University Hospitals Birmingham
NHS Foundation Trust

CONTROLLED DOCUMENT

# Ionising Radiation (Medical Exposure) Regulations 2017

# Procedure 8: Biomedical and Medical Research Programmes Involving Exposure to Ionising Radiation

Required under IR(ME)R 2017 Regulation 6 & Schedule 2 (g)

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| **CATEGORY:** | Procedure |
| **CLASSIFICATION:** | Health & Safety, Clinical Governance |
| **PURPOSE:** | For determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure. |
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| **Version Number:** | 3.0 |
| **Controlled Document Sponsor:** | Chief Operating Officer |
| **Controlled Document Lead:** | Chair to the Radiation Safety Board |
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| **Distribution:**<br>• **Essential Reading for:** | Staff who are designated as an IR(ME)R practitioner and/or operator.<br><br>Staff in training to become an IR(ME)R practitioner and/or operator<br><br>Managers of IR(ME)R practitioners and operators |

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| • **Information for:** | Any staff involved in research trials that require the use of procedures using ionising radiation; this includes Principle Investigators, Chief Investigators, Trial Co-ordinators, Trust Research,Development and Innovation Department<br><br>General managers of departments and areas that perform procedures involving ionising radiation |

## Contents

## 1. Procedure Statement

1.1 To enable the Trust to comply with the requirements of the Ionising Radiation(Medical Exposure) Regulations 2017 for radiation exposures taken as part of medical and bio-medical research trials, especially Regulations 11(1) and 12(4).

## 2. Scope

2.1 This procedure applies to any “research exposure” involving ionising radiation including imaging (diagnostic x-rays, CT scans or DXA scans), radiotherapy (including brachytherapy and therapy using unsealed sources) and radionuclide imaging (including diagnostic imaging and in vitro measurements).

2.2 A “research exposure” is any exposure required by the research protocol. It includes all exposures carried out on the participant as determined by the protocol, including those which would otherwise be part of the routine clinical care of patients treated outside the research setting.

2.3 UHB may be the lead site for the trial, or may be a participating site in a trial led by another centre. In any case, this procedure must be followed in order to ensure that the Trust is complying with IR(ME)R 2017

2.4 Guidance is available at: https://www.myresearchproject.org.uk/help/hlpradiation.aspx

2.5 Research exposures may be undertaken on:

- Patients who may directly benefit from the research; in which case a target dose level for the research exposures must be established
- Patients who agree to take part in procedures which will not benefit themselves directly, in which case a dose constraint for the research exposures must be established
- Healthy volunteers, in which case a dose constraint for the research exposures must be established
- Research exposures include exposures required by the *screening procedures* for research.

2.6 Trial exposures being undertaken by UHB on behalf of external referring centres are within the scope of this procedure.

2.7 In some cases, the *selection criteria* for participants refer to exposures received outside the study but the study procedures themselves do not

include any exposures. Such exposures may be considered normal clinical exposures rather than research exposures, and are therefore outside of the scope of this procedure, provided:

- Exposures are justified under IR(ME)R and undertaken in the course of normal clinical management and the decision to justify the exposures is clearly separated from the decision to include the participant in the research.
- Consent for such exposures is not sought as part of the consent to take part in the research.
- The information obtained from the exposure is not used as data for the purposes of the study.

## 3. Purpose

3.1 The single ethical review by the Research Ethics Committee (REC) addresses the radiation issues in the study as a whole i.e. all the ethical issues relating to radiation exposures will be addressed in the application. A favourable ethical opinion by a REC does not replace the statutory requirement within IR(ME)R 2017 for exposures to be individually justified by a practitioner. Studies involving radioactive materials must also have prior approval by the (Administration of Radioactive Substances Advisory Committee, ARSAC).

3.2 No research exposures may be undertaken until the trial has been approved by the REC and where applicable, ARSAC, alongside relevant Trust approval..

3.3 Research Participants must be informed of the risks associated with the research exposures and must participate voluntarily.

3.4 All research exposures must be clearly identified as such at the time of referral.

3.5 All research exposures within UHB must be individually justified by a local IR(ME)R practitioner.

3.6 Where UHB is the lead site for a trial, the Chief Investigator (CI) must identify a Clinical Radiation Expert (CRE). Guidance can be found on the NHS Health Research Authority (HRA) website at Radiation Assurance - Health Research Authority (hra.nhs.uk). The CRE will:

- Assess whether the exposures required for the research exceed the number required for normal clinical management
- Where additional exposures are required, advise on their suitability to the objectives of the study.

3.7 Where UHB is the lead site for a trial, the Chief Investigator (CI) must identify a Medical Physics Expert (MPE). Guidance can be found on the NHS Health Research Authority (HRA) website at Radiation Assurance -

Health Research Authority (hra.nhs.uk). The MPE will:

- Calculate the dose from each examination
- Calculate a total protocol dose, indicating what proportion of this dose is in excess of normal clinical practice
- Advise on a dose constraint or target dose, as appropriate
- Advise on the level of risk associated with the radiation dose

3.8 Where applicable, the CRE and MPE identified above will prepare all appropriate material for the REC submission and/or IRAS (Integrated Research Application System) or CWOW (Combined Ways of Working) documentation including ARSAC application

3.9 Where UHB is a participant site in a multi-centre trial the local research governance process must confirm to the Trust Research, Development and Innovation Department (RD&I) that:

- The Trust is able to comply with the agreed protocol
- All research exposures for participants at UHB have been identified to the REC and are ethically approved by the REC
- Confirm that local doses will not exceed the dose constraint/ target doses estimated in the REC application
- Confirm that the Participant Information Sheet (PIS) accurately informs individuals about the risks of the exposure. This applies to all participants regardless of whether the exposures are additional to normal care. Participants should be informed of the whole burden clarifying the element that is additional to normal care.
- Advise whether any exposures requiring the administration of radioactive materials (including brachytherapy) is covered by existing IR(ME)R licences (ARSAC) for research or would require an application for new or modified Practitioner Licence and/ or Employer Licence for the medical radiological installation.

3.10 If the Trust cannot comply with the above points, it will either be unable to participate in the trial or the matter should be discussed with the lead clinical radiation expert/ medical physics expert. If concerns cannot be resolved the principal investigator may need to refer the issue to the chief investigator for the trial - if appropriate, a Notice of Substantial Amendment may be submitted to the REC either for the whole study or for a particular site.

## 4. Responsibility

The *local principal investigator* of a trial is responsible for ensuring that:

4.1 A Local Research Approval form is started and relevant sections completed for the trial to permit review by the imaging department. This includes providing the necessary documentation (e.g. trial protocol,

research application form (IRAS/CWOW), PIS) and other relevant information required by the local research approval standard operating procedure.

4.2 This responsibility includes discussing the trial as necessary with suitable IR(ME)R Practitioners and local Medical Physics Experts. The Research Nurse and/or Trial Coordinator may undertake some of these tasks and completion of the form/local IR(ME)R approval is supported through the Imaging Research Team.

4.3 The study protocol is adhered to (i.e. no procedures involving radiation other than those described in the protocol will be requested) and ensuring that the inclusion/exclusion criteria are applied.

4.4 Subjects participate voluntarily and are informed in advance about the risks of exposure.

The lead *IR(ME)R practitioner*(s) identified for the trial is responsible for:

4.5 At the time of study consideration, confirming that the Trust can adhere with the trial protocol in relation to the radiation exposures requested.

4.6 Ensuring that additional exposures at UHB have been identified in the REC application and ethically approved by the REC and any additional exposures are justified

Individual *IR(ME)R practitioners* are responsible for:

4.7 Following approval of the trial, justifying any medical exposure involving ionising radiation for research.

4.8 Alternatively, the lead IR(ME)R Practitioner may choose to produce guidance to permit an operator to authorise each exposure as per IR(ME)R requirements.

The *local IR(ME)R licence holder* (ARSAC) is responsible for:

4.9 At the time of study consideration, confirming that the Trust can adhere with the trial protocol in relation to the radiation exposures requested.

4.10 Ensuring that additional exposures at UHB have been identified in the REC application and ethically approved by the REC and any additional exposures are justified.

4.11 Ensuring that they hold a current IR(ME)R license (ARSAC) with all applicable procedure codes included within the study and that these are authorised for research on their license. They will confirm that all procedure codes for research are also held on the Employer's IR(ME)R License for the site.

4.12 Following approval of the trial, the IR(ME)R license holder (ARSAC) (entitled as per IR(ME)R Employer's Procedure 2) must justify any medical exposure involving ionising radiation for research.

4.13 Alternatively, they may choose to produce guidance to permit an operator to authorise each exposure as per IR(ME)R requirements.

The local *Medical Physics Experts* (MPE) is responsible for:

4.14 Confirming that the Trust can carry out the exposures required for the trial within the estimated range of doses made by the lead MPE

4.15 The MPE will also check that the PIS accurately reflects the additional radiation dose and risk and can also give general advice on compliance with IR(ME)R.

The *Trust RD&I Department* is responsible for:

4.16 Ensuring that the Local Research Approval form has been suitably completed and submitted before moving forward to Trust approval.

The *referrer* of individuals for medical exposures as part of a research study is responsible for:

4.17 Providing sufficient demographic details to allow the patient to be identified, in accordance with IR(ME)R Employer's Procedure 2.

4.18 Giving a clear indication on the referral that the exposure is required for research for this reason (see IR(ME)R Employer's Procedure 2).

4.19 Clearly identifying the trial for which the exposure is being undertaken.

4.20 Clearly indicating the exposure protocol to be used, if different from standard practice

The *operator* initiating the exposure is responsible for either:

4.21 Ensuring that each individual exposure is justified by a Practitioner or;

4.22 Authorise the exposure according to the guidelines issued by the IR(ME)R practitioner.

4.23 Using techniques so that doses are optimised and therefore local dose constraint/target doses are adhered to.

4.24 Performing the appropriate exposure protocol, as indicated in the referral, if different from standard practice

## 5. Practice

5.1 The Local Research Approval form has been designed to enable the Trust to comply with its responsibilities under the IR(ME)R 2017

regulations. Electronic versions of the form are available from the Trust Intranet.

5.2 A Standard Operating Procedure describing the steps of the approval is held in the quality management system of the relevant department.

## 6. Contingencies

6.1 Any failure in compliance with this procedure must be reported to the relevant Divisional General Managers or Medical Physics Expert in their absence. Failure to comply with the above procedure may result in the Trust's Disciplinary Policy being invoked.