Appendix One – Research Involving the Use of Ionising Radiation/X-rays

Please complete and attach this appendix to your application if your study involves ionising radiation (radionuclide materials, diagnostic or therapeutic ionising radiation). If your study involves both radioactive materials and other ionising radiation, please complete both part A and B. It is advisable to discuss the proposed research at an early stage with (a) a Practitioner who can justify any additional exposure under The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) and (b) a specialist Radiation Protection Adviser/Medical Physics Expert.

PART A – Radioactive Materials

1. Which radiopharmaceutical materials will be given?

*Give details by completing the table below.*

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Radiopharmaceutical</th>
<th>Quantity (MBq)</th>
<th>Route</th>
<th>Frequency per subject</th>
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</thead>
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2. What is the dose constraint (where there is no direct benefit to the individual) or individual target level of dose (where there is expected benefit) expressed as the effective dose (mSv) or target tissue dose (Gy) from these exposures for the participant? A copy of the dose and risk assessment prepared by the Radiation Protection Adviser/Medical Physics Expert should be enclosed with the application.

3. Is an ARSAC certificate required for the research?  

| Y | N |
### 4. Name and signature of person acting as Radiation Protection Adviser/Medical Physics Expert for the radioactive materials exposure

<table>
<thead>
<tr>
<th>Name:</th>
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<tbody>
<tr>
<td>Position:</td>
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<tr>
<td>Address:</td>
</tr>
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<td>Telephone:</td>
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<td>Email:</td>
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<td>Fax:</td>
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</tbody>
</table>

I am satisfied that the above dose information is a reasonable estimate.

Signature:  
Date (dd/mm/yyyy)

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### 5. Justification of radioactive materials exposure by IRMER Practitioner

This section should be completed by a Practitioner who can take responsibility for these research exposures in accordance with the requirements of IRMER.

#### 5.1 Will the exposure exceed the exposure that might be received as part of normal care at any proposed research site?

| Y (please complete 5.2) | N |

#### 5.2 Justification of additional exposure

Explain how the planned exposure compares with normal practice and justify the additional element in 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.

#### 5.3 Declaration by Practitioner

I am satisfied that the exposure to radioactive materials planned in this research study (as defined in A1) is justified and that the risks are adequately described in the participant information sheet for the study.

Signature:  
Date (dd/mm/yyyy):  
Name:  
Address:  
Telephone:  
Email:  
Fax:
PART B- Other Ionising Radiation

1. Will the research participant be exposed to any other ionising radiation not listed in A1?
   
   Give details by completing the table below:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Examination</th>
<th>No of Examinations</th>
<th>Estimated maximum dose</th>
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</table>

2. What is the dose constraint (where there is no direct benefit to the individual) or individual target level of dose (where there is expected benefit) expressed as the effective dose (mSv) or target tissue dose (Gy) from these exposures for the participant?

   A copy of the dose and risk assessment prepared by the Radiation Protection Adviser/Medical Physics Expert should be enclosed with the application.

3. Name and signature of the person acting as Radiation Protection Adviser/Medical Physics expert

   Name:

   Position:

   Address:

   Telephone:

   Email:

   Fax:

   I am satisfied that the above dose information is a reasonable estimate.

   Signature:

   Date (dd/mm/yyyy)
4. Justification of exposure by IRMER Practitioner
This section should be completed by a Practitioner who can take responsibility for these research exposures in accordance with the requirements of IRMER. The justification should cover potential exposure at all research sites, taking account of possible variation in normal clinical practice. The guidance notes give advice to Chief Investigators on who can act as a Practitioner and advice for Practitioners on the application of IRMER to research.

| 4.1 Will the exposure exceed the exposure that might be received as part of normal care at any proposed research site? | Y (please complete 4.2) | N |

4.2 Justification of additional exposure
Explain how the planned exposure compares with normal practice and justify the additional element in 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.

5.3 Declaration by Practitioner
I am satisfied that the exposure to ionising radiation planned in this research study (as defined in B1) is justified and that the risks are adequately described in the participant information sheet for the study.

Signature:
Date (dd/mm/yyyy):
Name:
Position:
Address:

Telephone:
Email:
Fax: