

SPECIMEN IR(ME)R 2000 PROCEDURE

PROCEDURE FOR THE CONDUCT OF MEDICAL RESEARCH (IR00SC8a)

APPROVED BY: _____ REVISION : 0 DATE EFFECTIVE : OCTOBER 2000

Employer:NHS Trust

Establishment:Hospital/Clinic

Department:

Purpose

To identify considerations when carrying out a radiation exposure as part of a research programme.

Scope

Applies to all persons exposed to radiation as part of a medical or biomedical research programme.

Responsibility

It is the responsibility of the practitioner to ensure compliance with this procedure.

Procedure

1. All research programmes must have approval from the Local Research Ethics Committee (LREC) before commencing.
2. Each research project involving exposure to individuals for whom no direct benefit is expected from the exposure must be subject to a dose constraint. The proposed dose constraint should be included in the submission to the LREC. The dose constraint should be based on the total dose from all radiodiagnostic procedures included in the protocol and must not be exceeded.
3. All volunteers must be screened to ensure suitability. Pregnant women and children should not normally be accepted as volunteers unless the project concerns their population group specifically. Adults who lack the capacity to consent must be excluded as volunteers, as normally should radiation workers and healthy volunteers who have taken part in any other research projects during the previous year.
4. The risks of the exposure must be communicated to the volunteers by the practitioner and confirmed by the operator prior to any radiation exposure.
5. Practitioners who authorises a research exposure must:
 - a) satisfy themselves that the subjects participate voluntarily
 - b) ensure that the subjects are informed in advance about the risks of exposure
 - c) where no direct medical benefit for the individual is expected from the exposure, ensure that the employer's dose constraint is adhered to
 - d) where there is a direct benefit, plan a target for the dose to an individual volunteer.
6. As for standard medical radiation exposures, there should be a record of the exposure factors or administered activity, to enable an estimate of the effective dose to the individual and to ensure compliance with the dose constraint.

