Research participant information and consent form (PICF)

PURPOSE

This guideline outlines best practices for the process of obtaining informed and voluntary consent from participants, via a Participant Information and Consent Form (PICF), for the acquisition of participant clinical data and samples surplus to clinical requirements, specifically for use in research in Metro South Health (MSH).

OUTCOME

This guideline aims to:

- Outline general principles that can be used in most situations to ensure that the interests of the participant are safeguarded in obtaining voluntary and informed consent from MSH research project participants. It should be noted that the National Statement on Ethical Conduct in Human Research (2023) ('National Statement') (2.2) addresses the issue of informed consent comprehensively. This guideline is intended to provide a summary relevant to MSH research projects but does not in any way supersede the National Statement.
- Ensure participant recruitment is carried out in a non-coercive and equitable manner whilst being mindful of power dynamics in relationships. During the recruitment process there are different ways to ensure the research practices are independent of clinical practices (e.g., the person performing the recruitment is independent from the lead investigator). It should always be made clear to potential participants that agreement or refusal to participate will not have any effect on their clinical care.

SCOPE

This guideline applies to all applicants seeking ethical approval for their research from the Metro South Human Research Ethics Committee (MSHREC). It is particularly pertinent to MSH employees and collaborators who conduct human research within or in association with MSH, or through access to MSH participants, health records or data.

GUIDELINE

1. PATIENT INFORMATION CONSENT FORM (PICF)

1.1 Informed Consent

- Participants must be given enough time to make an informed decision and have all questions answered prior to giving consent.
- Information provided to potential participants needs to be clear, explicit, and concise and in simple language. Consent must be obtained voluntarily, without manipulation, influence or coercion. It must also be made clear that a participant can revoke consent at any time, and that a decision not to

participate in the program will in no way compromise the standard of medical care the participant will receive.

- Prior to requesting signed consent, the Principal Investigator (PI) must ensure participants are provided with detailed information about the research.
- Research projects must take reasonable measures to avoid discrimination against or stigmatisation of a person, family, or group whether or not they have contributed to the study.
- During the informed consent process, participants should have the opportunity to meet with a health professional and/or appropriately authorised/qualified scientific employee to discuss the nature and scope of the research project. Participants should also be provided with the opportunity to discuss with appointed designees and/or research project personnel. The PI must ensure that such meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the research project.
- The research project design must ensure that potential participants are provided with reasonable time periods for providing their consent.
- Informed consent for the collection, retention and use of data and/or samples is a process that offers participants sufficient information to allow them to make an informed choice about whether to provide samples and data to the research project and agree, where applicable, to future research use.
- Consent must only be obtained under circumstances that provide the prospective participant or the participant's representative sufficient opportunity to consider whether or not to participate and minimises the possibility of coercion or undue influence.
- The information that is given to the participant or the representative must be understandable to the subject or their representative.
- During the informed consent process, the PICF should provide potential participants with sufficient information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation and can make an informed decision on whether to participate. This information should be presented so as to not constitute an improper inducement to participate in the research.
- The informed consent materials should be written in clear, concise and simple language. While the goal of the informed consent process should be to provide as much information as is relevant, the document provided must remain as straight-forward, readable and accessible as possible, with a reading level of grade 8 English/13 years old as a guide.
- All research projects submitted to MSHREC must develop a PICF at the time of establishment if their project involves the consenting of participants, substitute decision makers, other health professionals and/or carers.

1.2 Types of consent

- A MSH consistent approach to participant information and consent processes not only supports consistent practice and facilitates research, but also allows for the future use of data and/or samples for quality and research purposes as well as storage for future purposes.
- Voluntary and informed consent is a key mechanism for protecting the rights of the participants.

Consent encompasses the process that starts with initial contact and carries through to the end of the involvement of the participants in the research project.

- Consent may be obtained for a specific research project, such that the details of the project can be specifically outlined. Alternatively, consent may be obtained for unspecified future research (for which ethical approval will be sought), in which case general information about the possible future research uses are provided, in accordance with applicable national or local regulations and policies.
- Mechanisms must be in place to assure that future research uses of data and/or samples are consistent with the original consent (eg through review by a Human Research Ethics Committee (HREC) or other mechanisms consistent with applicable regulations and guidelines).
- Participant consent must be obtained unless waived by an authorised HREC constituted in accordance with applicable laws or regulations. Consideration should be given to providing participants with graduated consent options to allow varying levels of involvement.
- Consent should be recorded in writing when possible (and always when legally required). If the person giving consent is unable to write or is giving verbal consent, this should be clearly documented, including when consent was given and for what purposes. Consent should ideally be witnessed, normally by the researcher, signed by the witness and kept for future reference.
- Further, as will be elaborated below, in view of the limited consent that can be obtained at the time that samples and information are collected, research projects have an ongoing obligation to provide more information once it becomes available, for example, about who is accessing the resource and for what purposes.

1.3 Broad and enduring consent

- During the informed consent process, the research project must provide potential participants with sufficient information on the nature, implications, foreseeable risks and benefits of their participation, so that they can realistically assess the implications of their participation and can make an informed decision on whether to participate.
- Whilst it may not be possible to know details of specific research projects, efforts should be made to describe the nature and purpose of the research as specifically as possible. The amount of detailed information that can be provided to people when their consent is sought will vary depending on the nature of the collection.
- In the latter case, it will be important to provide clear information on the nature and purpose of the research project. When obtaining consent for use of data and samples in research, it is important to consider the potential value for future research.
- MSH recommends that broad and enduring consent (also known as generic consent), that is consent which is broad in both scope and time, should be sought whenever possible. This allows for efficient use of data and samples, fosters trust with participants and avoids the need to either obtain further consent at a later date or to use samples without consent.

1.4 Withdrawal of consent and/or permission

- Participants have the right to withdraw/revoke consent, either orally or in writing, to have their unused samples and data removed from the research project unless the data cannot be linked by the research project to participant identities.

- Participants must be informed that they may exercise their right to withdraw without any explanation being required and that there will be no negative consequences for themselves or their family regarding the provision of healthcare services. This includes paediatric subjects and their parents or legal guardians.
- The conditions under which a participant may make this request as well as the logistics for how a participant initiates this request must be specifically outlined in the informed consent document and documented process.
- At the time of consenting, participants must be informed of the various options. In some situations, the right to withdraw may be restricted, and participants should be informed of this.

1.5 Consent for existing collections

- Throughout the lifespan of the research project, the research use of samples and data should be consistent with the original informed consent or new consent should be sought, except where otherwise provided by ethical guidelines, domestic law and consistent with state, national and international legal norms.
- For a research project established from existing collections, the initiators or the PI should consider whether the intended scope and purpose of the research project and intended research uses are consistent with the original informed consent.

1.6 Feedback

- The release of non-validated results (aggregated or individual) from research using the research project to participants is not recommended. If the researcher decides it is ethically necessary to release the results advice should be given to the participant about the difference between research and clinical results, clarifying the need for clinical testing of research results.
- In certain circumstances, as permitted by applicable law and the appropriate authorities, where the participants may be provided with feedback of individual-level results arising from research, the research project should provide clear information to the participant of the consequences of receiving such results and should inform the participant of their right to opt out from receiving such results.

1.7 Aggregated results

- Consideration should be given to providing feedback to participants of aggregated results of the research as a minimum.
- Where individual feedback is allowed, possible and appropriate, participants should be able to decide whether or not to receive feedback of individual results arising from research. If individual results are given to participants the PI should ensure a trained professional gives this feedback or for counselling to be available to participants when this is appropriate.

1.8 Re-contact

- Participants must be provided, at the time of consent with information about the conditions under which they will be re-contacted if applicable. This should include the circumstances under which they will be re-contacted, whether re-contact is obligatory for participation in the research project, and by whom they will be re-contacted.

1.9 Re-consent

- There are situations where, although a patient's/participant's consent was given at the start of participation, new consent needs to be considered (there will also be circumstances where a research project holds samples and data obtained without specific participant consent); see Section 2.1 Waiver of consent. It may also be necessary to obtain fresh consent from participants if there are major changes to the research project. However, even where broad consent is obtained for prospective research projects, there may be circumstances in which there has been a major modification to the research direction for the research project such that it is of a fundamentally different nature to that initially proposed. In these circumstances, it may be appropriate to seek re-consent from participants or, where that is not possible, to seek waiver of consent from a HREC.

