

**Master Protocol and UK Protocol: Social, ethical and behavioural aspects of COVID-19  
(SEB-COV)  
OxTREC Ref: 520-20**

**Country protocols have been adapted from the master protocol to comply with national regulations and ethics requirements**

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**Sponsor: University of Oxford**  
**Funder: Wellcome Trust, SoNAR-Global**

### **Confidentiality Statement, Investigator Agreement and conflict of Interest**

This document contains confidential information that must not be disclosed to anyone other than the sponsor, the investigator team, regulatory authorities, and members of ethics committees. This information cannot be used for any purpose other than the evaluation or conduct of the ethics and social science research investigation without the prior written consent of Principal Investigator.

We have read this protocol and agree to abide by all provisions set forth therein. We agree to comply with the principles of the International Conference on Harmonisation Tripartite Guidelines on Good Clinical Practice.

We declare no conflict of interest.

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Chief Investigator

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Signature

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Date

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## 1. SYNOPSIS

<b>Project title</b>	Social, ethical and behavioural aspects of COVID-19
<b>Short title</b>	SEB-COV
<b>Study participants</b>	The study participants will be persons aged 18 years and above, who have provided consent for quantitative method and written informed consent for qualitative method
<b>Study design and methods</b>	Mixed methodology will use online/remote methods to collect research data
<b>Planned sample size</b>	Quantitative method: approximately 600 participants online surveys per country  Qualitative method: approximately 25-35 participants for online interviews per country
<b>Inclusion criteria</b>	The following are the inclusion criteria: <ul style="list-style-type: none"> <li>• Adults (age may vary between country)</li> <li>• Residing in Thailand, Italy, Malaysia, UK and Slovenia (for online survey only)</li> <li>• Willing to give consent to participate in the study</li> <li>• Able to use a computer or smart phone</li> </ul>
<b>Exclusion criteria</b>	The following are the exclusion criteria: <ul style="list-style-type: none"> <li>• Individuals who are illiterate (because the data collection is online)</li> </ul> <p><b>Note:</b> Individuals who are tested positive for coronavirus will not be excluded unless they meet other exclusion criteria e.g. too ill, illiterate</p>
<b>Objectives</b>	<b>Overarching objective:</b> To produce evidence to inform (nonpharmaceutical) interventions such as communications, quarantine, travel restrictions, social distancing and other public health measures to the COVID-19 epidemic. <b>Objectives:</b> <ol style="list-style-type: none"> <li>1. To understand the factors that impede and facilitate the compliance of quarantine, self-isolation, social distancing and travel restrictions at different phases of the epidemic</li> <li>2. To explore people's understanding about quarantine, self-isolation, social distancing and travel restrictions</li> <li>3. To identify information sources and investigate any rumours/misinformation and to reverse and correct any rumours/misinformation about COVID-19</li> </ol>
<b>Study duration</b>	The study duration is expected 9 months from April to December 2020

## 2. ABBREVIATIONS

BKK	Bangkok
EC	Ethics Committee
FTM	Faculty of Tropical Medicine
GDPR	General Data Protection Regulation
GCP	Good Clinical Practice
IDI	In-Depth interview
MORU	Mahidol Oxford Tropical Medicine Research Unit
OxTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
MU	Mahidol University
COVID-19	Novel coronavirus disease

### 3. Background

COVID-19 is a respiratory disease caused by a novel coronavirus (SARS-CoV-2) and causes substantial morbidity and mortality. There is currently no vaccine to prevent COVID-19 or infection with SARS-CoV-2 or therapeutic agents to treat COVID-19. Outbreak forecasting and mathematical modelling suggest that these numbers will continue to rise [1].

Managing the COVID-19 pandemic poses considerable challenges for global and public health actors. Responding institutions and organizations have to utilise non-pharmaceutical interventions such as quarantine, isolation, social distancing, travel restrictions and other public health measures[2].

In the current situation of expanding transmission and uncertainty, it is important to have evidence to inform such public health interventions to ensure maximum public acceptance, success, and minimum disruptions to the lives of those affected. It is also necessary to understand how the people acquire, interpret and act upon diverse information about COVID-19. This will help public health authorities with approaches to communication, and choice of communications channels and messaging.

Vaccines and drugs for the treatment and prevention of COVID-19 require robust evidence generated from clinical trials before they can be used. Decisions on how to apply non-pharmaceutical interventions such as quarantine, isolation, social distancing and travel restrictions should also be based on evidence. There are some experiential and mathematical modelling data for these interventions [3, 4], but there is lack of data on the social, ethical and behavioural aspects of these interventions in the literature [5, 6].

Therefore our study aims to produce evidence to inform (non-pharmaceutical) interventions such as communications, quarantine, social distancing, travel restrictions and other public health measures to the COVID-19 pandemic. We propose to conduct a mixture of quantitative surveys and qualitative interviews to answer our research questions.

#### Description and rationale of study sites

At the time of writing, Italy, UK, Malaysia, **Slovenia** and Thailand governments have initiated strict public health measures and varying degrees of “lockdowns” to curb the pandemic.

At the time of writing, [Italy](#) has recorded one of the highest number of COVID-19 cases in the world and has been restricting the movements of its residents since 9<sup>th</sup> March. On 22<sup>nd</sup> March, the Italian Government ordered the shutdown of all non-necessary activities and movement between cities. In the [United Kingdom](#), as of 23<sup>rd</sup> March, people must stay at home except for shopping for basic necessities, daily exercise, any medical needs and travel to and from work (if they cannot work from home). **On May 6<sup>th</sup>, the United Kingdom became the first country in Europe to pass 30,000 COVID-19 deaths.**

Malaysia and Thailand have recorded some of the highest number of cases in Southeast Asia, and number of cases are still on the steep rise. The Malaysian government declared



[“Movement Control Order”](#) on 16 March 2020 which prohibits mass movements and gathering, closure of non-essential businesses and closing its borders. On 25<sup>th</sup> March, the Thai Prime Minister declared a state of emergency in [Thailand](#).

In Slovenia, strict preventive measures were taken early after the virus outbreak in Italy, the neighbouring country. The epidemic was declared on 12<sup>th</sup> March, followed by complete lockdown of all non-essential activities. Movement was only allowed within individual municipalities.

It is anticipated that these public health measures will be continued in some countries (e.g. Italy, Malaysia) or tightened (e.g. Thailand, UK) to control the spread of the disease in the coming weeks and months. The data generated from our study could inform these strategies in real time.

#### 4. Objectives and Research Questions

**Overarching objective:** To produce evidence to inform (non-pharmaceutical) interventions such as communications, quarantine, travel restrictions and other public health measures to the COVID-19 epidemic.

##### **Objectives:**

1. To understand the factors that impede and facilitate the compliance of quarantine, self-isolation, social distancing and travel restrictions at different phases of the epidemic;
2. To explore people’s understanding about quarantine, self-isolation, social distancing and travel restrictions;
3. To identify information sources and investigate any rumours/misinformation and to reverse and correct any rumours/misinformation about COVID-19

##### **Research questions:**

1. What are the perceptions and experiences, on quarantine, self-isolation, social distancing, and travel restrictions?
2. What are the economic, social and ethical impacts (e.g. lost wages, challenges in child care, food and household supplies, loneliness) of quarantine, self-isolation, social distancing, and travel restrictions?
3. How do people define these terms (quarantine, self-isolation, social distancing and travel restrictions)? What are the barriers and enablers of complying with these measures? How do people cope?
4. What are individuals from various communities (e.g. parents, caretakers, people from different occupations) most fearful of (e.g. loss of wages, dying, spreading to others; being unable to care for children/elder/other family members; isolation; being unable to get care)?
5. What are the rumours circulating in social media, conversations and discussions? To what extent has public information been clear? How do people obtain information?

#### 5. Project timeline

The duration of the study and primary analyses is expected to be 9 months from April to December 2020. The duration of data collection is 3 months.

## 6. Study design

We will conduct a mixture of quantitative surveys and qualitative interviews to obtain contextual information from communities on the following four themes:

- (1) Quarantine and self-isolation
- (2) Social distancing and travel restrictions
- (3) Wellbeing and mental health
- (4) Information, misinformation and rumours

## 7. Study Site

The study will be conducted in UK, Italy, Malaysia, Thailand and Slovenia. In light of limitations of travel and holding meetings, we will primarily use online/remote methods for collecting data. In person qualitative interviews may be conducted when it is safe to do so and in compliance with local regulations.

### 7.1 Study participants

The study participant will be persons aged 18 years and above, who have provided informed consent.

Subject inclusion/exclusion criteria below are applied to both quantitative and qualitative methods.

### 7.2 Inclusion criteria

- Adults (age may vary by country)
- Residing in Thailand, Italy, Malaysia, UK and Slovenia (quantitative survey only)
- Provided consent to participate in the study
- Able to use a computer or phone

### 7.3 Exclusion Criteria

- Individuals who are illiterate (because the data collection is online and self-administered)

**Note:** Individuals who are tested positive for coronavirus will not be excluded unless they meet other exclusion criterion

## 8. Study Procedures

## 8.1 Recruitment

### Quantitative method:

The research team will be using many social media channels to promote the study (e.g. Twitter @MORUBKK, @TropMed and other relevant University social media accounts). In addition, in order to minimize the sampling bias, the researcher team will use the service of commercial poll providers to recruit a more diverse national population sample.

### Qualitative method:

There will be three ways of recruiting participants to in-depth interviews.

1. Via online survey – at the end of the quantitative online survey [Survey 1], survey participants will be asked if they wish to take part in further qualitative research. They will be asked to click on a link [URL link to Survey 2] that will take them to a different webpage. Survey 2 invites participants to register their interest to take part in an interview and contains screening questions which will enable the research team to recruit a diverse group of participants for an interview from those who have registered their interest. Those who complete Survey 2 will be asked to provide an email address so that the research team can contact them to provide further information about the study, set up an interview and seek consent. Email address will not be linked to the answers given on Survey 1.
2. Direct contact with the study team – recruitment advertisements in the form of flyers and text will be posted via websites, social media and mailing lists. The recruitment flyer will contain QR code which link to the URL of Survey 2. Once they click the link, they will be asked to provide email address to enable us to contact them. The email address will not be linked to the survey answers [Survey 1]. The study team will contact selected participants to provide further information about the study, set up an interview and seek consent.
3. Snowball sampling and referrals will be used to reach additional participants and those who are not familiar with emails, in order to facilitate greater diversity of participants in the sample. The steps include:
  - Recruitment via personal and professional networks, including families, friends and colleagues who may represent/have contact with persons we wish to include in order to gain maximum variation within our sample.
  - The member of the research team making contact will give information on the research project, including an invitation for interested individuals to take part in the study.
  - The study team will then contact the potential participants, provide further information about the study, set up an interview and seek consent.

Participants will be selected with the aim to recruit a maximum variation sample, based on characteristics including participant age, gender, education, profession, number of household members and self-perceived level of risk of exposure to COVID-19. Email addresses and responses to the screening questions for not selected participants will be deleted and will not be stored

## 8.2 Informed consent

Participants will be asked to provide consent online. There will be separate consent for participating in the survey, and the qualitative interviews.

### **8.3 Data collection methods, study participants, sample size and topics for discussion**

We will conduct the following:

Quantitative method: About 600 online surveys per country. No formal sample size calculation has been performed. This number is more than what is recommended for a mixed methods study [7]. Furthermore, it is feasible for data collection within three months. Surveys will be self-administered and participants will take approximately 15-20 minutes to complete the survey. The online survey will be available in English, Thai and Italian.

