 

**HSE Reference Research Ethics Committee for X : Local Information and Checklist for APPLICANTS**

**This is a Checklist to ensure that all applicants submit the required documentation along with their Standard Application Form (SAF). This checklist is mandatory, must be completed and signed when submitted.**

## Reference Research Ethics Committee Contact Details:

|  |  |
| --- | --- |
| Name of Manager |  |
| Email Address |  |
| Website for HSE Reference Research Ethics Committee |  |
| HSE Website (general information) | <https://hseresearch.ie/research-ethics/>  |

## The HSE Reference Research Ethics Committee for X will provide a service to:

• Hospitals (HSE or HSE funded): XXXXX

• Community areas in (HSE or HSE funded): XXXXX

• [HSE Corporate and National Services]

## What applications can and cannot be submitted to HSE Reference Research Ethics Committee:

Regulated studies, such as Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (MD), must submit their application to the National Research Ethics Committee (<https://www.nrecoffice.ie/>).Research taking place in organisations listed above, that involves the participation of health service users, their personal data and/or their biological samples, health and social care staff, or the use of HSE healthcare services, premises or infrastructure, either directly or indirectly, must be reviewed by a HSE Reference Research Ethics Committee.

**Retrospective approval from Research Ethics Committees is not permitted.** HSE Reference Research Ethics Committees review ethical applications for research activity and do not review audits, service evaluation, or quality improvement programme studies. For definitions of research, audit, evaluation, and other activities please visit <https://hseresearch.ie/what-is-research-2/>.

## Amendments

If you have any amendments or queries after your application has been submitted to the HSE Reference Research Ethics Committee, please refer to the date of your original submission and, if applicable, the date of the relevant Committee meeting/recommendation.

When the applicant(s) is asked to clarify any aspect of their application, or supporting documentation, they must submit their reply to the Manager of the HSE Reference Research Ethics Committee by email at XXXXX.

Any amendments for studies approved by a Research Ethics Committee no longer in operation can be submitted to this committee.

## Submission Requirements:

Please note that the following are required for ALL applications:

* Completed application form,
* Completed checklist,
* Study protocol/proposal,
* Evidence of indemnity,
* CV(s) of chief/principal investigator(s),
* Data Protection Impact Assessment (DPIA) screening form or DPIA (where necessary).

Depending on the study type, not all documents on the checklist may need to be submitted.

Please note that:

* If you need participant consent for your research project you must also submit all consent related documentation (i.e. participant information leaflet, informed consent form)
* if you are doing a research study that involves children aged under 18 years you must also submit age appropriate patient information leaflets and assent forms for each paediatric age grouping in your study.

It is the responsibility of the Principal Investigator to ensure all documentation is completed honestly and truthfully.

**If relevant and required documentation is not included at the time of submission, the application will be returned without review.**

## Report Requirements

If the HSE Reference Research Ethics Committee approves the research study the approval letter will include information indicating that the Principal Investigator, or the person they have nominated, will be required to report serious adverse reactions related to study drug/ intervention/ procedures to the HSE Reference REC. The approval letter will also state that the Principal Investigator, or the person they have nominated, will need to submit an annual update, end of study notification, and a final report to the HSE Reference Research Ethics Committee.

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## CHECKLIST for all Applications[[1]](#footnote-1)

**Research Study Title:**

**Chief Investigator/Principal Investigator:**

**Project Data Controller(s):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Documents**  | **Please indicate Yes, No or N/A** | **Date of document & version number** | **Please state reason for N/A** |
| Checklist *(required)* | Yes [ ]  |  |  |
| Standard Application Form (RECSAF version 5.6) *(required)* | Yes [ ]  |  |  |
| Protocol/study proposal *(required)* | Yes [ ]  |  |  |
| Cover letter on headed paper  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Letter of support from the relevant Head of Service/Lead Consultant where the research study directly involves patients under their care | Yes [ ] No [ ] N/A [ ]  |  |  |
| Completed Data Protection Risk Assessment and decision/opinion of the DPO | Yes [ ] No [ ] N/A [ ]  |  |  |
| Proof of insurance  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Evidence of fee payment  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Copies of recruitment material for research participants, e.g., posters, newspaper adverts, website posts, printed script for video or audio recordings  | Yes [ ] No [ ]  |  |  |
| Participant consent forms  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Participant assent forms  | Yes [ ] No [ ]  |  |  |
| Research participation information leaflets  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Participant letter of invitation  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Letter to GP informing them of the patient’s participation in the research study[[2]](#footnote-2)  | Yes [ ] No [ ] N/A [ ]  |  |  |
| Letter to consultant informing them of the patient’s participation in the research study[[3]](#footnote-3) | Yes [ ] No [ ] N/A [ ]  |  |  |
| Have you included in your submission, all patient facing materials (written, electronic or otherwise) that will be provided to the participants? | Yes [ ] No [ ]  |  |  |
| Have you included, in your submission, all materials (written, audio-visual, etc) that will be used during the course of the study e.g. * Validated questionnaire
* Non-validated questionnaire
* Interview or focus group schedule
* Case report form
* Any other written materials provided to the participant e.g., participant diary
 | Yes [ ] No [ ] N/A [ ]  |  |  |
| Data Protection Impact Assessment Screening Form *(required)* | Yes [ ] No [ ]  |  |  |
| Is a Data Protection Impact Assessment (DPIA) required?If yes, has the Data Protection Officer(s) for the site(s) involved reviewed the DPIA? (you need to include this decision/opinion of the Data Protection Officer(s) in your application) | Yes [ ] No [ ] Yes [ ] No [ ]  |  |  |
| Evidence of GDPR training  | Yes [ ] No [ ] N/A [ ]  |  |  |
| If you are utilising potential participants (i.e. patients or staff or carer list(s), from any organisation, for contact purposes, have you included a letter of support from the person who has data control of the list(s) stating:* You have their support for the study
* They are happy to disseminate the study information, or study materials, themselves to the participant list
 | Yes [ ] No [ ] N/A [ ]  |  |  |
| Curriculum Vitae of Chief Investigator/Principal Investigator (including previous research) (Maximum 2 pages) | Yes [ ] No [ ]  |  |  |
| Short Curriculum Vitae of all co-investigators and researchers (Maximum 1 page) | Yes [ ] No [ ] N/A [ ]  |  |  |
| Other documents or materials submitted with this application | Yes [ ] No [ ]  |  |  |

The Principal Investigator in signing this checklist for the study’s application to the HSE Reference Research Ethics Committee:

* takes responsibility that all required data protection assessments, and recommendations from the research site(s) Data Protection Officer(s), has been completed accurately.
* is responsible for checking that all investigators/researchers have ensured they have adequate insurance cover for the activities they will undertake as part of this research by contacting the relevant authority/insurance provider
* is responsible for both the standard and quality of this application and for the conduct of the research in accordance with the protocol and ethics committee application.
* Is responsible for the conduct of the study in compliance with HSE policies and procedures.

Name of Chief Investigator/Principal Investigator:

Signature of Chief Investigator/Principal Investigator:

Date of Signature:

1. Please note that this is not an exhaustive list. Please submit all materials and information that are needed to support for SAF. [↑](#footnote-ref-1)
2. It should be clear in the PIL and consent form that the GP will be informed of the patient’s participation in the research study. [↑](#footnote-ref-2)
3. It should be clear in the PIL and consent form that the Consultant will be informed of the patient’s participation in the research study. [↑](#footnote-ref-3)