1.10 Payment

- Participants must not be paid for their participation in a MSH research project however, if approved by an accredited HREC, participants may be reimbursed for reasonable costs incurred in their participation in research (e.g., transport, parking and to be paid for their time), provided that the payment is not disproportionate or an inducement to take risks or participant in the research project.
- Refer to MSH work instruction WI2023-297 Gift cards (for use as research incentives) for more information.

1.11 Legally acceptable representatives, impartial witnesses or an intermediary

- When seeking consent, information for participants, legally acceptable representatives, impartial witnesses or an intermediary should be presented in a clear form that can be easily understood.
- Communication strategies must take into consideration the different needs of participants including health literacy.
- Lack of proficiency in the operating language should not disqualify participants. In this case, an intermediary competent in the language should translate the relevant information and the participant should acknowledge in his or her language an understanding of the research project, the extent of his or her participation, the risks involved and freely give consent.
- Where a potential participant lacks the capacity to consent (eg due to age or mental incapacity), a person or appropriate statutory body exercising lawful authority for that individual should be provided with relevant information to decide whether he or she will participate.

1.12 Registered health professional and/or appropriately authorised/qualified scientific employee

- A registered health professional and/or appropriately authorised/qualified scientific employee who witnesses the consent process; is not only certifying that the consent was given in their presence but is also stating that they are satisfied that the participant is aged 18 years or older, at that time the person was of sound mind, consent was freely given, and that medical advice has been duly furnished to the person.

2. LEGAL AND ETHICAL CONSIDERATIONS SPECIFIC TO PARTICIPANTS

- MSH research projects must ensure careful consideration is given to any special issues related to the participation of vulnerable populations or groups, including children, individuals with impaired decision-making capacity, and prisoners. For research relating to a large portion of a population (e.g., looking at the correlation between a specific heritage and a specific disease) the initiators and the research project PI must give consideration to the potential for discrimination not only for participants but also for

individuals, families and groups who have not participated. For example - it should be disclosed that individual and population-based genetic data may have repercussions for a participant, his/her family, a group he/she is part of and his/her community as a whole. It should be disclosed where these repercussions may include insurance or employment difficulties or a loss of dignity.

- Where substitute consent has been obtained for a participant lacking capacity (e.g., a minor or individual with impaired decision-making capacity), consideration will need to be given to what will occur once the participant gains or re-gains capacity to consent. In accordance with applicable law and ethical principles, consent may need to be obtained from the participant to continue in the research or to collect further data or samples from them or their withdrawal of consent.
- For example, particular consideration may be needed in situations where a minor has been recruited as part of family studies. Refer to MSH work instruction WI2023-299 Ethical and scientific review of research for more information.
- Prior to commencing research or collecting data the written PICF and any other written information to be provided to the participants must have the written approval of an appropriate HREC.

2.1 Waiver

- Consent must be given by an appropriate person. Usually this would be the participant themselves, or if they are not able to do so the appropriate substitute decision maker should be consulted.
- MSH acknowledges the importance of many existing collections (including pathology archives, data repositories, medical records) in supporting research, even when consent is not in place or is not practicable, desirable, or ethical to obtain retrospectively.
- There are also times when it is not practicable to obtain consent and it is considered ethical to include a participant in research without consent. In this case, research without consent can be undertaken provided the legal requirements are followed, the proposed use of samples, data or information (without consent) can be justified and use would be considered ethical and reasonable.
- Under certain circumstances, the MSHREC may provide a waiver of consent. Researchers must contact the MSHREC Coordinator to discuss the proposed research project and identify whether a waiver of consent is appropriate under relevant circumstances.
- Where the request for the Waiver of Consent is to conduct research on retrospective data, include the specific date period in the request (I.e. 1st January 2016 – 1st January 2018). These dates must be retrospective and prior to the submission date of the project.
- MSH proposes two (2) approaches to ‘reasonableness’:
    - The stronger test - would a reasonable person have refused to allow their data or samples to be used, if you had asked them?
    - Would a reasonable person be distressed if they discovered that their data or samples had been used without their consent?
- Researchers should consider both justification and reasonableness in proposals when intending to enrol a participant without consent and ensure that the confidentiality of all participants and their associated health and research information is maintained.
- For a Waiver of Consent to be considered by the MSHREC, the researcher must submit their

justification for the request via the HREA and the protocol and in doing so must address each individual criteria (a through to i) of Section 2.3.10 of the NHMRC National Statement, as per below:

