Health Sciences Research Ethics Committee

RESEARCH DATA MANAGEMENT PLAN

Researchers are directed to the Protection of Personal Information Act 4 of 2013 for guidance regarding POPIA.

Note that this MUST be signed by the principal investigator and this cannot be delegated.

Protocol information		
Principal Investigator name and surname		
Protocol title		
Collaborator(s)	**Name**	**Role**
Signature of principal investigator ***My signature confirms that the information provided are true and acurate***		**Date**

Version table		
Version	**Changes made**	**Date**

For more information on the Data Management Plan please visit: *https://ufs.libguides.com/c.php?g=977378&p=8142054*

Risk profile	
Check all that are relevant	**N/A☐**
Personal information of children is used in the research activity	☐
Research involves further processing of personal information that was collected for another purpose	☐
Personal information will be available for further processing in other research activities	☐
Personal information will be linked with personal information collected by another institution	☐
Personal information will be transferred to another country	☐
Personal information is collected from a source other than from the data subject, e.g., patient records	☐
The research uses a unique identifier (e.g. an identity number or hospital number)	☐
Data subjects/participants are not deidentified, anonymised or pseudoanonymised	☐

Research Data Management Plan

1. Data collection

Provide a short description of the data that you plan to collect or create
How will the data be collected or created?

Frequency of new data - how often will you get new data and over what time period? Will the data be collected continuously or at specfic time-points ? Will the frequency of data collection change over time?
If using existing data, where will this data be obtained from? Describe the existing data that will be used. Do you have permission to use existing data, are there any restrictions on their re-use of data? Please provide appropriate documentation to support the use of existing data.

2. Documentation and metadata

Provide a short description of the documentation and metadata that will accompany the data, if relevant.

3. Ethics and Legal Compliance

"Personal information" means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to:

1. *information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person;*
2. *information relating to the education or the medical, financial, criminal or employment history of the person;*
3. *any identifying number, symbol, e-mail address, physical address, telephone number, location information, online identifier or another particular assignment to the person;*
4. *the biometric information of the person;*
5. *the personal opinions, views or preferences of the person;*
6. *correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;*
7. *the views or opinions of another individual about the person; and*
8. *the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person;*

"Special personal information" means

1. *the religious or philosophical beliefs, race or ethnic origin, trade union membership, political persuasion, health or sex life or biometric information of a data subject; OR*
2. *The criminal behaviour of a data subject to the extent that such information relates to –*
   a. *The alleged commission by a data subject of any offence; or*
   b. *Any proceedings in respect of any offence allegedly committed by a data subject or the disposal of such proceedings.*

ACCOUNTABILITY:

Who is responsible for ensuring that the data will be managed in accordance with POPIA principles? Note that this person will be held liable for non-compliance in certain situations.
How will this person ensure that the data is managed in a POPIA compliant manner?
Do you plan to collect information that is considered "Special personal information" or personal information of children.
If identifiable data will collected, please mention how long it will be kept, how it will be destroyed and who will destroy it.

PROCESSING LIMITATION:

Who is ultimately responsible to ensure that all data that is processed is done so lawfully and in line with the documented informed consent, research ethics approvals and other role player regulations?
Will data be obtained directly from the participants? Is the participant aware that you have gathered his/her information and has the participant consented to the use of the information? If the infomration is not collectd directly from the participant, please justify this.
Is the data that is collected relevant to answer the aims and objectives of the research, and not excessive?

PURPOSE SPECIFICATION

Elaborate on how the researchers will ensure that data that is collected for a specific purpose will only be used for the purposes specified. If you intend to reuse personal information is it in accordance and compatible with the purpose for which it was collected? Is the participant aware of the continued use of their personal information? For what time period may you retain this specific data (this is especially relevant in the case of use of data from a third party, e.g. Department of Health)? How will you keep track of when the personal information must be destroyed (if relevant). What process will be used to destroy personal information that prevents its reconstruction after you no longer require it. What futuer purposes might the personal information be used for? If the personai information will be de-itintified, specify how the personal information will be deidentified.