Qualitative method: Online (via MS Teams, telephone or other approved platforms) interviews with 25-35 participants per country. Actual numbers will depend on context, changes in epidemic, and data saturation. Qualitative data collection will be conducted by in-country interviewers in the language (English, Malay, Thai or Italian) preferred by the participant and the interview will take approximately 30-45 minutes.

Questions for both quantitative and qualitative will be guided by the following themes:

- (1) Quarantine and self-isolation
- (2) Social distancing and travel restrictions
- (3) Wellbeing and mental health
- (4) Information, misinformation and rumours

We will target different communities (based on age, gender, risk and socio-economic status) within Thailand, Italy, Malaysia and the UK. Potential communities include those working in the healthcare sector, tourism industry, taxi drivers, market vendors, university students and public advisory groups.

## **9. Data analysis**

Interviews will be audio recorded where possible.[8] They will be transcribed, cleaned and translated to English where needed, and exported into the latest version of NVivo (© QSR International Pty Ltd), the software that will be used to manage the data. Codes will be established for each participant to enable appropriate collation of data sets and sub-themes and themes for qualitative data. This coding will be known only to the project team members and details will be held in a security access (password protected) file on computer and in hard copy in a locked filing cabinet of the Principal Investigators.

Qualitative data analysis will be based on thematic content analysis. Initial themes and categories will be developed iteratively through successive coding of the raw data, and informed by the research objectives, issues emerging from the raw data and media. To support the validity and trustworthiness of the data and analysis, two researchers will independently develop their own coding categories, followed by a discussion of similarities and differences. Where information gathered by different methodologies is contradictory

rather than complementary, divergences will be outlined and discussed in reports and publications.

Quantitative survey data will be entered and analysed using SPSS software. The quantitative data may also be analysed using Stata 15.0 (or later) software. Once the data have been collected we will review the data and bring together the related responses. Frequency counts and percentages will be used to summarise categorical data. Associations between categorical variables will be assessed using the Pearson Chi-Square tests or Fisher's exact tests as appropriate. Data will be presented in different tables, graphical displays and summary statistics. Further analysis to see the significance of relationship between variables will be performed. Tests of significance will be performed at 5% significance level for quantitative data.

Data will be analysed by country and pooled for comparison among countries.

## **10. Discontinuation/Withdrawal of Participants from Study**

Each participant has the right to withdraw from the study at any time. Withdrawal of consent to participate from this study will result in exclusion of the data for that participant from analysis and withdrawn participants will not be replaced. If identified, the reason for withdrawal will be recorded.

In addition, investigators may discontinue a participant from the study at any time if the investigator considers it necessary for any reason.

The audio recording will be deleted if the participant decides to withdraw mid-interview.

## **11. DATA MANAGEMENT**

### **11.1. Access to Data**

Direct access will be granted to authorised representatives from the sponsor, ethics committees, and regulatory authorities to ensure compliance with regulations.

### **11.2. Data Handling and Record Keeping**

Qualitative data includes audio recordings of interviews, interview transcripts and field notes. Audio files will be transcribed verbatim and translated to English where necessary. [8]. Alternatively, detailed summary notes will be made directly following the interview with selected verbatim quotes being used. The interview transcripts will be managed using the latest version of NVivo. These audio files will be kept in country until they have been transcribed and the transcribed interviews will be kept securely. All audio files will be destroyed when all the transcripts have been completed and verified.

Quantitative data will be entered and analysed using SPSS software. Stata 15.0 (or later) software may also be used for analysis.

De-identified data will be stored indefinitely digitally.

De-identified data collected may also be shared with other groups of researchers. All applications for data sharing will be reviewed by the MORU Data Access Committee. All researchers accessing the data need to adhere to a set of terms and conditions that aim to protect the interests of research participants and other relevant stakeholders.

Data generated from this study will adhere to the 2016 “Statement on data sharing in public health emergencies”.

