National Research Ethics Committee for Clinical Trials

Appendix form: Clinical trials of investigational medicinal production in combination with exposure to radiation

Version 1.0

**Instructions**

* This Appendix must be submitted along with the main application form for ethics review to clinicaltrials@nrec.ie .
* All sections of the Appendix form should be completed. If a section does not apply, select “No” or “N/A”, or enter “N/A” in the text box, as appropriate.
* Digital signatures are accepted and encouraged.
* Please provide a copy of this Application and Appendix to your Research Office or equivalent body in your research institution
* All communications to the NRECs should be directed to the National Office via clinicalrials@nrec.ie

1.0 General

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| 1.1 (a) Does this study involve exposure to radiation?  |
| [ ]  Yes [ ]  No |  |

If answer is no, please do not complete this NREC-CT appendix form.

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| 1.1 (b) If yes, please specify:  |
| i) Exposure to radioactive materials | [ ]  Yes [ ]  No |
| ii) Therapeutic ionising radiation | [ ]  Yes [ ]  No |
| iii) Diagnostic ionising radiation  | [ ]  Yes [ ]  No |
| iv) Other | [ ]  Yes [ ]  No | Details: | Click or tap here to enter text. |

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| 1.2 (a) Does this study involve additional radiation exposure other than normally received as part of standard care?  |
| [ ]  Yes [ ]  No |  |

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| 1.2 (b) If yes, please describe.  |
| Answer: | Click or tap here to enter text. |

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| 1.3 Please specify if this study is due to take place at a:  |
| i) Radiation oncology unit | [ ]  Yes [ ]  No |
| ii) Diagnostic imaging facility  | [ ]  Yes [ ]  No |
| iii) Clinical laboratory  | [ ]  Yes [ ]  No |
| iv) Academic research centre  | [ ]  Yes [ ]  No |
| V) Other | [ ]  Yes [ ]  No | Details: | Click or tap here to enter text. |

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| 1.4 Has each study site/institution in the republic of ireland been licensed by the radiation protection society of ireland?  |
| [ ]  Yes [ ]  No |  |

2.0 Radiotherapy trials

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| 2.1 Does the study involve exposure of patients to radiotherapy?  |
| [ ]  Yes [ ]  No |  |

If answer is no, please skip the remaining questions in subsection 2.0.

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| 2.2 (a) Is the planned radiotherapy part of standard treatment or is it experimental in terms of dose / technique / rationale? |
| [ ]  Standard treatment [ ]  Experimental |  |

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| 2.2 (b) If experimental, please elaborate.  |
| Answer: | Click or tap here to enter text. |

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| 2.3 In relation to the radiotherapy please provide details of the following: |

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| 2.3 (a) Dose delivery technique to be used e.g. 3-dcrt (3-dimensional conformal radiation therapy), imrt (intensity modulated radiation therapy). |
| Answer: | Click or tap here to enter text. |

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| 2.3 (b) Imaging/verification technique to be used e.g. Igrt (image guided radiation therapy) etc.  |
| Answer: | Click or tap here to enter text. |

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| 2.3 (c) Radiation treatment schedule:  |
| (i) Total dose: | Click or tap here to enter text. |
| (ii) Dose per fraction  | Click or tap here to enter text. |
| (iii) Number of fractions per day  | Click or tap here to enter text. |

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| 2.3 (d) Expected spectrum of acute and long-term radiation-induced side effects |
| Answer: | Click or tap here to enter text. |

To the radiotherapy please provide details of the following:

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| 2.4 Radiotherapy planning |

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| 2.4 (a) Planning volumes of interest (tumour related volume and organs at risk) |
| Answer: | Click or tap here to enter text. |

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| 2.4 (b) Planning dose volume constraints (dvcs) for organs at risk (oars). |
| Answer: | Click or tap here to enter text. |

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| 2.4 (c) Details of patient positioning/set-up/immobilization, inclusive of pre-treatment preparation e.g. Bladder filling protocol, iv contrast etc. |
| Answer: | Click or tap here to enter text. |

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| 2.4 (d) Details of radiotherapy plan evaluation parameters (i.e. Planning target volume [ptv] coverage) |
| Answer: | Click or tap here to enter text. |

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| 2.4 (e) What toxicity scoring criteria are to be used? |
| Answer: | Click or tap here to enter text. |

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| 2.5 For experimental radiotherapy, please provide the following information: |
| (a) Standard alternatives. Please ensure to detail and contrast the experimental protocol with ‘standard’ therapy. |
| Answer: | Click or tap here to enter text. |
| (b) Potential additional risks/toxicities associated with the experimental protocol.  |
| Answer: | Click or tap here to enter text. |

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| 2.6 (a) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. Physics quality assurance (beam and dose). |
| Answer: | Click or tap here to enter text. |

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| 2.6 (b) Radiotherapy quality assurance at delivery: please describe the quality assurance programme i.e. Clinical quality assurance. |
| Answer: | Click or tap here to enter text. |

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| 2.7 Clinical monitoring/assessment during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study / trial. |
| Answer: | Click or tap here to enter text. |

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| 2.8 Criteria for radiotherapy adverse event reporting  |
| Answer: | Click or tap here to enter text. |

3.0 Radionuclides

Please complete the tables below for each radionuclide to be administered.

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| 3.1 (a) Will any of the study participants be patients? |
| [ ]  Yes [ ]  No |  |

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| Details of patients to be studied: |
| Number (whole study) | Age range | Sex | Clinical condition | Total effective of target tissue dose per individual |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

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| 3.1 (b) Will any of the study participants be healthy volunteers? |
| [ ]  Yes [ ]  No |  |

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| Details of healthy volunteers to be studied |
| Number (whole study) | Age range | Sex | Total effective dose per individual |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

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| 3.2 Dose and risk assessment |

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| 3.2 (a) What is the total research protocol dose from the exposure (if any)?  |
| Answer: | Click or tap here to enter text. |

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| 3.2 (b) What component of this is the additional dose over and above standard practice? What are the risks associated with this dose?  |
| Answer: | Click or tap here to enter text. |

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| 3.2 (c) Declaration by medical physicist (for section 3.0 radionuclides).I am satisfied that the information in sub-section h3.1 and the assessment in sub-section 3.2 provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks.  |
| Signature: |  |
| Date: | Click or tap to enter a date. |
| Print name: | Click or tap here to enter text. |

4.0 Clinical assessment

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| 4.1 Will the exposure exceed the exposure that might be received as part of normal care?  |
| [ ]  Yes [ ]  No |  |

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| 4.2 Assessment of additional exposure |

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| 4.2 (a) Please explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation. |
| Answer: | Click or tap here to enter text. |

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| 4.2 (b) If pregnant or breastfeeding mothers are to be studied give reasons and details of special radiation protection measures to be taken. |
| Answer: | Click or tap here to enter text. |

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| 4.3 Declaration by radiation oncologist.I am satisfied that the exposure to ionising radiation planned in this research study (as defined in sub-section 2.0 and/or 3.0) is reasonable and that the risks are adequately described in the participant information sheet for the study. |
| Signature: | Click or tap here to enter text. |
| Date: | Click or tap to enter a date. |
| Print name: | Click or tap here to enter text. |