Who must comply with this procedure?
Principal Investigator and all staff conducting research at, or under the auspices of Monash Health

This policy applies in the following setting:
This procedure is applicable to all Monash Health staff, patients, clients and their families and carers.

Background
Occasionally, research projects conducted at Monash Health involve patients staying at JMPH. JMPH is a wholly owned subsidiary of Monash Health and located on the premises of the Monash Medical Centre but it is a separate legal entity.

Examples where JMPH patients may be involved in research projects are as follows:

1. A pregnant woman may be recruited into a study which involves collection of cord blood. The delivery occurs at Monash Medical Centre and the sample is provided whilst they are at Monash Medical Centre. Then after the delivery, the Mother and baby stay at JMPH.

2. A JMPH patient undergoes a procedure where a stent is inserted into a coronary artery. The procedure is conducted at Monash Medical Centre. However, there may be some nursing care and blood sample collection following the procedure while the patient is recovering at JMPH.

1. Appropriate approvals and documentation must be in place in order for patients of JMPH to be participants in human research. Actions or documentation include the following:

   1.1 Discuss the project with the Chief Executive of JMPH or their authorized delegate.

   1.2 Any project documentation including the procedure as requested by the JMPH Chief Executive in order to make an informed decision as to whether JMPH would agree to involvement in the research study.

   1.3 A Form 4 approval document signed and dated by the Principal Investigator must be signed and dated by the Chief Executive of JMPH or their authorized delegate.

   1.4 Ethical approval for the project must be given by a National Health and Medical Research Council (NHMRC) accredited Human Research Ethics Committee (HREC).
   JMPH must be listed as a participating site on the HREC Review Only approval letter.

   1.5 Site Specific Authorisation of the project must be given by Monash Health.
   JMPH must be listed as a participating site on the Monash Health Site Specific Authorization letter.

   1.6 A Medicines Australia HREC Review Only Indemnity provided by the sponsor listing the Principal Investigator and Kitaya Holdings Pty Ltd (ABN 49 006 610 368).

   1.7 A Medicines Australia Standard Form of Indemnity provided by the sponsor indemnifying Kitaya Holdings Pty Ltd (ABN 49 006 610 368).

   1.8 JMPH must be included as a site in the research agreement signed between Monash Health and the sponsor of the study.

   1.9 A Clinical Trial Notification (CTN) must be submitted electronically to the Therapeutic Goods Administration (TGA) prior to commencement of any drug or device clinical trial.

Keywords or tags
Human Research, Ethics, Research Governance, Participants, Researchers, Committee, Indemnity.

Document Management
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Executive sponsor: Chief Medical Officer
Person responsible: Director, Research Governance