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| **HOST SITE AUTHORISATION FORM****(For use in Non-Regulated studies)** |

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| * ***This form should be completed before the research project commences.***
* ***Principal Investigator refers to the PI at the Research Site ( or Chief Investigator for a single site study)***
* ***This form should be consistent with the planned or submitted Research Ethics Committee application***
* ***Please return completed form along with any supporting documents to the appropriate Research Office***
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| **RESEARCH PROPOSAL AND SITE IDENTIFICATION** |
| Study Registration number: (as provided by Research Office) |  |
| Title of Research Study: |  |
| Submission Date: |  |
| Name of Host site: |  |
| Planned number of participants at the site: |  |
| Expected Start Date: |  |
| Expected Duration in months: |  |
| Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet. |
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| **1. Study type? (Decide which option applies to your study and then select from the corresponding dropdown)**  |
| **Option 1 - Interventional: Regulated Clinical Trial[[1]](#footnote-1)**Before they can start Regulated Clinical Trials need approval from both the HPRA and the applicable National Research Ethics Committee (NREC). DO NOT use this form if your study is a Regulated Clinical trial. Refer to [www.nrec.ie](http://www.nrec.ie) for the appropriate Site Suitability Form  | Choose an item |
| **Option 2 - Interventional: Non-Regulated Clinical Trial1**These are studies that meet the definition of a Clinical Trial but are not regulated. *Non- IMP clinical trial*: where the intervention isn’t a Drug or device for example nutritional, cosmetic, surgical procedures, radiological procedures, behavioural treatments, process-of care changes, or preventive care.*Ionizing radiation*: research projects where the radiological procedure is a primary focus of the research, i.e. is undertaken to assess the safety, performance or effectiveness of a medical radiological procedure, and/or research projects that propose a medical radiological procedure that significantly deviates from standard care. | Choose an item |
| **Option 3 - Non-Interventional: Additional Assessment**A study that doesn't directly intervene in the care journey but involves additions to the standard of care, i.e. testing or procedures that are only conducted because the service user is enrolled in the study. | Choose an item. |
| **Option 4 - Non-Interventional: - Observational only**A study that doesn't intervene in the care journey or require additional testing or procedures. for example an observational clinical study that involves non-invasive data collection only i.e. surveys | Choose an item. |
| Option 4 – Other (more details) |  |
| **2. Who is the Principal Investigator for the research study?** |
| Principal Investigator Prefix/Title: | Choose an item. |
| Principal Investigator name: |  |
| Principal Investigator Position: |  |
| Principal Investigator Organisation Affiliation: |  |
| Principal Investigator Address: |  |
| Principal Investigator Email Address: |  |
| Principal Investigator Contact Number: |  |
| **3. If Principal Investigator is not an employee at site then please indicate who is supporting this study at site (Research Liaison who is employed at site).** |
| Research Liaison Prefix/Title: | Choose an item. |
| Research Liaison name: |  |
| Research Liaison Position: |  |
| Research Liaison Organisation Affiliation: |  |
| Research Liaison Address: |  |
| Research Liaison Email Address: |  |
| Research Liaison Phone Number: |  |
| **4. Outline the qualifications and experience of investigators and staff relevant to the current study.** |
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| **5. What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?** (Include information on interventions, additional assessments/visits, focus groups, completion of surveys/questionnaires/diaries etc.) |
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| **6. Outline the study procedures (if any) which will take place at the site.** (Include information on interventions, additional assessments/visits etc.) |
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| **7. Outline the suitability of the site adapted to the nature and use of the intervention (if any).** |
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| **8. Outline the suitability of any facilities required at the proposed site.** |
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| **9. Outline the suitability of any equipment required at the proposed site.** |
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| **10. Outline any additional requirements for Human Resources and expertise at the site.** |
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| **11. Outline any potential impact on the site’s ability to deliver its services during the conduct of this research study.** (For example staff resources used to collate data sets not available for routine work of the department, use of a questionnaire during clinic visits requiring longer appointments etc.) |
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| **12. If service delivery impacts are expected please explain how will they be mitigated?** (For example budget to hire additional staff to administer questionnaire, benefit in kind support(s) available) |
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| **Declaration of Head of Relevant Service, Chief Executive Officer, Head of Clinic / Institution, Director of Research, Clinical Director, or delegate at site:** |
| This declaration confirms that the host site/host department/service is in agreement with the research study taking place within such, provided that appropriate Research Ethics Approval and Research Office (or equivalent) approval are in place as per [www.HSEResearch.ie](http://www.HSEResearch.ie)  |
|  |
| Name: |  |
| Position: |  |
| Signature: |  |
| Date: |  |

1. Clinical trial: A clinical trial is a type of health research. These types of studies prospectively assign human participants or groups of humans to one or more health related intervention in order to evaluate the effects on health outcomes. Interventions include, but are not restricted to, drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of care changes, or preventive care. Clinical Trials can be regulated or non-regulated [↑](#footnote-ref-1)