LSHTM Ethics Application & CARE Form

Project Information

Staff members/students based at:

- (•) LSHTM
- ( ) MRC Gambia@LSHTM
- ( ) MRC Uganda@LSHTM

1. Full project title

Measuring Behavioural Change during COVID-19 Epidemic

2. Is this Project in fulfillment of a degree?

( ) Yes (•) No

2f(staff). Is this an original submission, or are you responding to a request for clarification from the LSHTM ethics committee?

- (•) Original submission
- ( ) Responding to request for clarification

Applicant Details

3a. Details for LSHTM lead investigator

Title	First Name	Surname
5.1.2e	5.1.2e	5.1.2e

Address	Keppel Street
City	London
Postcode	WC1E 7HT
Telephone	5.1.2e
Email	5.1.2e @lshtm.ac.uk

3b. Job title of LSHTM Lead Investigator

5.1.2e

3c. Faculty or Unit of LSHTM Lead Investigator

Epidemiology and Population Health (EPH)

3d. Department of LSHTM Lead Investigator

Department of Infectious Disease I

3e. Are you the Chief Investigator for the research project?

- ○ Yes
- ◉ No

3e (i). Name of Chief Investigator (CI)

5.1.2e

3e (ii). Institution of Chief Investigator (CI)

University of Antwerp

3f. Please list all all co-investigators, including their institution and contact email

5.1.2e, University of Antwerp; 5.1.2e, LSHTM; 5.1.2e (RIVM); 5.1.2e (Bern); 5.1.2e (ISI, Turin)

Project Type

Note: Completing the filter will enable and disable sections of the form so you may not see all questions.

4. Does the research involve primary data collection, analysis of data/samples that have already been collected, or a mix of both?

- ◉ Primary
- ○ Previously collected data/samples
- ○ Mixed

4a. Is this research project classed as interventional or observational?

- ○ Interventional
- ◉ Observational

4a(ii). Select type of project:

Project involving quantitative methods only (e.g. Questionnaires)

4c. Does the project involve extraction of data from patient records (e.g. medical, social care, service user records)? (This refers to primary data collection from records and does not include data that was previsously collected and is now being used in a secondary analysis).

- ○ Yes
- ◉ No

6. Is this project being undertaken by Chariot Innovations or by the Rapid Support Team?

- ○ Yes
- ◉ No

Samples

6a. Does this research project involve the collection, or use of previously collected, human tissue samples e.g urine, stool, blood etc? (Please select yes even if the samples are not considered relevant material under the Human Tissue Act)

- ○ Yes
- ◉ No

6b. Will this project involve living animals (either laboratory, livestock or wild animals) AND/OR biological material that has been obtained from animals in the experiments planned?

- ○ Yes
- ◉ No

Fast-Track

7a. will this project be conducted in conjunction with NHS staff, premises or any other connection to the NHS?

- ○ Yes
- ◉ No

7b. Is this application for fast-track? Note: MSc applications are not currently available for fast-track

- (•) Yes
- ( ) No

7c. Select reason for fast-track

Using anonymised and unlinkable secondary datasets only

Vulnerable Groups

8(i). Does this research project involve vulnerable groups? Vulnerable groups include: children, individuals with mental disability or learning difficulties, pregnant women, prisoners etc (see information icon for full description).

- ( ) Yes
- (•) No

Security Sensitive Research Material

9. Does this research involve access to and/or storage of security sensitive research material? Please note that while some data is considered sensitive, such as HIV status, it is not necessarily considered security sensitive. If you are using data that could be considered sensitive, but not security sensitive please answer no to whether your research involves access to and/or storage of security sensitive research material. Please see information icon for what is considered security sensitive material.

- ( ) Yes
- (•) No

Geography

10. List the countries where the research project is to be conducted (For example: if you are conducting a secondary data analysis for your project and you will be based in the UK, select UK regardless of where the original data has come from):

Belgium

10. List the countries where the research project is to be conducted (For example: if you are conducting a secondary data analysis for your project and you will be based in the UK, select UK regardless of where the original data has come from):

Netherlands

10. List the countries where the research project is to be conducted (For example: if you are conducting a secondary data analysis for your project and you will be based in the UK, select UK regardless of where the original data has come from):

United Kingdom

Please be aware that all primary health research conducted in the UK requires a sponsor. Please contact the RGIO at 5.1.2e@lshtm.ac.uk for more information on sponsorship.

Outline

Note: Please do not copy and paste directly from the protocol. Applications where large portions of text have been copied and pasted directly from the protocol, and therefore do not properly answer the question, will be invalidated

12. Give an outline of the proposed project, including background to the proposal. Include information from any systematic reviews that have been conducted. Sufficient detail must be given to allow the Committee to make an informed decision without reference to other documents.

Adequate response to Covid-19 requires an understanding of the epidemiological and behavioural drivers of disease transmission. Social mixing, a key determinant of Covid-19 spread, is likely to change over the course of the epidemic in relation to health risk perception. Due to the dynamic nature of the epidemic and with the spread of the disease in the UK and Europe, analyses of the main factors affecting transmission need constant updating to provide relevant data-driven evidence to inform public health policies.

The predictive capabilities of mathematical models have been transformed through quantifying social contact rates. However, these data (such as the POLYMOD survey) were collected in "peace-time" and individuals' behaviour may change during a severe epidemic. Therefore, timely data on social contacts and uptake of protective behaviours will be needed for shaping public health messaging and monitoring its effectiveness during the COVID-19 response and beyond.

We will conduct a social contact survey to assess changes in social mixing in relation with health risk perception. We aim to survey 1500 adults in three countries (500 per country) every two weeks using an online survey, for a total of ten weeks (five surveys). The study will be conducted among individuals who are already subscribed to internet panels from a market research company, in the United Kingdom, Belgium and the Netherlands. The company will ensure a sample that is representative of the national population on age of adults, sex, geographical location, and socio-economic status.

We will monitor contact patterns over the course of the epidemic, and assess psychological factors associated with contact. We will ask participants about knowledge, uptake and perceived efficacy of certain interventions (such as home-working). We will ask about cases in their social networks and the country, and measure how their behaviours change if/when they become unwell. Panel members will answer questions regarding symptoms and impact of interventions (such as school or work closures) in the seven days preceding each survey, while answering questions about their social contacts for the day preceding the survey.

Behaviour tracking will be integrated in real-time models to improve the efficacy of public health interventions (e.g. messaging) and epidemic forecasts. These data will be used to refine transmission models, improve forecasting, and assess the effectiveness of social distancing measures. The development, piloting and analysis of the work will be led by 5.1.2e (University of Antwerp) and 5.1.2e (London School of Hygiene and Tropical Medicine). Real-time analysis and presentation of the data will be conducted by the LSHTM team, with additional input from partner organisations (RIVM, Bern, ISI Turin).

12a. Upload the study protocol (compulsory for staff and doctoral students), including data collection forms, questionnaires and topic guides. Please upload each document separately, ensuring that the date and version number of each document is correct.

Type	Document Name	File Name	Version Date	Version	Size
Protocol / Proposal	H2020 Project Proposal	H2020 Project Proposal.pdf	12/03/2020	1	58.7 KB
Protocol / Proposal	Covid-19 contact and KAP survey	Covid-19 contact and KAP survey.pdf	12/03/2020	1	135.7 KB

13. State the intended value of the project, detailing why the topic is of interest or relevance. If this project or a similar one has been done before what is the value of repeating it? Give details of overviews and/or information on the Cochrane database. This area is of increasing importance – please ensure you give a full response.

This study will provide a timely insight into how social distancing measures affect social contacts patterns among different populations. This will be highly relevant and of immediate interest as governments around the world try to decide on appropriate responses to Covid-19. Many interventions, of which some very disruptive, are being applied and without an appropriate assessment of the impact we will be unable to determine the individual level effects and overall effects of different strategies on reducing contacts between people. In addition, this data will allow us to determine on the required duration of interventions put in place.

Multiple social contact surveys have been conducted, but never during an ongoing epidemic. To our knowledge, the actual effect of social distancing behaviours on social mixing has never been quantified. Linking (at an individual-basis) changes in perceived and actual risk and changes in perceived efficacy of interventions with the uptake of different precautionary behaviours and individuals actual contact patterns will give unparalleled quantitative insight into how and why behaviours change during an epidemic.

The data will analysed, presented, and utilised in real-time to inform public health policy decisions. These data will be essential for improving transmission models and forecasting.

15. Overall aim of project

This study aims to identify the impact of social distancing interventions implemented by the government and the perceived and actual threat of the Covid-19 epidemic on social mixing behaviours.

