*[Insert Facility Logo]*

***TITLE OF DATABASE***

***Data Custodian: [insert: name or organisation]***

***Please DELETE this instruction box***

*Please ensure that you complete all sections of this Template or it may not be approved.*

*Please note that this document should be written in accordance with the National Statement, further guidance regarding the general requirements for consent can be found in Chapter 2.2 of the National Statement (follow link):* [*National Statement*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

*For research to be ethical the right of people to make their own decisions, including deciding to participate in research, must be respected. To enable an informed decision about whether to participate in research, an individual must be provided with sufficient information regarding the nature of the proposed research and the implications of participating in it.*

*This information should be comprehensible to a person with average literacy levels. It has been demonstrated that 59% of Australian adults have a health literacy level below the minimum required to meet the complex demands of everyday life (ABS 2009).* ***The NHMRC recommends a reading level of Grade 8 or below and complex medical terms and abbreviations must be explained.***

*Please refer to RHC Plain Language Guide - Medical Terminology and General language. This summary sheet is based on guidelines issued by the NHMRC and should be suitable to use for most research projects typically reviewed by the Ramsay Health Care Human Research Ethics Committees.*

*Version number and date should be populated e.g.Version 1 - 8/09/2020 in the Footer section*

*\*Only include Site Specific version details if conducting at more than one site.*

*Please note that this is a Template only and the Committee may require further changes depending on the nature of your study.*

*.*

**PARTICIPANT INFORMATION SHEET - DATABASE**

|  |  |
| --- | --- |
| **Title** | *[Project Title]* |
| **Short Title** | *[Short Project Title]* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *[Project Sponsor in Australia]* |
| **Coordinating Principal Investigator/ Principal Investigator** | *[Coordinating Principal Investigator/*  *Principal Investigator]* |
| **Associate Investigator(s)**  *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location(s)]* |

**1. Introduction**

You are invited to contribute your health information (this could be health, personal or sensitive information) to a database of patients receiving medical treatment for *[name of disease or condition]* at the *[name of hospital and/or Dr’s private rooms]*.

Researchers will use the information collected in this database to help better understand the nature of *[name of disease or condition]* and assist in developing future clinical research *[or as appropriate]*. You will not be told if or when your data is used in a research study.

*[delete for single-site application:]* The database is being established and overseen within this institution by … *[names, positions, and institution. If there are several custodians, listing the names and details one below the other may be clearer.]*.

*[If appropriate otherwise delete:]* The database is part of a national / international collaboration coordinated by *[Australian, European, US researchers …] [If appropriate otherwise edit or delete:]* *Your individual/identifiable data will/will-not be sent to another country/other countries. Only aggregated data and meta-data will be sent overseas, this is to ensure your privacy is protected. Aggregated data means your data is mixed or averaged with other people’s data in a way that cannot be undone. Meta data means data that describes characteristics of large groups within the database, you cannot be identified from metadata.*

*[if appropriate otherwise delete:] [study sponsor] may benefit financially or commercially from the results of the data [give details]. You will/will not benefit financially from your involvement [give details].*

*[If appropriate otherwise delete:]* The database is being sponsored by … *[name of commercial or other entity. Include a statement about any conflict of interest which one or more of the investigators have.]*

**2. Contributing to the database**

If you agree to contribute to this database, you will not be required to do anything/ [if required to complete questionnaires outline here] other than sign the Patient Consent Form. Relevant information will then be obtained from your medical record and stored in the database. *[state other sources e.g. other databases, registries etc.]* This will include information on … *[insert a summary of the data fields to be included in the database]*

In the database your health information will be identified with a number to protect your privacy. Your name will be recorded in connection with this number, but information about you will only be linked to your number.

*[If data linkage will be used specify, otherwise delete:]* The researchers will be using data linkage\* through *[insert how data linkage will be used here]* this data is kept secure by *[insert method (i.e. coded).]* Data will be linked by *[insert method of how data will be linked]*

Your information will always be treated confidentially, and only *[name of database custodian – name or Principal Investigator]*, (the database custodian), their assistants and authorised researchers will have access to it.

All data will be stored on a secure server hosted by the *[insert server eg REDCap or Dr Practice or other]* and backed up to *[insert information].* Only the investigators of this study will be able to assess this data.

\*Data linkage, is a method of bringing together information, from different sources, but relating to the same individual.

**3. Benefits**

While we intend this database to be used to further medical knowledge and to improve treatment of *[name of disease / condition]* in the future, it may not be of direct benefit to you.

**4. Costs**

Contributing to this database will not cost you anything, nor will you be paid.

**5. Voluntary Participation**

Contributing to this database is entirely voluntary. If you don’t want to take part or aren’t sure, you can say ‘no’ and you don’t have to give a reason.

