Research Involving the Jessie McPherson Private Hospital Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff including honorary appointees conducting or participating in research at, or under the auspices of Jessie McPherson Private Hospital (JMPH) or which involves Jessie McPherson Private Hospital staff, resources, patients, their tissue samples, test results or medical records.

PURPOSE

Occasionally, research projects conducted at Monash Health involve patients of Jessie McPherson Private Hospital (JMPH). JMPH is a wholly owned subsidiary of Monash Health and located on the premises of the Monash Medical Centre Clayton campus of Monash Health 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 Clayton, Monash Health and the sample is provided whilst they are at Monash Medical Centre Clayton. 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 Clayton, Monash Health. However, there may be some nursing care and blood sample collection following the procedure while the patient is recovering at JMPH.

DEFINITIONS

JMPH – refers to Jessie McPherson Private Hospital

Kitaya Holdings Pty Ltd refers to the legal parent of Jessie McPherson Private Hospital.

PRECAUTIONS/CONTRAINDICATIONS

All researchers at JMPH must strive to conduct research in the manner indicated in the Human Research Strategic Policy.

Appropriate approvals and documentation must be in place in order for patients of JMPH to be participants in human research.

STANDARD REQUIREMENTS

All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), National Statement on Ethical Conduct in Human Research (NHMRC 2018), Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016).

When undertaking any clinical interaction with a patient, staff are expected to;

- Perform routine hand hygiene. Refer to the Hand Hygiene Procedure.

- Introduce themselves to the Patient and Carer/ Family if in attendance
- Check patient identification. Refer to the Patient Identification Procedure.
- Obtain consent as per the Consent to Medical Treatment Procedure.
- Keep the patient/carer informed and involve them in decision making.
- Document interaction in the electronic medical record or health record using black pen; including date, time, signature and designation.

PROCEDURE

Actions or documentation include the following:

1. The project must be discussed with the Chief Executive of JMPH or their authorized delegate.
2. Any project documentation including the protocol 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.
3. A Supporting Department Certification by Head of Department form signed and dated by the Principal Investigator must be signed and dated by the Chief Executive of JMPH or their authorized delegate.
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.
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.
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).
7. A Medicines Australia Standard Form of Indemnity provided by the sponsor indemnifying Kitaya Holdings Pty Ltd (ABN 49 006 610 368).
8. JMPH must be included as a site in the research agreement signed between Monash Health and the sponsor of the study.
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.

BACKGROUND

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

KEY STANDARDS, GUIDELINES OR LEGISLATION

NHMRC *National Statement on Ethical Conduct in Human Research* 2007 updated *2018*

Australian code for the responsible conduct of research (NHMRC, 2018),

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6 (R2) (2016)

REFERENCES

Australian code for the responsible conduct of research (NHMRC, 2018),

KEYWORDS

Medical Treatment, Guardianship, Medical Treatment Decision Maker, Consent.

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