

## Peer Review Process for Studies

The **Wellcome HRB CRF at St James Hospital** supports a broad portfolio of clinical studies and an objective of the facility is to continue to support studies, including clinical trials, from an early stage.

A trial may not be funded but may warrant resource input from the CRF for a number of reasons. For example, it may become competitive for funding with input from the CRF, it may be a pilot study which will lead to a subsequent larger study or it may align with the objectives of the CRF.

To support the PI in terms of trial design, the CRF and Principal Investigator (PI) may agree that the proposed study protocol undergoes external peer review.

**The aim of the peer review might be to further develop the research proposal in terms of:**

- A clearly stated hypothesis/objective for the trial
- The novelty of the research
- Underpinning basic and clinical research
- Trial design e.g. sample size, comparators, analysis
- Safety concerns
- Ethical issues
- The approach to IMP management

**The CRF SJH will then:**

- Request that the PI suggest a number of external peer reviewers with expertise in the study's subject matter.
- Contact one or more peer reviewers to request their acceptance to participate.
- Suggest timelines and the format of a peer report before commencement of the review.
- Share the report with the PI when complete.
- Collate the PI's replies to the review report, if provided, for the reviewer to respond to.

The peer review process occurs with due consideration for the **National Clinical Trials Co-ordination Programme Roadmap for Enabling of the Irish Academic Clinical Trial Ecosystem** which may offer additional supports and a trialist network to the PI.

**Peer Review Principles:**

1. The CRF aims to support the PI wishing to pursue investigator led trials.
2. The CRF will support and advise the PI throughout the process.
3. An external peer review process is not routinely initiated as it can be a time-consuming process, however, in certain situations it may be beneficial for the PI and/or help inform CRF resource allocation.
4. The intensity and form of peer review will be proportionate to the resources requested from the CRF.
5. The CRF does not seek to replace research funding agencies.
6. The CRF has limited discretionary resources/budget to assign to individual studies so that support may be modest.