- involvement in the research carries no more than low risk to participants
- the benefits from the research justify any risks of harm associated with not seeking consent
- it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
- there is no known or likely reason for thinking that participants would not have consented if they had been asked
- there is sufficient protection of their privacy
- there is an adequate plan to protect the confidentiality of data
- in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
- the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
- the waiver is not prohibited by state, federal or international law.

2.2 Communication strategies

- Consideration must be given to employing different communication strategies, formats and modes for providing information to participants during the informed consent process and during the lifespan of the research project. Where appropriate, participants should be provided with the opportunity to communicate with representatives of the research project, or as required designees.
- Communication strategies should take into consideration the different needs of the participants and that consideration should be given to employing different formats and modes for providing information to participants.
- One way in which to facilitate the consent process and help the participant make an appropriately informed decision is by providing an information sheet. This must be presented in a form that can be easily understood.
- Researchers must be aware that members of some ethnic or religious groups might find some types of research, or contribution of certain types of human material, unacceptable, which will influence the sensitivity of approach.
- When providing information various methods to provide information should be considered, whether during the consent process or to provide information to the public. Efforts should be made to employ the most environmentally sound and cost-efficient means of communications.
- Information and feedback of results to participants may be provided in different forms and in more than one form including: the publication of results, leaflets; annual reports; information sessions; newsletters; meetings with counsellors; television; radio; newspapers; internet blog sites or websites which may hold summaries of research findings and lists of publications.
- Decisions on the communications approaches to be employed should consider the diversity of the

targeted audience. Consideration should be given to technology issues (i.e., paper versions of the documents should be made available especially for those who are not familiar with technology), language issues (i.e., do the documents need to be translated into a language of a large segment of the population, even if it is not an official language) and diverse challenges (i.e., information may be more accessible for a portion of a population if it is made available in video format, and it may be more accessible for the visually impaired if converted into Braille script). Communication strategies should also consider the consent process for children.

- While it is recognised that for certain research projects it may not be possible for some information provided during the consent process to be made publicly available (e.g., protected or proprietary information) it should always be provided to potential participants.
- If, during the informed consent process, participants meet with staff from the research project, the PI must ensure the meetings are fair and neutral and do not, either directly or indirectly, create the potential for participants to feel pressure to participate in the research project.
- In certain circumstances, where decision makers are unable to attend consent discussions in the timeframe required then informed verbal consent may be appropriate for enrolment in research. The consent documentation must always be forwarded to the decision maker and where possible, signed consent subsequently obtained.

2.3 Incapacitation or death

- During a period of incapacitation or death the beliefs of the participant may not be known to the researcher, particularly where an enrolled patient is dying prior to written consent being obtained for a study they are enrolled in. Due sensitivity should always be shown when approaching relatives to ask for consent. Since consent is being sought at a particularly stressful time, relatives should wherever possible, be given time to reflect before making their decision, and it is particularly important that written information is provided for later reference. In some cases, the balance between the wishes of a deceased participant and those of the relatives may be difficult to reach (ie the relatives object despite consent from the deceased before death).
- In situations where it is known that a potential participant's illness is terminal, a relationship can be established between the participant, their relatives, and the research team before they die. This aids the communication of the wishes of the participant to their family and the researchers. The research team may wish to seek permission from the next of kin to be contacted after the death of the potential participant to inform them about the research. There are several ways to approach what should happen when a participant becomes incapacitated or dies. For example:
    - participants could be informed their samples and data will remain with the research project
    - participants could be offered the option for a legal representative to withdraw the participant
    - participants could be informed their samples and data will be made non-identifiable following notification of their death.
- In terms of confidentiality, identifiable participant information about a deceased person should continue to be treated as confidential.