## **12. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES**

The study will adhere to the relevant guidelines for surveys and qualitative research. All interviewers, and transcribers will be trained prior to the study.

The study will be conducted in accordance with relevant national and international guidance and regulations.

**Interview topic guides have been pilot tested in all countries.**

Survey questions have been pilot-tested and have undergone cognitive testing [9].

## **13. ETHICAL AND REGULATORY CONSIDERATIONS**

### **13.1. Risk and harm**

This is a minimal risk study posing minimal risk and harm to the participants.

The main ethical issues in this study relate to privacy and confidentiality. Care will be taken to maintain privacy during the audio recording of interviews and interactions with individual participants.

### **13.2. Declaration of Helsinki**

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki 2013[10].

### **13.3. Approvals**

The protocol, informed consent form, participant information sheet and any associated material will be submitted to relevant ethics committees for written approval.

The Chief and country PIs will submit and, where necessary, obtain approval from the above parties for all amendments to the original approved documents.

### **13.4. Participant Confidentiality**

The study staff will ensure that the participants' confidentiality is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the EU General Data Protection Regulation (GDPR) and country specific data protection regulations. Any personal information in quantitative survey will not be collected.

### **13.5. Compensation**

Participants will not be offered any payment to complete the online survey. Participants who take part in the interviews will be compensated in kind according to country guidelines for their time.

### **13.6. Benefits**

There will be no immediate benefits for any of the study participants. The chief benefit to participation in this study is that participants will be afforded the opportunity to contribute to the generation of new knowledge.

### **13.7. Public engagement and involvement**

As part of the development of our study and data collection tools, we have conducted a series of public engagement or public involvement activities e.g. with the existing community advisory boards,[11] and Bangkok Health Research Interest Group. The INVOLVE group, the UK's national advisory group for public involvement in defines public involvement as research that is actively carried out 'with' or 'by' members of the public rather than 'to', 'about', or 'for' them.

### **13.8. Reporting**

The country PIs shall submit once a year throughout the study, or on request, an Annual Progress report to the relevant ethics committees. In addition, an End of Study notification will be submitted to the same parties, if requested.

## **14. FINANCE AND INSURANCE**

### **14.1. Funding**

The study is funded by the Wellcome Trust the Sonar-Global project which has received funding from the European Union's Horizon 2020 Research and Innovation Program under Grant Agreement No 825671. Funding from other donors are being sought.

## 14.2. Insurance

This research will be appropriately covered through the University of Oxford's legal liability insurances.

## 15. PUBLICATION POLICY

The Chief Investigator will lead writing and reviewing of drafts of the manuscripts, abstracts and any other publications arising from the overall study. The country PIs will lead the writing of country publications in collaboration with the CI. Authorship will be based on the set of criteria set by the International Committee of Medical Journal Ethics. The study results will also be published as regular short reports, and evaluation report of the online data collection approach.

## 16. Dissemination of information

Regular short reports will be made available in real time to public health authorities and researchers, including:

- WHO COVID-19 Research Roadmap Social Science Research Working Group (the Chief Investigator, PYC is a member of the group)
- UK Emergency Preparedness and Response Health Protection Research Unit
- Health professionals and healthcare staff from the Department of Disease Control, Thailand Ministry of Public Health, e.g. Division of Communicable Diseases, Bureau of Epidemiology, Health Intervention and Technology Assessment Program (HITAP)
- Italian Ministry of Health
- Italian Ministry of Innovation Technologies and Digitalisation
- Ministry of Health, Malaysia
- Network of research ethics committees in participating countries
- Research networks for pandemics and infectious diseases e.g. SoNAR-Global Network, Public Health Emergency Preparedness and Response Ethics Network (PHEPREN)
- University researchers and other organisations working on COVID-19 response

Results of the will be published as academic publications and presented at academic conferences. They will also be available in lay language for dissemination to the wider public.

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