**Instructions for Applicants**

Request for Approval for Research in Primary Care by the National Primary Research Committee.

All research proposals or requests to engage with primary care services/staff/providers for research or evaluation purposes must be brought for approval to the National Primary Care Research Committee before engagement with primary care services/staff/providers commences.

**NOTE: The following types of research DOES NOT REQUIRE APPROVAL FROM THE National Primary Care Research Committee**

* Research utilising existing publicly available documents or data
* Observational studies in public places in which the identity and location of the participant remains anonymous
* Quality assurance studies
* Clinical Audits
1. **SUBMISSION of DOCUMENTS**

 The following documents (see relevant templates in Appendix) must accompany the submission of the completed Approval Application form:

* Letter of approval from an appropriate Research Ethics Committee (REC) **or** a certificate indicating ethical approval is not required for this project.
* Signed approval by the Applicants Line or Service Manager and the Head of Service Primary Care of the applicant
* Signed approval by applicants Chief Officer or delegated Officer (in application form)
* Signed Decision Framework document
* Signed Declaration by Applicant (in application form)
* Signed Data Protection Declaration by Applicant (in application form)
* Copy of Patient/Staff Information Leaflet (if relevant)
* Copy of Patient / Staff Consent form (if relevant)
* Copy of Patient/ Staff Survey/Interview Questions (If relevant)
* If the research application has been submitted to another research approval forum, copies of letters of review outcome should be submitted.
* Applicants Signed Consent form to enable the PCRC to share with the applicants Line or Service Manager and Head of Service Primary Care, documentation as appropriate, including pre-publication drafts.
* Undertaking to notify Line or Service Manager and Head of Service Primary Care, of any adverse outcomes / risks to patients or concerns related to the impact of the research in the HSE which may be identified as a result of this research. (in application form)
* Undertaking to apply to the Head of Service Primary Care and Chief Officer/Delegated Officer for approval to publish any research that may emanate from this research. (in application form)
* Confirmation you are covered by the CIS / GIS? (in application form) See \* below for further information
* Copy of Indemnity and Insurance (applicable to third parties and section 39 organisations only)

**\*Note the State Claims Agency (SCA) operates two schemes which are provided to the HSE:**

* **Clinical Indemnity Scheme (CIS)** – Covers personal injury risks and subsequent claims/liabilities arising from the negligent act or omission associated with the provision of, or failure to provide professional medical services on the part of the HSE i.e. medical malpractice;
* **General Indemnity Scheme (GIS**) – Covers personal injury and third party property damage risk and subsequent claims/liabilities arising from the negligent act or omission on the part of HSE i.e. employers liability, public liability, third party motor liability insurance;
* These schemes will apply to research which is approved and under the control of the HSE. S38 organisations (excluding Cork Dental Hospital) are also covered by the GIS & CIS and some S39 organisations have CIS cover only.
* State indemnity does not extend to indemnify any third party (i.e. non-HSE locations, academic institutions etc.), its servants and/or agents concerning their negligent acts. Therefore third parties will be required to have insurance in place for their negligence.

*All applications submitted without the relevant documentation above will be returned to the applicant without review.*

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| 1. **SUBMISSION PROCESS**

Submissions must be made by email to Muriel Farrell Chair of the Primary Care Research Committee at the following address muriel.farrell@hse.ie as a single pdf document. 1. **REVIEW PROCESS**
* Research applications can be received any time, but will only be reviewed by the committee on a quarterly basis. Completed applications received 8 working days in advance of meeting will be listed as agenda items. Applications received less than 8 working days in advance of the meeting will be listed as agenda items at the subsequent quarterly meeting.
* Decisions, including rationale for decisions, for approval requests will be issued to the relevant researcher by email. **Research cannot commence until approval from the PCRC is received.**
* Incomplete proposal missing any of the required documentation will be returned without review.
* If the PCRC requires further information the applicant will be communicated and the particular research request will be included as an Agenda item for the next meeting.
1. **PRIOR PUBLICATION OF THE RESEARCH**
* The applicant must complete and submit an Application for Approval to Publish form to the PCRC and a final draft of any proposed publication, **prior to submission to the publishers or prior dissemination (internal or external).**
* Application for Approval form must be signed by Line or Service Manager and submitted to the Head of Service Primary Care for approval at a **minimum of 8 weeks in advance of the PCRC quarterly meeting**. Once approved by the Head of Service Primary Care and Chief Officer / Delegated Officer, applicant must submit this application to the Chair of PCRC muriel.farrell@hse.ie 4 weeks in advance of the PCRC next quarterly meeting.
* Publication requests will be considered by the PCRC at quarterly meetings.
* In cases where the PCRC considers it appropriate, it may send the pre-publication draft for expert technical peer-review to validate the robustness of the approach and the quality of the results.
* **The research results should not be disseminated or submitted to the publisher until approved to do so by the PCRC.**
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