

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 task cannot be delegated.

All text written in grey are provided as guidance and may not be relevant to all research.

| Protocol information | | |
|---|-------------|---|
| Principal Investigator | | |
| Protocol title | | |
| Collaborator(s) | Name | Role |
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| | | |
| Salutation, name and surname of Principal Investigator | | Signature: Principal Investigator <i>My signature confirms that the information provided is true and accurate</i> |
| Date Signed: _____ | | |

| 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>

| POPIA Risk profile | | |
|--|------------|-----------|
| Answer all questions | Yes | No |
| Will the Research Participants include Children or Special Personal Information? | | |
| Will the research involve processing Personal Information on a large scale? | | |
| Will the research involve the evaluation or scoring of Personal Information to make automated decisions with legal consequences or that will have a significant effect on Research Participants? | | |
| Will the Research involve Processing where researchers are getting Research Participants' Personal Information from sources other than the Research Participants themselves? | | |
| Will the Personal Information of Research Participants be disclosed to Third Parties? | | |
| Are any people or organisations that will have access to the Personal Information located in another country? | | |
| Will unique identifiers be used to link, combine, compare or match Personal Information from multiple sources? | | |
| Does the Research involve the use of new technology or technology that is, or might be, perceived by individuals as intrusive on their privacy? | | |
| Would the Processing of Personal Information contemplated by the researcher be outside of the reasonable expectations of the individuals? | | |
| Will the Research involve contacting or interacting with individuals in ways they might find intrusive? | | |

| Research Data Management Plan |
|---|
| <p>1. Data collection</p> <p><i>Provide a short description of the type of data you plan to collect or create.</i></p> <p><i>How will the data be collected or created?</i></p> <p><i>Frequency of new data - how often will you get new data, and over what period?</i></p> <p><i>Will the data be collected continuously or at specific time points? Will the frequency of data collection change over time?</i></p> <p><i>If using existing data, where will this data be obtained from?</i></p> <p><i>Describe the existing data that will be used.</i></p> <p><i>Do you have permission to use existing data, are there any restrictions on the re-use of data?</i></p> <p><i>Please provide appropriate documentation to support the use of existing data.</i></p> |

2. Documentation and metadata

Clarify whether metadata will be collected and processed?

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 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 the 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.

3.1. 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?

3.2. PROCESSING LIMITATION:

Who is ultimately responsible for ensuring 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 using the information? If the information is not collected directly from the participant, please justify this.

Is the collected data relevant to answer the aims and objectives of the research, and not excessive?

3.3. 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 the 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 future purposes might the personal information be used for?

If the personal information will be de-identified, specify how the personal information will be de-identified.

3.4. FURTHER PROCESSING LIMITATION

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

3.5. INFORMATION QUALITY

What measures have been put in place to ensure that personal information collected is complete, accurate, not misleading and up to date?

What quality control measures will be put in place to ensure this?

What processes do you have in place to allow participants to update their information or withdraw consent (if applicable)?

3.6. OPENNESS

Which measures have been implemented to ensure that the participants and/or other role players (e.g. relevant head of department) have been informed of the data collection?

Does the 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 as 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 of their rights to access information and right to object to the processing of information?

3.7. 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 foreseeable internal and external risks to data? Is data deidentified, anonymised or pseudonymised?

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 the right to access data?

What processes do you have in place to alert you 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 previously implemented safeguards?

What processes do you have in place to prevent a recurrence of a data breach?

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?

3.8. DATA SUBJECT PARTICIPATION

Will participants be able to access their personal information?

What process should they follow 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?

If identifiable data will be collected, please mention where data will be stored and backed up.

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? Where will you preserve your data?

If identifiable data will be collected, please mention how long it will be kept, how it will be destroyed and who will destroy it. 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>)

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 there 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 organisation 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 the right 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? This does not refer to the costs of conducting the research but the costs of data management and curation. Have such costs been budgeted for?

9. What are the relevant policies that influence data management activities?

What are the relevant policies, laws, and 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 it safely, including plans to anonymise 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?