16. Specific objectives of project

1. To collect accurate estimates of the following data during the Covid-19 outbreak
    a. Frequency of age-specific social contacts and their characteristics, at different points in the epidemic
    b. Household and individual level exposures to social distancing interventions
    c. Uptake of individual preventive measures
2. Changes in attitudes and risk perceptions regarding the Covid-19 epidemic
3. To create social contact matrices that can be used to parametrize epidemiological transmission models
4. To assess the impact of different social distancing interventions on social mixing within the population
5. To use mathematical models to inform public health policy decisions related to Covid-19 outbreak.

Methods

Note: Please do not copy and paste directly from the protocol. Applications where large portions of text have been copied and pasted directly from the protocol, and therefore do not properly answer the question, will be invalidated

18. Specify the procedures/methodology to be conducted during the project. Please include outcome measures and plans for data management and analysis. For literature reviews, include details on search strategy, search terms, inclusion and exclusion criteria.

We aim to survey 500 adults per country every two weeks using an online survey, for a total of ten weeks (five surveys). The study will be conducted among adults who are already subscribed to internet panels from a market research company in the United Kingdom, Belgium and the Netherlands. They will ensure a sample that is representative of the national population on age of adults, sex, geographical location, and socio-economic status. Participants will be paid an incentive for every survey they complete.

Panel members will answer questions regarding symptoms and impact of interventions (such as school or work closures) in the seven days preceding each survey, while answering questions about their social contacts for the day preceding the survey. Surveys will be conducted using an online webform, supplied by the market research company. Data will be stored on their secure encrypted servers and then provided to LSHTM. The data will be anonymised and summary data will be made publicly available.

We will use multilevel count models such as negative binomial regression techniques to assess the age-specific number of daily contacts, and control for confounding factors such as sex and household size. We will perform a stratified analysis by contact type (all contacts, only physical contacts, only nonphysical contacts) and setting (e.g. household, workplace, school, social settings).

In order to develop social contact matrices that can be used to parameterize epidemiological transmission models. We will estimate age-specific transmission parameters by correcting the age-specific daily frequency of social contacts between different age groups for the reciprocity of contacts, adjusting for the population age distribution. These estimates will be used in ongoing and future response work conducted by LSHTM and partners to help inform public policy.

20. Please specify the total number of participants to be recruited into the research project.

1,500 people in total with 500 people per country. We are awaiting the results of further grant proposals which may allow for an increased sample size.

20a. Please provide the scientific justification for the sample size. Please include justification for the age, gender, source and method of recruiting participants for the research project.

We estimate that with two records per individual we can detect a difference of 2.5 contacts between pairs of observations with 90% power, 5% Type 1 error, and 20% loss to follow up. Therefore, we should be able to detect differences within each country. Combining the country results (if appropriate) and recording repeated measurement of individuals should provide adequate power for further assessment of other endpoints.

23. Proposed start date of the project

16/03/2020

24. Proposed end date of the project

31/12/2020

Risks and Discomforts

29. Give details of all clinical and non-clinical procedure(s) that will be received by participants as part of the research protocol. Non-clinical procedure(s) can include seeking consent, interviews, non-clinical observations and use of questionnaires. Clinical procedure(s) can include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.

Informed consent will be obtained prior to any respondent completing the first survey. All panel members will already have given their consent to be included in the internet panel and to be approached for online research. We will inform participants about the rationale and topic of the survey, and the incentive they will receive upon completion. They will need to provide their explicit consent before the survey will start.

The right of the participant to refuse to participate without giving reasons will be respected at all times. All participants are free to withdraw at any time from the survey without giving reasons.

Questionnaires will be conducted online. No other procedures will be received.

29a. Please provide details of who will conduct the procedure, the average time taken per procedure (minutes, hours or days) and where it will take place.

The market research company will send a link to the questionnaire to a subset of individuals in their internet panel that is representative of the national population in terms of the age and sex distribution of adults, their geographical location, and socio-economic status.

Individuals will be informed through the invitation e-mail, and will need to provide explicit consent on a webform before they will proceed to the questionnaire.

On average, the survey will take between 15-25 mins depending on the total number of individual contacts and interventions individuals are affected by.

29b. State the potential discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological) as a result of all procedure(s).

