Research Governance Protocol Template

Please use this information as a guide for writing your protocol. ***This is the minimum criteria so provide any extra information you think is necessary.***

Remember

- Add a header and footer to this template, which must include the Sponsors Logo, a protocol version and date
- The Bullet points should be used as sub headings and expanded upon

Title

- Full and Short Title

Introduction

- Rationale
- Background information including literature review
- Potential risk and benefits

Aim / Primary and Secondary Objectives

Methodology

- Inclusion and Exclusion Criteria
- Study design / Plan – Study Visits
- Durations of participation
- Study Drugs - Indicate if appropriate or state "We do not plan to test new drugs in the present study but will use some marketed ones to affect the system in a known way to make sure that our answers are sensible. Note that this is not a trial of safety or efficacy of these existing agents."
- Concomitant Medications
- Criteria for discontinuation
- Procedure for collecting data [including Case Report Forms (CRFs)] and storage

Statistical Considerations

- Sample Size
- Method of analysis

Ethics

The Principal Investigator must ensure that the study will be carried out in accordance with the ethical principles in the Research Governance Framework for Health and Community Care, Second Edition, 2006 and applicable legal and regulatory requirements.

Before the start of this study, the protocol and informed consent form must be reviewed and approved by the Ethics Committee (EC). Applications can be made using the NRES system

(see http://www.nres.npsa.nhs.uk/). The EC and the relevant NHS management approval letters must be provided to the Investigator before any study procedures can commence.

Finance and Indemnity

Brief details on how the study is funded should be included here.

NHS employed researchers will be covered for negligent harm through the NHS CNORIS indemnity scheme. If you are a University employee you may need extra cover for non-negligent harm through your University. Please check this with your Research and Enterprise department.

Publications

Study results whether, negative or positive, should be disseminated. Details of your plan for dissemination should be included here.

Reference