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An alternative REC review pathway for non-complex studies

1. Background

As research activity grows in volume and diversity, the need to streamline review processes without compromising ethical standards becomes increasingly important. Full Research Ethics Committee (REC) meetings are particularly valuable for complex applications or those where there may be potential concerns about risk to participants or the research processes employed, and where discussion within a broad, multidisciplinary committee can add important context and understanding. However, a significant proportion of applications to the Irish College of GPs' REC are studies that are methodologically straightforward, familiar to reviewers, and where the potential for harm is minimal. In these instances, a full committee discussion may not be necessary. In such cases, an alternative review process provides an efficient and proportionate approach.

This document proposes the development and implementation of an alternative review process within the College's REC for non-complex studies.

2. Objectives

- To optimise REC resources and improve efficiency
- To maintain robust ethical oversight while reducing unnecessary administrative burden for both applicants and reviewers.

3. Summary of proposed changes

- Such applications may be submitted on a rolling basis and not tied to meeting dates and submission deadlines.
- Criteria for alternative reviews will be published on the College's REC website and applicants will be asked to declare whether their submission meets the criteria for the alternative review process dedicated to non-complex studies.
- A sub-committee of the REC will be convened to review studies submitted though this alternative process (this group will rotate every 6-12 months to ensure variety for members).
- The REC Chair will nominate a sub-committee lead, who will also attend the full REC meeting and provide a short report on the low-risk studies reviewed in the previous two months.

- These applications may be referred for standard REC review at the next available meeting if deemed necessary by the sub-committee lead or reviewers.
- The review process for applications deemed eligible by the sub-committee for this alternative review process will be completed within four weeks of submission by the applicant.

4. Proposed criteria for alternative review

Inclusion criteria

- Anonymous cross-sectional surveys where all recruitment processes are deemed appropriate, such as the use of an appropriate gatekeeper and participant privacy is protected (for example no IP addresses are collected).
- Stakeholder or qualitative studies involving professionals only as long as their identities are protected and they cannot be easily identified.
- Single-site retrospective chart reviews where data are extracted by a clinician with legitimate access and only de-identified, aggregate data leave the practice.

Exclusion criteria

- Interventional or experimental studies
- Any studies recruiting vulnerable groups
- Complex or multi-phase studies (e.g., mixed-methods projects with follow-up or longitudinal components).
- Any of the included studies deemed not to meet the required standards in relation to GDPR, confidentiality, data sharing, informed consent or anonymity.

5. Proposed Process

Step 1: Applicant declares whether their submission is appropriate for alternative review upon submission via Vidatum

Applicants submit all documentation and complete the REC application online in the usual manner, with the addition of a checkbox (pending Vidatum costs) or letter noting that this application meets the alternative review pathway criteria.

Step 2: Triage by sub-committee lead

The sub-committee lead screens the application for completeness and determines whether the application qualifies for the alternative review pathway based on the checklist and supporting materials.

- Applications deemed inappropriate are sent by the lead for consideration at the next meeting. The applicant is informed of this including the rationale for the decision and the date of the committee meeting.
- Applications deemed appropriate are sent for review to the sub-committee.
- The sub-committee lead will complete this process within one week of receipt of the application.

Step 3: Review by sub-committee

Each application will be reviewed by two scientific reviewers and one PPI reviewer.

- Any sub-committee member can refer the application back to the lead if they feel it would be more appropriate for a standard full-committee review. In cases where there is disagreement within the sub-committee, the application will be sent to the REC Chair who will have the deciding vote. once no conflict of interest exists (if so, an alternative committee members will be appointed to this task).
- When an application is sent for standard review the applicant will be informed of this, including the rationale for the decision and the date of the next committee meeting.
- The sub-committee reviewers will complete the review process within one week of receipt of the application.

Step 4: Decision and response to applicant by sub-committee lead supported by administrator

- Upon completion of the review by all reviewers, the lead will collate the reviews and make a final decision.
- The lead will complete this process within one week of receiving all the reviews for the application.
- Where revisions are requested, applicants will have one month to provide the revised documentation (as per current process).

6. Implementation Plan

- Seek feedback and endorsement from REC members (November meeting)
- Nominate sub-committee lead and members
- Pilot pathway for 3 months prior to publishing on the website (lead and Chair to review regularly)
- Integrate the pathway into the Vidatum submission system
- Gather feedback from applicants and reviewers for refinement

7. Governance and Review

The REC will oversee the implementation and performance of this alternative review pathway. A formal review will be conducted after six months to assess effectiveness, with revisions implemented as needed.