

Application for ethical approval – Annex 11

Radiation dose annex

11. Information about radiation doses

11.1 Assessment of anticipated benefit

Make your own assessment of the anticipated benefit of the study according to the table below. You must indicate which category you consider the study falls under and also give reasons for your assessment.

Category	Anticipated benefit
I	The research will only result in increased knowledge. The research may not result in improvement to health.
IIa	The research will lead to increased knowledge, which in turn may lead to improvement to health.
IIb	The research will result in medical conditions being relieved or cured.
III	The anticipated benefit of the research is significant and usually involves a direct link to knowledge that may save lives or prevent or limit severe medical conditions.

Category	Reasons for selection of category

11.2 Summary of radiation doses from x-ray procedures and nuclear medicine investigations

X-ray procedures include diagnostic radiology, interventional radiology and x-ray fluoroscopy.

Procedure or investigation	Effective dose per investigation (mSv)	The number of additional investigations and procedures which participation in the study involves	Effective dose that being part of the study (mSv) additionally involves

Total effective dose from the investigations which participation in the study additionally involves	
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11.3 Critical organs

Radiation therapies and certain x-ray procedures may involve a risk of radiation-related side-effects whereby organs may be damaged. Organs that will receive a radiation dose involving a particularly increased risk (e.g. cancer) may be stated here – complete if relevant.

Procedure, investigation or method of treatment	Organ	Side effect	Absorbed dose (Gy)