University Hospitals Bristol and Weston NHS Foundation Trust

What is IRMER approval?

There is a legal requirement for the employer at the site where ionising radiation exposures are conducted to establish a governance framework to ensure compliance with IR(ME)R for research. It is the site's responsibility to confirm whether it can adhere to the research protocol.

For any research study, a research protocol will be written by the study sponsor, and a 'total research protocol dose' will be calculated. Before a participating site takes part in the study, a local review by a Medical Physics Expert (MPE) verifies that the site can deliver the research protocol within that radiation dose.

A local dose constraint will then be set, taking into consideration local practice and equipment.

Does my research trial need IRMER approval?

The Health Research Authority (HRA) defines a research exposure as one where **both** the following criteria are met;

a. The exposure is required as an integral part of, and for the purpose of, the research. This specifically includes
   i. exposures undertaken prospectively to confirm the eligibility of potential participants in the study and/or to provide (qualitative or quantitative) data regarding disease status at baseline; and/or
   ii. Radiotherapy as part of a treatment strategy to which patients are assigned prospectively by the protocol, either as part of an experimental or control arm, and which will be evaluated by the study;
   and/or
   iii. exposures undertaken at formal time points within the trial protocol schedule to assess disease status or response to treatment;
   and/or
   iv. exposures where there are clear requirements as to how they should be conducted e.g. machinery to be used, imaging slice thickness;
   and/or
   v. image-guided procedures undertaken whilst the patient is enrolled in the study

b. Consent for the exposure is sought from potential participants as part of their consent to take part in the research (including screening for eligibility).

Exposures which meet these criteria are considered to be research exposures **even where they would otherwise be part of normal clinical care** for patients in the same population treated outside the research setting, **and whether or not research participation will result in 'additional' exposure** over and above routine care.

If you will be using information from the exposure as data for the purposes of the study e.g. to provide (qualitative or quantitative) data regarding disease status, **then it is a research exposure**.

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Still not sure if the exposure is a research exposure?

In some cases, study protocols may refer to other radiation exposures, which are administered as part of clinical care outside the study rather than as research exposures.

Such exposures are **not** research exposures **provided that**:

- They are authorised in the course of normal clinical care, not for research purposes;
  and/or
- The decision to authorise the exposures is clearly separated from the decision to include the participant in the research and is not determined prospectively by the research protocol;
  and/or
- Consent for the exposure is not sought as part of the consent to take part in the research or to be screened for eligibility;
  and/or
- The information obtained from the exposure is not used as data for the purposes of the study e.g. to provide (qualitative or quantitative) data regarding disease status.

Information supplied by

Medical Physics Experts, University Hospitals Bristol and Weston NHSFT using:

IR(ME)R Implications for clinical practice in diagnostic imaging interventional radiology and diagnostic nuclear medicine

Ionising radiation - Health Research Authority (hra.nhs.uk), November 2022