None

29c. What precautions are being taken to control and modify these? Include information on hazardous substances that will be used or produced, and the steps being taken to reduce risks.

N/A

Experience

30. State the personal experience of the applicant and of senior collaborators in the research project in the field concerned, and their contribution to this project. Indicate any previous work done related to the project topic including student and/or professional work, or publications

[redacted]

[redacted], University of Antwerp; [redacted] (CHERMID)

[redacted] (ISI, Turin); Computational and Digital Epidemiology.

[redacted], LSHTM; [redacted] has been involved in numerous social contact studies.

30a. Upload the CVs for all main investigators working on the project. For MSc students, please upload your CV only.

Type	Document Name	File Name	Version Date	Version	Size
Investigator CV	[redacted]CV_3Pages1	[redacted]CV_3Pages1.docx	11/03/2020	1	20.6 KB
Investigator CV	[redacted] short bio 2019 for ibof	[redacted] short bio 2019 for ibof.docx	10/03/2020	1	15.8 KB
Investigator CV	[redacted]_cv	[redacted]cv.pdf	11/03/2020	1	115.6 KB
Investigator CV	[redacted]	[redacted]doc	11/03/2020	1	387.5 KB
Investigator CV	[redacted]	[redacted]	12/03/2020	1	335.9 KB

30e. Have the main investigators undertaken any Research Ethics/Human Subjects Protection training (either online or face to face)?

- (●) Yes
- ( ) No

30e(i). Please upload a copy of the certificate(s) (if available)

Informed Consent - Primary

If any photographs are to be taken, whether for teaching or research purposes, ensure that the participant's consent to their use has been given in line with the provisions in British Medical Journal, 1998, 316, 1009-1011.

32. Who will be responsible for taking consent and what training/experience do they have?

We will be using a market research company who have extensive experience in conducting online surveys. We will be involved in the design of the survey and will ensure that LSHTM policies on informed consent will be adhered to.

32a. Will you be obtaining written consent?

- (•) Yes
- ( ) No

32a(i). State the manner in which consent will be obtained (how and from whom). Where appropriate, state how the information and consent form will be translated into local languages.

They will give explicit consent by ticking a box in the online survey.

32b. Do you expect any of your potential participants to be illiterate?

- ( ) Yes
- (•) No

32f. Please upload the information sheet(s) and consent form(s). Please upload each document separately, ensuring that the date and version number of each document is correct.

Type	Document Name	File Name	Version Date	Version	Size
Information Sheet	Information sheet _ email	Information sheet _ email.pdf	12/03/2020	1	45.5 KB

32g. Upload recruitment procedures (eg advertisements, emails, posters). Please upload each document separately, ensuring that the date and version number of each document is correct.

Payments

37. Will payments be made to participants? These should usually not be for more than travelling expenses and/or loss of earnings and must not represent an inducement to take part.

- (•) Yes
- ( ) No

37a. Give details and justification for payments made to participants.

As is commonly done in market research, participants will be provided a small payment for completing each survey. We believe this will be necessary to obtain this information and is fair to compensate for the time spent completing the survey and contributing to research.

Confidentiality & Data

39. Specify how confidentiality will be maintained with respect to the data collected. When small numbers are involved, indicate how possible identification of individuals will be avoided. Where data will be anonymised, specify how this will be done.

We will not be collecting names of participants but will be collecting first name or initials of household members. These will be removed after data collection. Spatial information such as postcode will only be collected for the first letter and numbers and therefore will over a large scale.

40. State how your data will be stored and what will be done with it at the end of the project.

The data will be stored on the market research companies secure servers. Upon completion of the survey data will be stored on encrypted and secure LSHTM servers. During the project summaries of the data will be made publicly available. Any remaining individual level identifiable information will be anonymised removed before making data publicly available.

41. Are there plans to share the data, or add the data to a repository in the future?

- (•) Yes
- ( ) No

If yes, please be aware of the following:

Explicit consent should be obtained from participants regarding the possible use of their anonymised data in the public domain via a data repository.

42. How will the data be shared and what safeguards are in place to ensure the use of the data is for valid research?

The anonymised aggregated data will be stored online. We will provide a detailed data description about the data, methods, study sample, and code used for analyses.

