As per Health Information and Quality Authority Guidance on Dose Constraints in Medical Exposures to Ionising Radiation, 20 February 2020,

"An undertaking shall ensure that dose constraints, as specified or approved by an ethics committee on a case by case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety for persons. The European Commission Guidance on medical exposures in medical and biomedical research (Radiation Protection 99) and International Commission on Radiological Protection ICRP 103 guidance documents provide useful information for ethics committees when reviewing potential research projects involving the use of ionising radiation. **Ethics committees must consider the radiation dose to the individual and the potential benefit to society.** Each dose category acts as a dose constraint as long as the potential societal benefit is commensurate. For example, a project subjecting individuals to an effective radiation dose of 6 mSv should only be granted ethical approval if there is a moderate societal benefit arising from the exposure such as directly aiding the diagnosis cure or prevention of disease. More information is given in Table 2."[1]

General guidance

For medical or biomedical research involving medical exposure:

- the potential benefits should outweigh the hazards
- the potential subject is able to consent, knowingly and willingly, having appreciation and understanding of the relevant facts which should include:
  - aims
  - methods
  - benefits
  - potential hazards
  - any potential discomfort[10]
- a reliable assessment of the likely doses to be delivered must be made.[9]
- the use of ionising radiation should only be undertaken by practitioners after approval by an ethics committee in line with the regulations [4]
- approval should only be granted in such cases as potential hazards involved are judged to be predictable[9,11]
- in circumstances where the dose might exceed the level for tissue reactions, such as interventional radiology and radiotherapy, the risk of tissue reactions must be considered and suitable methods to avoid such adverse reactions taken.[11]

[1] Page 7-13

Table 2. Effective dose categories/constraints, detriment probability and societal benefit

Effective Dose Categories*	Probability of detriment from exposure	Potential benefit to society
Less than 0.1mSv	One in a million, or less	Minor — This category involves a level of risk which can be considered as trivial. The level of benefit to society from exposures at this level may be minor and include investigations whose primary aim is just to increase knowledge.
0.1–1 mSv	One in a hundred thousand	Intermediate — This category carries a risk of an adverse effect of the order of one in a hundred thousand. The benefits from such an exposure would expect to increases knowledge and lead to a health benefit.
1–10 mSv	One in ten thousand	Moderate — An exposure in this dose category carries a risk of one in ten thousand to the irradiated individual. Therefore, to justify such an exposure the benefit to society would be expected to directly aid the diagnosis, cure or prevention of disease.
Greater than 10 mSv	Greater than one in a thousand	Substantial — For an irradiated individual having received doses in this category, the probability of an adverse effect occurring are in the order of one in a thousand. This level of risk might be considered as verging on unacceptable for continued or repeated exposure. Justification of exposures in this category would usually be directly related to the saving of a life or the prevention or mitigation of serious disease. Doses should not exceed the threshold for tissue reactions.

*For adults over 50 years, the effective dose can be increased by a factor of five to ten. In the case of children, the effective dose should be reduced by a factor of two to three.