If you do take part, you can withdraw your health information at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the doctors and staff who are caring for you.

**6. Withdrawal Process**

If you decide to withdraw from this research database, you will need to notify a member of the research team (details listed under further information section below) and you may be asked to complete *[insert process for withdrawal eg. Withdrawal form, email, phone call]*

If you decide to leave the research database, the research team will not collect additional health information about you, although information already collected will be retained to ensure that the results of any research conducted prior to your withdrawal can be measured properly and to comply with law. If you do not want your data to be included, you must tell the researchers when you withdraw from the project.

**7. Confidentiality and length of data storage/data destruction**

*[Note: the amount and detail of information given should take into consideration the sensitivity of information, security risk and the participants needs. For instance more assurance around security and privacy is needed for extremely sensitive topics such as sexual health and domestic violence.]*

All the information collected from you for the study will be treated confidentially and will be stored on a research database *[enter location].* The data from the data linkage study will be stored *[enter location if applicable].*

Only the researchers *[or others as appropriate]* named *[enter names]* will have access to it.

**Add below information where relevant:**

* Add a statement about how data will be recorded using unique ID codes, who will have access and where they will be kept.
* Include the length of time the data/samples will be stored for (e.g. fifteen years etc.).
* Who will have access to the data
* Who is the data custodian
* The location of where the samples will be analysed and stored should be stated (i.e. the samples will be stored in [insert name of Biobank])
* The future use of the data and /or samples and that it may be shared locally and internationally with other research collaborators should be mentioned]

**[Identifiable or De-Identified]** data will be stored on an online secure password protected research database accessed within *[insert location]* at *[insert institution/Hospital,]* supported by *[e.g. name of IT department supporting the database].* Any identifiable hardcopy data will be stored on either a secure, password protected shared drive (supported by XXX) or in a locked cabinet in a locked office of *[insert location and whose office],* at *[insert institution details*].

*(if applicable; The study results will be used in a higher research degree project. Your data will also be stored at [insert details]*

The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable.

**8. Future use of Data**

The data collected in this project may also be used in future research studies. The results of this study and de-identified data may be shared in the future with Australian and international collaborators, however the use of the data will be subject to ethics approval.

*[Choose one of these two paragraphs]* Future research involving this database and your data is restricted to studies related *[insert disease or condition etc]*

*[Choose one of these two paragraphs]* Future research involving this database and your data is unrestricted and could involve any studies related to health *[If appropriate otherwise delete]* and studies that are not related to health.

**9. Further Information**

When you have read this information, *[name of database custodian]* will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on *[telephone number].*

*If the person to be contacted for further information is different from the person named in line 1 of this paragraph, then give name and phone number]*.

This information sheet is for you to keep.

**10. Ethics Approval and Complaints**

The establishment of this database has been approved by the Ramsay Health Care HREC A or WA|SA HREC (as appropriate). Any person with concerns or complaints about it should contact the Executive Officer on [HREC.RHC@ramsayhealth.com.au](mailto:HREC.RHC@ramsayhealth.com.au) or [RamsayHREC.WA-SA@ramsayhealth.com.au](mailto:RamsayHREC.WA-SA@ramsayhealth.com.au) [delete as applicable] or phone (02) 9433 3854, and quote reference number 20XX/ETH/YYYY

*[If appropriate otherwise delete:]* Contribution to this database by patients at the *[name of hospital]* has been authorised by Ramsay Health Care. Any person with concerns or complaints about its conduct may also contact the Research Administration Manager, National Research Unit on (02) 9433 3854 or researchgovernance@ramsayhealth.com.au and quote research Governance Approval *20XX/RGO/YYYY.*

***[Insert Logo***

***[Project Title]***

***[Short Project Title]***

***TITLE OF DATABASE***

**PARTICIPANT CONSENT FORM - DATABASE**

I: [*name]*

Of: *[address]*

have read and understood the Participant Information Sheet on the above named database and

have discussed it with

[investigator responsible for conducting informed consent].

* I have been made aware of the information that will be collected about me as part of this database and how this information will be used.
* I understand that contributing my information to the database will allow the researchers to have access to my medical record, and I agree to this.
* I understand that my information / data will be stored in *[insert details]* at *[insert details]* location, for *[insert details]* purposes.
* I freely choose to contribute to the database and understand that I can withdraw my health information at any time.
* I also understand that the database is strictly confidential.
* I hereby agree to contribute my health information to this database which will be used for future research purposes and/or shared with other national / international collaborators.
* I understand that any data that is used for related or future research, will first be reviewed and approved by an appropriately constituted Ethics Committee.

Name:

Signature:

Date:

Name of Person conducting Informed Consent:

Signature:

Date: