



# NWRC PROJECT DEVELOPMENT GUIDANCE VERSION 2.0

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## INTRODUCTION

This document has been written and agreed by the NWRC Committee to provide guidance for the development of new studies run on behalf of the collaborative. It outlines a framework to ensure that each study has a robust protocol design and realistic time scale.

## GENERATING AN IDEA

Ideas for an audit or study from any member of the collaborative are to be encouraged. The member will be asked to discuss the idea with the committee and then present to other members of the collaborative the next meeting. At this meeting it is expected that a clear project aim is outlined and that the literature has been reviewed to ensure originality. Preferably the idea will be presented in the form of a PowerPoint presentation or similar. Should the member wish to pursue it, they will be supported in the development of their idea into a NWRC project. The individual will be encouraged to become Chief investigator for the project.

## LITERATURE REVIEW

A literature review should be undertaken by the member proposing the project idea. This will ensure originality of the project and form the basis for the background section in the project write up. It will include a search of the relevant libraries (i.e. PubMed, Medline, EMBASE) and other information sources to identify a new angle to take forward the idea. Once a literature review has been performed, it will be placed on the agenda for the next meeting and presented to members of the collaborative, who can express their interest in further development of the project.

## AIMS AND OBJECTIVES

A brief outline should be written for the project. This should clearly define aims and objectives of the project. It will be presented at the collaborative meeting and will be posted on the NWRC website projects page.

## FORMING A STEERING GROUP

Once it has been agreed to take a project forward, a designated Chief Investigator will form a steering group from other members of the collaborative. All steering group members will be expected to complete training in Good Clinical Practice (GCP). All members of the steering group are expected to contribute to the development of a study protocol and timeline and to participate in project management.

Additional steering group responsibilities include:

- 1. Recruitment of other members of the collaborative to act as Lead Investigators across regional hospital sites.**
- 2. Provision of regular project updates to the NWRC committee and webmaster (via [NWRCsurgery@gmail.com](mailto:NWRCsurgery@gmail.com)), so the website can be kept up to date with progress. There should be a minimum of monthly updates. This should be the designated responsibility of one member of the steering group.**
- 3. Ensuring a representative of the steering group is present at each collaborative meeting to give a brief update on study progress. If a member of the committee is on the steering group then it will be his or hers responsibility to provide updates to the rest of the committee.**
- 4. Nomination of a steering group guarantor, who will be responsible for the storage of data. The data collected should be kept on a designated computer at a designated hospital site, preferably the site where the Principal Investigator is based**

Members of each steering group will be listed on the NWRC and there will be a dedicated contact address for the group. A list of individuals involved in each study will be listed on the Study Authorship Template, which can be found on the NWRC website. There will be a dedicated member of the NWRC committee who will liaise with each steering group to provide support and feedback.

## STUDY PROTOCOL

A protocol should be developed within an agreed reasonable time from the decision to begin the project. This protocol should include an outline of the timeline for the rest of the project, feasibility of undertaking the study, literature review, and relevant approvals (if applicable). The protocol should be published to the NWRC website so that it is available to download by those involved in data collection.

## TIMELINE

All projects are expected to submit a projected timeline with predicted milestones to ensure that momentum is maintained and to prevent incomplete projects. This will allow the collaborative to prepare for the development of subsequent studies to ensure there is a constant progress with idea generation and delivery of high quality research. It is expected that these timelines are adhered to as closely as possible. The timeline should include the following:

## DATA COLLECTION PERIOD

There should be a designated period during which all data is collected. This should include a deadline for submission of data which is strictly adhered to. Any data not submitted by the deadline should not be included within the study, and would result in contributors not being recognised. This should encourage individuals to ensure they are motivated to deliver.

## DATA ANALYSIS

An agreed period for data analysis should take place. This should include enough time for data to be reviewed, preferably by a statistician to ensure accuracy of results.

## WRITING UP

There should be a period of time set aside by the steering group to meet and discuss the generation of a manuscript. It is during this time the study should be considered for submission to conferences for presentation.

## SUBMISSION FOR PUBLICATION

There should be a predicted date by which the steering group considers realistic for a completed manuscript to be submitted to an appropriate journal.

## COMPLETION OF PROJECT

### PRESENTATION

#### COLLABORATIVE MEETING

Once the study has been completed and data analysed, the results should be presented at the next available collaborative meeting. At this meeting, discussion about further dissemination can take place.

#### REGIONAL / NATIONAL / INTERNATIONAL MEETINGS

It would be expected that each project completed through the NWRC is presented at a meeting appropriate to the topic of research. The presentation of this should adhere to the guidelines set out in the NWRC authorship Policy.

### MANUSCRIPT SUBMISSION

If appropriate, it is expected that each member of the steering group will be included in the write up of the data into manuscript form to be submitted to a journal. The writing of this should adhere to the guidelines set out in the NWRC Authorship Policy. It is suggested that preliminary drafts are submitted to the NWRC committee for review prior to submission to the relevant journal.