**CWoW Ethical Considerations Form**

**How to use this document**

This document should be complete for all applications which are being submitted under the Combined Ways of Working Pilot. Please complete the document and upload a PDF version as a supporting document.

Please ensure that the IRAS ID, Document Date and Version have been completed.

Sections which are not appropriate should be marked as Not Appropriate / NA.

1. **Interventions**

**1.1 Non-clinical interventions**

Please complete the columns for each intervention/procedure as follows:

1. Interventions/procedures to be received by each participant as part of the research protocol

2. Number of interventions/procedures which are part of standard care.

3. Number of interventions/procedures which are additional to standard care

4. Total number of interventions/procedures

5. Average time taken per intervention/procedure (minutes, hours or days)

6. Details of who will conduct the intervention/procedure and where it will take place

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| --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** |
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***Add rows as required***

**1.2 Clinical interventions**

Please complete the columns for each intervention/procedure as follows:

1. Interventions/procedures to be received by each participant as part of the research protocol

2. Number of interventions/procedures which are part of standard care.

3. Number of interventions/procedures which are additional to standard care

4. Total number of interventions/procedures

5. Average time taken per intervention/procedure (minutes, hours or days)

6. Details of who will conduct the intervention/procedure and where it will take place

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| --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** |
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***Add rows as required***

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| 1.3 | Will you withhold an intervention or procedure, which would normally be considered a part of routine care? |
| Click or tap here to enter text. | |

1. **Risks, benefits and burdens**

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| --- | --- |
| 2.1 | What are the potential risks and burdens for research projects and how will you minimise them?  *Please describe in lay language, any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.* |
| Click or tap here to enter text. | |
| 2.2 | Will interviews, questionnaires and group discussion include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?  If yes, please give details of procedures in place to deal with these issues.  *When answering this question, please consider from the perspective of the participant and the research ethics committee with regards to what they would consider to be sensitive, embarrassing or upsetting.* |
| Click or tap here to enter text. | |
| 2.3 | What arrangements are being made for continued provision of the investigational medicinal product for participants, if appropriate, once the research has finished? |
| Click or tap here to enter text. | |
| 2.4 | Will you inform the participants’ General Practitioner that they are taking part in the trial? (and/or any other healthcare professional responsible for their care).  If no, please explain why not. |
| Click or tap here to enter text. | |

1. **Transparency**

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| 3.1 How do you intend to report and disseminate the results of the trial? | |
| Scientific Journal |  |
| Internal report |  |
| Conference Presentation |  |
| Publication on a website |  |
| Other publication |  |
| Making raw data publicly available |  |
| No intention to report or disseminate |  |
| Other:  Click or tap here to enter text. |  |

|  |  |
| --- | --- |
| 3.2 | What arrangements are in place to inform participants of the trial results?  If there will be no arrangements in place, please explain why not. |
| Click or tap here to enter text. | |

1. **Scientific and statistical review**

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| --- | --- |
| 4.1 How has the scientific quality of the trial been assessed? | |
| Independent external review |  |
| Review within a company |  |
| Review within a multi−centre research group |  |
| Review within the Chief Investigator's institution or host organisation |  |
| Other:  Click or tap here to enter text. |  |
| Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:  Click or tap here to enter text. | |

|  |  |
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| 4.2 How have the statistical aspects of the research been reviewed? | |
| Review by independent statistician commissioned by funder or sponsor |  |
| Other review by independent statistician |  |
| Review by company statistician |  |
| Review by a statistician within the Chief Investigator’s institution |  |
| Other review by individual with relevant statistical expertise |  |
| No review necessary as only frequencies and associations will be assessed – details of statistical input not required |  |
| In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned:  Name:  Department:  Institution:  Address:  Postcode:  Telephone number:  E-mail address: | |

|  |  |
| --- | --- |
| 4.3 | How was the sample size decided upon?  *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.* |
| Click or tap here to enter text. | |

1. **Ionising Radiation**

Please note: This information is ***additional*** to the Ionising Radiation information which should be completed in Part B Section 3 of the IRAS form and therefore you **must** not just refer to the content of Part B Section 3 in this document although the information may be copied over.

|  |  |
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| 5.1 | Does the study involve exposures to radioactive materials? |
| Click or tap here to enter text. | |
| 5.2 | Does the study involve other diagnostic or therapeutic ionising radiation? |
| Click or tap here to enter text. | |
| 5.3 | Has the trial been authorised by a Clinical Radiation Expert (CRE) and a Medical Physics Expert (MPE)? |
| Click or tap here to enter text. | |
| 5.4 | What are the risks associated with ionising radiation exposures within the trial?  *It should be clear whether the risks relate to exposures which would be part of standard care or additional procedures due to participation in the trial.*  *This information should be provided by the MPE who authorised the trial* |
| Click or tap here to enter text. | |