ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
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IONISING RADIATION

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005), by confirming the roles and responsibilities of researchers, medical physicists (including those delegated as radiation safety officers) and the HREC in the management of research protocols which involve additional ionising radiation.

Definitions

Additional ionising radiation is defined as exposure to any ionising radiation which is considered additional to normal standard care.

Healthy volunteer is defined as a person who is exposed to ionising radiation, who would not normally have done so for the purpose of standard clinical care.

Researcher is defined as the person who proposes to undertake a project involving administration of ionizing radiation to research participants.

Medical physicist is defined as the person responsible for verifying or assessing the total effective dose, organ doses and undertaking the radiation risk assessment.

Procedure

The Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) provides regulatory standards which must be met when humans are exposed to ionising radiation that is additional to that received as part of normal clinical management, for the purposes of research.

Therefore, the Code applies to research involving healthy volunteers and/or patients and includes but is not restricted to research with diagnostic/therapeutic agents and procedures, including Phase I, II, III and IV clinical trials and novel procedures on selected groups of research participants. However, the Code does not apply the use of radiation outside a research project; even if it involves the use of a novel procedure.

To ensure adherence to the Code, the roles and responsibilities for researchers, medical physicists (including those delegated as radiation safety officers) and the HREC have been defined.

Responsibilities of Researchers

As per Section 2 of the Code, the researcher must ensure that:

- Module 4 of the Common Application Form (CAF) is completed

- A radiation report is obtained from the Medical Physicist/Radiation Safety Officer at St Vincent's Hospital, and for doses which exceed the dose limitations, an independent assessment or verification must also be sought from a medical physicist to confirm the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol and which are additional to those received as a part of the research participant's normal clinical management; whether these will exceed the dose constraints; and the risks associated with the radiation exposure in accordance with Annex 1 of the ARPANSA guidelines .
- The Participant Information and Consent Form contains the appropriate statement delineating the risks associated with exposure to ionising radiation, as recommended by the Radiation Safety Officer
- Approval is obtained from the Human Research Ethics Committee (module 4, the Participant Information and Consent Form, and the radiation report must be included in the submission for review)
- The selection of participants is conducted according to the requirements of the Human Research Ethics Committee and the Code, giving special consideration to age, pregnancy and breastfeeding.
- The methodology ensures that the radiation dose to each research participant is kept to the minimum level practicable, and that projects which expose healthy participants includes only those persons who have not previously been or who are not currently exposed to radiation from research unless it can be demonstrated that the dose constraints outlined in the Code will be met when those previous and current exposures are taken into account.
- Research participants are provided with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure to enable the research participant to give informed consent. Where the research participant cannot give informed consent, including the case of a child, the researcher must provide the parent or guardian with sufficient written information about the purpose, methods, radiation dose, associated risks and any discomforts of the radiation exposure, and obtain the parent or guardian's informed consent.

The researcher must also prepare an application to the Human Research including the following information regarding radiation exposure:

- The reasons why it is necessary to expose research participants to ionizing radiation for the purpose of the research;
- The radiation dose assessment and risk assessment
- A statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program such as the programs of the Royal Australian and New Zealand College of Radiologists or of the Australian and New Zealand Association of Physicians in Nuclear Medicine;
- The precautions to be taken to keep radiation exposure to a minimum;
- The written information to be given to research participants relating to the doses and risks associated with the radiation exposure; and
- For novel uses of radiation, the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records.

The researcher must also advise the research participant to retain the information about the procedure including the radiation dose for at least five years in the case of an adult or, in the case of a child, to age 18 or for five years whichever is the longer period, so that it can be provided to researchers in any future research project involving exposure to ionizing radiation.

Responsibilities of the Medical Physicist
The medical physicist must independently verify the total effective dose and organ doses and radiation risk assessment which have been provided by the researcher; or assess the expected total effective dose and organ doses which will be received by the research participant as a result of their participation in the research and the corresponding radiation risks. Where the dose constraints are exceeded, the Medical Physicist must also obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

When undertaking the dose assessment or verification, the medical physicist must assess only those radiological procedures which are performed specifically for the research protocol and which would not form part of the research participant's normal clinical management, and take into account the technical specifications of the radiological procedures as detailed in the research protocol.

The medical physicist must prepare a written report, which includes the assessed or verified expected total effective dose and relevant organ doses; a statement as to whether the dose constraints are likely to be exceeded; an assessment of the risks associated with the expected radiation exposure; and specify any text on the radiation doses and risks to be included in the information provided to the research participants, consistent with Annex 2 of the ARPANSA guidelines.

Responsibilities of the HREC
When assessing research proposals involving ionizing radiation the Human Research Ethics Committee should consider the balance between the likely benefits and risks associated with any radiation exposure including consideration of the advice provided in Annex 1.

The Human Research Ethics Committee should pay particular attention to:

- The estimates of expected radiation doses and associated risks, which must have been calculated or verified by a medical physicist;
- The dose estimates and radiation risk assessments and opinion of an independent medical physicist where the dose constraints are exceeded;
- The manner in which the radiation doses and risks are provided to the research participants in the information sheet;
- The justification for the radiation exposure particularly if the radiation dose exceeds the dose constraints; and
- The measures to be taken during the project to assess the radiation doses actually received from novel uses of radiation where these may differ from the expected radiation doses and the arrangements for the retention of records of these doses.

Associated Procedures/Instructions
Nil

Reference Documents

- Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)

Authorized by:

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