2.4 Standard Operating Procedures (SOPs)

- The PI must ensure there are SOPs in place on participation that include:

- the effects, if any, of the patient's/participant's death or loss of legal capacity.
- feedback that will be provided to participants and if individual results and/or aggregate results will be provided.
- whether participants will be re-contacted during the course of the research project's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact (the process should ensure any re-contact permitted is not unduly burdensome for participants).
- whether researchers using its database(s) will be allowed to contact participants directly.
- whether, when and how a child's assent will be obtained and including what steps, if any, will be taken once the child becomes legally competent to consent.
- whether autopsy material will be collected, what will be collected and under what circumstances this will be carried out, and that the necessary legislative requirements are complied with.
- if samples and data will be made available for analyses developed from technological advancements made since the original consent was collected particularly if these analyses are not covered by the original consent.

- SOPs may also be implemented instructing personnel to not perform specific tests, this could include things such as paternity testing, HIV/AIDS testing or testing for the use of illicit substances.
- Research projects involving participants who are minors must have a clearly articulated SOP on whether, when and how the minor's assent will be obtained, in accordance with applicable law and ethical principles.
- Additionally, the research project should have a clearly articulated SOP on feedback and the nature of the feedback, if any, that will be provided to participants.
- SOPs must also be in place ensuring that any re-contacting is not unduly burdensome for participants and is carried out by research project representatives or designees trained in dealing with sensitive issues and impartial in regard to the outcome of the research.

3. PARTICIPANT INFORMATION AND CONSENT FORM

- Appropriate consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research and should be given appropriate information to be able to make this choice. Participants asked to consent to the research project should be properly informed, have capacity to make the decision to participate under no coercion or pressure, and understand the right to withdraw from the research at any time without giving a reason, and in the case of patients, without their future clinical care being affected.
- The informed consent materials should be written in clear, concise and simple language that is easy to understand by the participant. Information provided to participants during the informed consent process should be presented in a way so as not to constitute an improper inducement to participate in the research. Participants should be given time to consider the information provided before being asked to sign the consent document. Participants should also be provided with a copy of their signed consent document, where applicable. Prior to requesting signed consent, the PI must ensure potential participants are provided with information including (refer to the specific section for further details on

these recommendations).

- Set-up and management:
  - background information behind, and the purpose of the research project
  - the ethical and site specific assessment framework and management responsibilities
  - if the research project has been or is being established in collaboration with the private sector or if it is involved in collaboration for commercial purposes
  - the nominated PI of the research project
  - the purposes for which the data will be used and/or disclosed
  - any conditions where the nominated PI may change
  - storage facilities and duration of storage
  - any legal or intellectual property rights that might be material to their participation
  - clarification of ownership issues with respect to the samples, information and the collection
  - SOPs governing the collection, storage, use and outcomes from research on samples and data and/or details of how participants can obtain further information on the policies
  - sample or data transfer and disposal/destruction processes
  - the samples and data to be collected, and which samples and data will be collected from the participants or from other sources
  - if identifiable data and/or samples will be stored, the circumstances where it may be released and if data and/or samples may be released interstate or internationally
  - the duration of storage, transfer and disposal procedures, including, for international transfer of data where applicable
  - whether third parties may be given access to samples or data and the conditions under which this will occur such as insurers, employers or law enforcement agencies or for public health emergencies
  - the conditions under which law enforcement agencies may access data and/or samples and any legislation that may apply
  - the level of privacy and confidentiality protection to which their samples and data will be subject, the procedures and safeguards that will be employed for this protection, and of any specific risks of unauthorised access
  - of any commercialisation that will result from the research performed on the research project, the conditions of this commercialisation and how this applies to the participants
  - if the research project closes, the manner in which the samples and data will be destroyed or transferred and what will be done with the research project assets
  - the possibility of sharing samples and data with commercial entities, including those from other countries, and the publication of data and its availability on the internet
  - the process with respect to the sharing of benefits from the research.

- Nature of consent:
    - the nature of the consent that is being sought (whether it is specific, extended or unspecified) (National Statement, paragraph 2.2.14)
    - circumstances in which re-consent might need to be sought and/or in which a waiver of consent may be sought
    - communication strategies and whether participants will be re-contacted in the future, the circumstances in which re-contact will be permitted and the conditions that will govern re-contact
    - whether information from or about family members, in addition to that provided by participants, is required for the research
    - whether child participants will be involved and whether, when and how a child's assent will be obtained.
- Implications for participation:
    - the nature of participating and the implications
    - any foreseeable risks and benefits of their participation to themselves, their blood relatives and their community
    - where to find further information including details for contacting the PI
    - if participants are entitled to withdraw from the research, conditions of withdrawal and consequences
    - if feedback of results to the participants will occur and the type of results included
    - if the participant will be re-contacted and the conditions of re-contact
    - the risk of psychosocial harms such as distress or potential stigmatisation, and the possibility that research may create or augment the risk of stigmatisation or discrimination of groups
    - whether or not individual or aggregate research results will be released to the participant and/or his or her family or health care provider
    - arrangements for the samples and data in the event of incapacity or death of the participant
    - proposed arrangements in the event of the discontinuation of the research project.
- Withdrawal:
    - the right to withdraw, the available types of withdrawal, the implications of such withdrawal, and whether it will be possible to withdraw samples and data
    - the research participant's absolute right to withdraw consent
    - how this right is to be exercised (including relevant contact details)
    - what will happen if this occurs (including what is to happen with any remaining samples and data)
    - the limitations on withdrawal if the person's sample and data have already been distributed.
- Access and use:
    - the intended uses of the research project (including if it is to be used for non-research purposes

e.g., quality assurance and proficiency testing)

- the terms and conditions of access to the research project samples and data
- if specific types of data will not be recorded or specific types of tests are not allowed to be performed on research project samples
- data linkage, health and other records to be accessed and/or their intended uses (where the PI intends to access data for inclusion in the research project from health or other records, which data will be extracted from such records, by whom and through which processes, and for which uses the data will be employed)
- if the data collected, and that obtained from the research will be linked with health data collections or other data collections
- the form in which the data will be stored (identifiable, re-identifiable, non-identifiable) but noting that genetic material is in principle re-identifiable, even if identifiers are removed
- the policy with regard to access to samples and data by third parties such as insurers, employers or law enforcement agencies
- information for contacting the research project
- mechanisms in place for ethical oversight of the research, including, where relevant, details of the governance model of the research project.

See Attachment 1 for a detailed Patient Information and Compliance Tool which details items which must be included in a MSH PICF. PIs may utilise this document to ensure they are compliant with all principles outlined in the National Statement.

4. PICF DEVELOPMENT

- The PI must consider obtaining a consent that will permit data and/or samples to be used to address unforeseen research questions.
- Participants must be fully informed of the breadth of such consent and there must be additional safeguards in place to ensure that participants are protected.
- The PI must also consider ethical considerations specific to participants when developing relevant PICFs.

4.1 Templates

- MSH research projects may opt to utilise a PICF Template as opposed to developing a project specific material. PIs are able to fill in specific details relevant to their collection.
- The NHMRC has developed templates to serve as a starting point for the development of written PICFs for research conducted in Australia. Information can be added and removed from the templates as required. During the consent process participants must be provided with information about (including but not limited to):
    - The purpose of the program/project
    - The type, manner in which and expected amount/frequency of data and/or samples to be collected, as well as follow up procedures, if applicable, and data anticipated to be derived from the analysis.

- The potential users of the research project (academic and commercial users).
- Potential risks and benefits if any to the participant.
- Storage and duration of storage of samples and data (if required).
- As known, who will access data and/or samples, personal clinical and research information, what information will be obtained and how the participant's privacy and confidentiality will be protected.
- A statement outlining that the project has received ethical clearance from the MS HREC, as well as details of the MSHREC contact person (MSH HREC Coordinator, 07 3443 8047, MSH-Ethics@health.qld.gov.au).

- If developing a project specific PICF then all principles of the National Statement must be incorporated, and provisions outlined in this guideline may be utilised. The Participant Information and Consent Form Compliance Tool (Attachment 1) can be utilised to ensure compliance with the National Statement.

4.2 Research Complaints and Misconduct

- Researchers are responsible for including relevant contact details for the for the research project in the Participant Information and Consent Form (PICF). All PICFs for research projects being conducted in MSH must include the following paragraph:

  The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the principal study doctor on [Contact phone number] or any of the following people:

  Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	[Name of HREC]
HREC Executive Officer	[Name]
Telephone	[HREC Executive Officer Phone number]
Email	[HREC Executive Officer Email address]

  Local HREC Office contact (Single Site -Research Governance Officer)

Name	[Name]
Position	[Position]
Telephone	[Phone number]
Email	[Email address]

- Participants may utilise the listed contact details on a PICF to submit a complaint either verbally (in person or by telephone), or in writing to the research project team and/or the reviewing HREC. Alternatively, complainants can lodge a concern, allegation, or complaint with the MSH:

- Research Integrity Advisor (RIA) or Designated Officer (DO)
- HREC Chair or Coordinator
- Ethical Standards Unit / Human Resources
- Patient Liaison Officer /Patient Safety Quality Unit
- department/division contact
- relevant delegate.

- Refer to MSH procedure PR2023-411 Research excellence for more information.

4.3 Revision

- Any revisions to the informed consent form or the written information must receive the HREC approval in advance of use through the amendment process.
- Where subsequent use of samples or data is envisaged that would not be consistent with the original informed consent, a new consent should be obtained from the participant or from the appropriate substitute decision-maker, or a waiver of consent should be obtained from a HREC or an appropriate authority, in accordance with applicable law and ethical principles pertaining to the protection of human subjects.

RESPONSIBILITIES

Position	Responsibility	Audit criteria
Human Research Ethics Committee (HREC)	• Ethically review research project Human Research Ethics Applications (HREAs) and associated documents (e.g., research protocol, PICF and Curriculum Vitaes) when required.	N/A
Metro South Research	• Update MSH ethical and scientific review documents in accordance with MSH HREC requirements. • Provision of secretariat/administrative support to maintain and uphold principles outlined in the Research Policy Framework.	N/A
Principal Investigator/Coordinating Principal Investigator - responsible officer	• Principal Investigators must ensure prior, free and informed consent is obtained from each participant or where applicable, from an appropriate substitute decision-maker. • Ensure Standing Operating Procedures (SOPs) are in place regarding recruitment, participation, and the process of informed	N/A

	consent. • Have a clearly articulated SOP on whether participants may be re-contacted during the course of the research project's existence, the situations for which re-contact will be permitted, and the conditions that will govern re-contact.	
Employees, researchers, research student supervisors and students	• Adhere to all relevant policies, procedures, guidelines research protocols and Standing Operating Procedures (SOPs) when conducting research. • Are required to be aware of and comply with this procedure when conducting research.	N/A

DEFINITIONS

Term	Definition
Broad and enduring consent	Consent, which is broad in both scope and time, usually applicable to a wide range of future medical research use.
Informed consent	Informed consent is a process of communication between a patient and a clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the patient understands the care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option.
Participant	An individual who agrees to be involved in a research study/research project/clinical trial and provides data and/or sample/s in accordance with established medical criteria, procedures and practice and in compliance with the law including any privacy requirements. See 'Human research participant'.
Standard Operating Procedure (SOP)	An established procedure to be followed in carrying out a given operation or in a given situation.

RELATED AND SUPPORTING DOCUMENTS

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	Attachments
	• Attachment 1: Participant Information and Consent Form Compliance Tool

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the Human Rights Act 2019, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the Human Rights Act 2019 is available at: https://www.forgov.qld.gov.au/humanrights.

GUIDELINE DETAILS

Guideline Name	Research Participant Information and Consent Form (PICF)
Guideline Number	GL2023-100
Current Version	1.0
Keywords	Participant Information and Consent Form, PICF
Primary MSH or Directorate Procedure Reference	PR2023-413 Research administration and compliance
Executive Sponsor	Chief People, Engagement and Research Officer
Endorsing Committee / Authority	Metro South Health Research Council
Document Author	Manager, Research Development, Metro South Research
Next Review Date	December 2026

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	7/12/2023	14/12/2023	Chief People, Engagement and Research Officer	• Supersedes PR2017/115 Participant Information and Consent Form Procedure