will be collected: step count, sleep time, screen usage for the preceding 6 months (where possible – this will not be possible if the YP have reset their phones) and a months' worth of data from the preceding year.
- Data is transferred at the end of each day from the app on: 1) answers to questionnaires (as above) 2) step count, sleep time, screen usage data and 3) e-mail address as the link identifier (which will link each subsequent data download and also link with data in the You-COPE study for further analysis)

- The app will send data securely encrypted to a platform hosted by AIMES (<https://www.aimes.uk>) – a secure data platform who have worked with UCL previously. This is secure, and will be hosted for free. [UCL has a contract for this with AIMES.](#)
- Every 2 weeks, data for each young person will be sent to the data safe haven in encrypted format where it will be stored in the data safe haven in a database linking numerical data values to the e-mail address. AIMES will destroy the data on their platform each fortnight.
- Data on the data safe haven can be linked to data from the online study for further analysis only by members of the research team.

Data transferred will only be a small number of MB per day and therefore will be a minimal burden on data usage on young people's phones.

Safety

- At the end of each questionnaire on a daily basis, the same safety information for the online study will be presented, with contacts for where to seek help. This information will also be present as a drop-down on the app (see above)

Other Information (provide any other information which you believe should be taken into account during ethical review of the proposed changes)

We have sent this amendment information and sheets for to data protection for update/amendment We have attached information sheets, consent and an amendment protocol doc with this form.

7 Data analysis

Data analysis will be aligned with the online study at baseline. The principal analysis from the app study will be to look for associations between well-being and activity, and between COVID status, lockdown status and wellbeing and activity outcomes using regression.

Declaration (to be signed by the Principal Researcher)

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendments to be implemented.
- For student projects, I confirm that my supervisor has approved my proposed modifications.

Signature: Professor R Viner (r.viner@ucl.ac.uk).



Date: 8/7/2020.