FURTHER PROCESSING LIMITATION

Elaborate on how researchers will address further processing of existing data. Reflect on "purpose specification" above. What measures have been put in place to ensure that there is oversight and regulation of further processing of data.

INFORMATION QUALITY

Which measures have been put in place to ensure that personal information that has been collected is complete, accurate, not misleading and up to date. What quality control measures will be put in plac toensure this? What processes do you have in place to allow participants to update their information or withdraw consent (if applicable).

OPENNESS

Which measures have been put in place to ensure that the participants and/or other role players (e.g. relevant head of department) have been informed of the data collection. Does participant information document have the contact details of the researcher(s) as well as the HSREC for queries regarding the research and their rights as participants/role players? Does the participant know who is responsible for data safety in the research project? Have you provided information to the participant oas to how to lodge a complaint about the use of their personal information? How will the personal information be collected? Has the participant been informed on their rights to access information and right to object to processing of information?

SECURITY SAFEGUARDS

Is this research high-risk or low-risk research based on the risk profile above?
Elaborate on data security safeguards. Which programme will you use to manage research data? Is that programme POPIA compliant?
What procedure do you have in place to identify an foreseeable internal and external risks to data? Is data deideintified, anonymised or pseudoanonymised?
What processes do you have in place to prevent data from falling into inappropriate hands?
What procedure do you have in place to establish and maintain appropriate safeguards against identified risks?
How do you determine who has access to and who has accessed data?
How do you determine who has rights to access data?
What processes do you have in place to alert you to when data is accessed or modified without consent/authorisation?
What processes do you have in place to identify the source of a data breach and the procedure to follow to neutralise the breach?
What process do you have in place that safeguards are continually updated in response to new risks or deficiencies in prviously implemented safeguards?
What processes do you have in place to prvent a recurrence of a data breech?
What procedure is in place to inform the participant that their data has been compromised?
What procedure is in place to inform the HSREC of any data security breach?

DATA SUBJECT PARTICIPATION

Will participants be able to access their personal information? What process should they follow in order to do so (if appropriate/applicable)? What processes do you have in place to allow participants to correct personal information that you hold or withdraw consent to use such information? What processes do you have in place to ensure that a request from a participant is adhered to?

4. Storage and Backup

How will the data be stored and backed up during the research? How will you manage access to data? Please refer to the HSREC research data retention plan for guidance on the duration of data retention (https://www.ufs.ac.za/health/departments-and-divisions/health-sciences-research-ethics-committee)
How will you maintain and store copies of informed consent?

5. Selection and preservation

Which data are of long-term value and should be retained, shared and/or preserved?
What is the long-term preservation plan for the dataset?
Where will the dataset be kept? How will you archive the data?
What data will you share with others? What licences apply?
What data/research material should be kept beyond the end of the project?
What data/research material should be destroyed? When? How?
How long will you preserve your data for? Where will you preserve your data?

6. Data sharing

Who else has a right to see or use this data, even before you share it?
Who needs access to your data? Members of the research team (e.g. biostatisticians)? How will you ensure that data is shared safely between members of the research team?
How will you share the data? Are their any restrictions on data sharing (outside of your research group) required?
Do you have a material/data transfer agreement in place?
Do you need to anonymise data during research or when preparing for sharing, and how will you do this?
Does the ogranisation comply with EU GDPR or the ASSaF Code of Conduct.
Is there a contract in place if this is a foreign organisation?

7. Responsibilities and resources

Who is ultimately responsible for data management in this research project?
Who will be assigned rights to make changes to this plan?
What resources do you need to implement the plan (filing cabinet, software, training, SOPs?)

8. Budget

What are the relevant costs related to the management and curation of your data?

9. What are the relevant policies that influence ?

What are the relevant policies, laws, procedures that influence your data management activities?
Are there any restrictions imposed by the primary data owner (e.g. the Department of Health, the University of the Free State)
If your data is personal, sensitive or commercial how will you share safely, including plans to anonymise your data?
Have you established who owns the copyright in your data?
Could the data be considered high value and/or vulnerable? For example, is your data likely to attract "hacktivists"? How could this be mitigated?
How will you destroy any personal, sensitive or commercial data identified above?