



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

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<b>Project Title:</b>	Developing and evaluating interventions at patient and practice level to improve asthma care
<b>Institute:</b>	University of Malaya, Kuala Lumpur, Malaysia
<b>Start Date:</b>	1 <sup>st</sup> September 2018
<b>End Date:</b>	31 <sup>st</sup> March 2021
<b>DMP version number and date:</b>	DMP Version 1 and 01.12.2020

### **Responsibilities & Resources (applicable across the sections below)**

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

**Person in charge:**

Principal investigator, principal investigator at the site and research manager of the project are listed below:

1. Principal/Coordinating Investigator: Professor Dr Ee Ming Khoo
2. Principal Investigator at the site: Dr Norita Binti Hussein
3. Research Manager: Jayakayatri Jeevajothei Nathan

**Resources:**

Hardware and software used in the management of data are listed below:

1. Laptop (encrypted and secured with username and password and kept in a locked cabinet)
2. Thumb drive (encrypted, password protected and kept in a locked cabinet)
3. Solid-state drive (encrypted, password protected and kept in a locked cabinet)
4. DataStore (to back up active research data)
5. Microsoft Word
6. Microsoft Excel
7. NVivo Qualitative Data Analysis Version 12.0 Software
8. SPSS Software version 25.0
9. Locked cabinet for any hard copies (research protocol, topic guide, participant information sheets, sociodemographic forms, informed consents, questionnaires, codebook and NVivo coding framework)

### **1. Data Capture**

*What data will be generated or reused in this research?*



Data that were generated are listed as below:

1. Baseline Phase:

(a) Patient stream

Quantitative - sociodemographic and personal profiles such as age, gender, ethnicity, level of education, occupation, personal income, total household income, main source of health payment, number of household members, marital status, distance from home to nearest clinical/hospital, family history of asthma, history of allergy and smoking status; health care use and cost; health profile: asthma status, other medical conditions, asthma treatment and management; clinical examination: spirometry and peak flow rate.

(b) Practice stream

(i) Quantitative (health care practice) - structure of asthma service; asthma emergency care; asthma treatment and patient education; asthma training and audit.

(ii) Quantitative (health care professional) - years of working as a doctor, number of patients seen on average in 1 month and diagnosis technique used.

2. Development Phase:

Qualitative transcripts of patients' and health care professionals' perception of asthma care and self-management support.

***How much data will be generated?***

250GB – 500GB

## 2. Data Management

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

1. Baseline Phase:

Source documents were documented in Microsoft Excel and SPSS. A codebook containing information about each of the variable in the dataset were created to ensure that the data is understood and interpreted properly.

2. Development Phase:

Each interview was assigned with a participant code and transcribed verbatim in Microsoft Word. The de-identified interview transcripts were exported into NVivo Qualitative Data Analysis Version 12.0 Software for data analysis.

***Where will the data be stored and backed-up?***

The electronic data were stored in two RESPIRE laptops, a thumb drive, a solid-state drive and will be backed-up in DataStore. Hard copies (research protocol, topic guide, participant information sheets, sociodemographic forms, informed consents, questionnaires, codebook and NVivo coding framework) were stored in locked cabinet.

### 3. Integrity

#### *How will you quality assure your data?*

The completed questionnaires were checked by researcher for completeness of the data before it was entered into SPSS Software version 25.0. Data entered were checked for errors by running a frequency distribution on each of the variables. Participants would be contacted for clarification if any missing data or error traced. Spirometry results were checked by researchers that includes investigators and pulmonary physician by looking at components such as the forced vital capacity (FVC), first forced expiratory volume (FEV1), forced expiratory time (FET) and good start, good peak, good curve and good inspiratory loop on the graph before determining if the test results were acceptable. Participants will be contacted to repeat the test if the test result is not acceptable.

The interviews were recorded by using two audio recorders and the non-verbal cues were noted down by a researcher. Interviews were transcribed verbatim and the transcripts were checked by two researchers for accuracy.

### 4. Confidentiality

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

1. The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP). All required approvals have been obtained.
2. The investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments.
3. All reports and other records will be identified in a manner designed to maintain participant confidentiality. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may 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 study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.
4. All Investigators and study site staff involved with this study must 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.

### 5. Retention and Preservation

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

##### **Identifiable Data**

All sociodemographic forms and informed consents of the participants will be kept for five years. Audio recordings will be permanently deleted at the end of the research project.

#### **Non-identifiable Data**

De-identified electronic data will be preserved for long term.

#### ***How will the data be preserved?***

The hard copies of these identifiable data will be kept in a locked cabinet and will be shredded and disposed in secure bins after five years. The non-identifiable data will be preserved in two RESPIRE laptops, a thumb drive, a solid-state drive and on DataVault.

## **6. Sharing and Publication**

#### ***Which data will be shared and how?***

The final de-identified analysed data, conference abstract presentations, journal articles and dissemination event will be shared in DataShare.

#### ***Are any restrictions on data sharing required?***

Yes, prior to release for sharing, there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, for data archived in Edinburgh DataVault, we will make the data available to users only under a data-sharing agreement that provides for:

1. A commitment to using the data only for research purposes and not to identify any individual participant;
2. A commitment to destroying or returning the data after analyses are completed.