RESPIRE Data Management Plan (DMP): Template (adapted from the University of Edinburgh)

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Project Title:	Exploring Personal Preparedness and Self-Protective Measures Against COVID-19 Pandemic: A Qualitative Study Protocol of Frontline Health Care Workers in Cox's Bazar, Bangladesh
Institute:	Fasiuddin Khan Research Foundation (FKRF) via Child Health Research Foundation, Bangladesh
Start Date:	01.07.2020
End Date:	30.09.2020
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Responsibilities & Resources (applicable across the sections below)

Who will be involved in the data management of this research?

Co-Principal Investigators:
Dr. Farzana Khan
Prof. Liz Grant

Co-Investigators:
Hasina Karim
Dr. Tasnim Azad
Saiduzzaman Bhuiyan
Prof. Samir K Saha

Data collection will be carried out by the Field Research Assistants
Data entry by the PIs and Co-Is

Additional resources for data management include the following:
1. Computers (desktop and laptops- data entry work).
2. External hard drives for backup during the data entry work.
3. Backup servers for storage of data at University of Edinburgh

The project data will be submitted to Edinburgh DataShare (https://datashare.is.ed.ac.uk/) for sharing data in public domain and for long term preservation on DataVault (https://www.ed.ac.uk/information-services/researchsupport/research-data-service/after/datavault).

1. Data Capture

What data will be generated or reused in this research?

Remote online interviews using MS-Teams will be the core data for this research. A semi-structured questionnaire will be used for this purpose. Language of interview will be Bangla. The interview data will be converted into verbatim transcription as well as translation from Bangla to English.

Data generated includes:
Quantitative data in CSV format:
Name, age, sex, religion, length of employment at work station, unique numeric identifiers, location data, designation, years of experience
Collected on paper through administered questionnaires.
Qualitative data collected during in depth qualitative interviews with 30 health workers.
Data was collected on the following areas using a theoretical framework:
Knowledge of pandemic and where participant got information
Knowledge of symptoms of COVID-19 infection, avoiding infection
Concerns about catching COVID-19 during duty
Ways of feeling prepared to face COVID-19 pandemic
Worries about lack of preparedness
Previous training for other health crises such as influenza pandemic?
Knowledge of process –
checklists or any frameworks for pandemic preparedness
Types of activities to recommend to stop the Corona virus from being transmitted?
(hand hygiene, cough etiquette, social distancing, quarantine, personal protective equipment, vaccination, duty to care, absenteeism)
Access and type of personal protective equipment
Knowledge and beliefs about protection
Ease of wearing
Disadvantages
Concepts of social distancing
Data was collected in hard copy
Data will be destroyed after 5 years
All data has been anonymised

How much data will be generated?

30 interviews were conducted, 10 doctors, 10 nurses and 10 community health workers all employed at the primary health centres in Rohingya camps in Cox's Bazar.

2. Data Management

How will the data be documented to ensure it can be understood?

The interview data was collected in Bangla language, as the majority of the participants were comfortable to share data in Bangla.
Data has been translated in English for reporting and publication purpose. The core transcription and translation data is documented in MS-Word file.
The demographic data is documented in a table using MS-Word.
All data was collected on hard forms using structured interview questionnaires.
Questionnaires collected formal professional and participant data alongside data on attitudinal perspectives.
The methodology and analysis of data is incorporated in a research report and research paper that will be documented in both MS-Word and PDF files.

Where will the data be stored and backed-up?

All personal identifiable data was kept initially in a secure storage area in FKRF office desktop, in a password-protected encrypted file, only accessible by the research team. A data storage container was set up on the desktop and also on the University of Edinburgh One Drive on the advice of the Data manager.

https://www.ed.ac.uk/information-services/research-support/research-data-service/during/data-storage

A copy of all data will be retained by FKRF securely. This copy will not be uploaded to any other public access data repository unless agreed by FKRF and RESPIRE .

All in-process data, i.e., active research data that may need sharing with group members remotely may be put on UoE's DataStore (https://www.ed.ac.uk/information-services/research-support/research-dataservice/during/data-storage).

The paper copies are stored separately in a locked cabinet, only accessible by the researchers.

3. Integrity

How will you quality assure your data?

Data was quality assured at three levels.
Those involved in data collection checked for completeness and logical checks.
Once data was brought to the office the PI performed a quality check using pre-defined criteria (all sections complete as appropriate, legibility, clarity of wording).
Data was further checked and assessed through a steering group in discussion on the findings, jointly by the PIs and the research team.

4. Confidentiality

How will you manage any ethical and Intellectual Property Rights issues?

All the investigators and all staff involved in the study will conform with the requirements of the General Data Protection regulation GDPR 2018 with regard to collection, storage, processing and disclosure of personal information and uphold the Act's core principles

Only the research team will access participant data.

All identifying information collected about participants will be kept confidential.

Published results will not contain any personal data that would allow identification of any participant.

The study processes were guided by principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP) with all formal required approvals sought and obtained.

All participant informed consent was obtained before any protocol specific procedures were carried out. The decision of a participant to participate in clinical research is voluntary and is based on a clear understanding of what is involved.

Participants received full oral and written information – appropriate Participant Information and Informed Consent Forms.

The oral explanation to the participant was performed by the Principal Investigator and a qualified delegated persons including co-investigators.

It covered all the elements specified in the Participant Information Sheet and Consent Form.

The participant were given every opportunity to clarify any points they did not understand and, if necessary, could ask for more information. The participant was given sufficient time to consider the information provided. It was emphasized that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The Investigator or delegated member of the trial team signed and dated the Informed Consent Form(s) to confirm that consent has been obtained.

5. Retention and Preservation

Which data do you plan to keep and for how long?

Non-identifiable data from this project will be stored in DataShare the research data repository at the University of Edinburgh to allow knowledge sharing and learnings about this study.https://www.ed.ac.uk/information-services/research-support/research-data-service/after/data-repository

https://datashare.is.ed.ac.uk/

All study documentation will be kept for a minimum of 5 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

How will the data be preserved?

The anonymised copy of the study data will be backed up and preserved on the UoE's DataVault for long term preservation

(https://www.ed.ac.uk/information-services/research-support/research-dataservice/after/datavault)

We will ensure that the soft copies of all data collected in this study is anonymised with identifier mapping master.

A complete copy of the anonymised data validating the results will be preserved for long term in the above-mentioned data storages for five years.

6. Sharing and Publication

Which data will be shared and how?

All the anonymised data generated from this study will be shared through the University of Edinburgh's DataShare (https://datashare.is.ed.ac.uk/).
The data will must follow the principles of findability, accessibility, interoperability, and reusability (FAIR) and the submitted dataset will have a Digital Object Identifier (DOI) assigned.

Are any restrictions on data sharing required?

The Investigator and study site staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.
All Investigators and study site staff involved with this study will comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act 2018) with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Access to collated identifiable participant data will be restricted to individuals from the research team treating the participants, representatives of the sponsor(s) and representatives of regulatory authorities.
Computers used to collate the data will have limited access measures via user names and passwords. Published results will not contain any personal data that could allow identification of individual participants.