Funding

46. Do you have external funding for this project?

- (•) Yes
- ( ) No

46a. Please provide the Letter of Intent reference number

100222

46a(i). Please provide the name of the funder

European Commission

46a(ii). Please include details of the funding available for this project.

100,000 EUR

Date grant accepted or funding agreed:

31/03/2020

Date end of funding:

31/03/2020

46c. Are you in receipt of any funding from the United States? Or will you be collaborating with (or with individuals from) a US Institution/organisation?

- ○ Yes
- ◉ No

47. Has the project been sent out for peer/independent scientific review (please select yes if the project is being sent to the SCC)?

- ○ Yes
- ◉ No

47a. If no, why has the project not been sent peer/independent scientific review?

The proposal for this project has been peer-reviewed by the funding body, as part of the grant application process. It was rated 4.5/5 in their assessment.

49. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- ○ Yes
- ◉ No

50. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- ○ Yes
- ◉ No

Local Approval

66. For all countries listed in Q9, please provide details of the arrangements being made to obtain local ethical and/or regulatory approval. Please electronically append copies of local approval letter(s) where this has already been obtained. Where you believe local approval is not required, please explain why not and describe any less formal permissions, invitations or support you are being given for this work. Upload local permission letters as applicable. (Where the research is to take place overseas, ethical approval must be obtained in the country(s) concerned. Approval from the LSHTM Committee is dependent on local approval having been received. You MUST NOT start your project until all relevant approvals are in place.)

Ethics approval is being sought from LSHTM first for the research in the UK. Ethics approval will be sought separately in Belgium and the Netherlands unless LSHTM is able to provide ethics approval in these countries.

66a. Where the research is taking place in the UK, please list other UK Committees (including other LSHTM ethics committees) from which approval is being, or has been, sought.

We seek approval from the LSHTM Ethics committee

DPIA Screening

A Data Protection Impact Assessment (DPIA) is a way for you to systematically and comprehensively analyse your processing and help you identify and minimise data protection risks. DPIAs are a legal requirement for processing that is likely to be high risk. The below questions aim to help determine whether it is likely a DPIA would be required for your project.

For advice or guidance, or to request help with a DPIA, please contact 5.1.2e at 5.1.2e@lshtm.ac.uk

131. Does your research involve the collection of primary data?

- (•) Yes
- ( ) No

132. Does your research involve the processing of identifiable data in the UK at any stage? (for the purposes of this question pseudo-anonymised data is still considered identifiable. Please see the information icon for additional information on the anonymisation of data.)

- ( ) Yes
- (•) No

Signature Instructions

The form should be completed and finalised prior to signing or requesting signatures. Students should ensure that the Supervisor signs prior to the Course Director/Project Module Organiser. For external supervisors, please ensure that they have registered for an account prior to requesting the signature.

Signature - Applicant

LSHTM Lead Investigator Declaration

- ☑ The information in this form is accurate to the best of my knowledge and I take full responsibility for it
- ☑ I have read and understood, and agree to abide by the LSHTM Good Research Practice policy as well as all applicable Standard Operating Procedures, including on informed consent
- ☑ I undertake to abide by all regulations, guidelines and standards of good practice, including but not limited to the Data Protection Act 2018, GDPR, and the Declaration of Helsinki
- ☑ I undertake to abide by all local rules for non-UK research
- ☑ I will report any unexpected serious adverse reactions or other serious unforeseen events which occur to the LSHTM Ethics Committee promptly
- ☑ I will provide an annual progress report until the end of the research
- ☑ I will provide notification of the end or early termination of the research project
- ☑ I will inform the LSHTM Ethics Committee if there are any changes to the research protocol or personnel which affect the ethical aspects of the project
- ☑ I will assist LSHTM Ethics Committee in any continuing review of the project deemed necessary by the Committee or Faculty members
- ☑ I undertake to adhere to the project protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval and will not start the project until all required approvals are in place
- ☑ I confirm that there are no conflicts of interest that preclude my participation in the study

Signed: This form was signed by 5.1.2e 5.1.2e (5.1.2e @lshtm.ac.uk) on 12/03/2020 3:29 PM

Signature - Other

Note:

The form will automatically submit upon receipt of all required signatures.

After submission, you will receive a confirmation email with further details.

If you have not received a confirmation email within 5 working days please email 5.1.2e @lshtm.ac.uk (staff) or 5.1.2e @lshtm.ac.uk (students) to check the status of your submission.