SWSLHD Research Directorate Training Webinar 19th February 2020

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Research Directorate

- Research Ethics and Governance Manager – Jessica Grundy *(oversee all office functions including HREC, Research Governance and Research Contracts)*
- Research Ethics and Governance Coordinator – Andrea Lee *(HREC and Research Governance)*
- Senior Administration Officers
  - Malina Peng *(HREC and Research Governance Administration)*
  - Logan Lown *(HREC and Research Governance Administration)*

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Today’s Topics

- Protocol Requirements

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Protocol Requirements

What is a research protocol?

- Writing a research proposal is probably one of the most challenging and difficult tasks particularly when research is a new area for postgraduates and new researchers. The purpose of this presentation is to summarize the most important steps and necessary requirements for producing a good quality research protocol.

- SWSLHD Research Directorate has a comprehensive protocol template available on our website under: Forms and Templates

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Protocol Requirements

What is a research protocol?

- A research protocol outlines the plan for how a study is run.
- The study plan is developed to answer specific research questions.
- It provides scientific merit feasibility of a study, detailed objectives, design, methodology, statistical considerations and how the study will be conducted and evaluated.
- A well written and complete protocol is essential for a high quality study and will make publishing the results easier.

Protocol Requirements

The following tips and tricks are essential to enable the HREC Committee to understand the scientific merit of your study.

- All references should be listed at the end of the protocol.
- It is imperative to use lay language.
- SWSLHD recommends getting a Peer Review prior to submitting the ethics application and disclosing any conflicts of interests in the protocol.
- Please see the Peer Review Guide and the Disclosure of Interests and Management of Conflicts of Interest Guide, which support the implementation of the Australian Code for the Responsible Conduct of Research (the Code).

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Protocol Requirements

Main Components of a protocol:

- Background
- Aims/Objectives
- Plan of investigation
- Recruitment and Screening
- Inclusion/Exclusion Criteria
- Consent Process
- Study Procedures
- Ethical Considerations including but not limited to: Risk and Benefits, Confidentiality and Privacy, Data Storage and Record Retention, Safety Requirements
- Funding
- Outcomes

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Protocol Requirements

BACKGROUND AND RATIONALE

The background and rationale should provide*:*

- *An introduction to the study*
- *What is already known (please ensure this includes a summary of a* ***literature review****)*
- *What is missing*
- *What the study is going to find out*
- *How* this *is going to be achieved and what impact the study will have.*

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Protocol Requirements

BACKGROUND AND RATIONALE

All references should be listed at the end of the protocol. (It is imperative to use lay language). The above is essential to enable the HREC Committee to understand the scientific merit of your study.

Present evidence that is relevant to the merit and integrity of the project. This may include:

- The importance of the problem you are addressing
- The gap in knowledge you are seeking to fill
- The consequence for policy or practice of the addressing the study aim.

Protocol Requirements

STUDY AIMS/OBJECTIVES

- Provide a clear and concise statement of primary and secondary objectives and a clearly defined hypothesis (where relevant).
- The aim is the broad overall aim and the objectives are how you will achieve the aim.

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STUDY AIMS/OBJECTIVES

*The **aim or goal** is the overall reason for working in this field. What are you trying to achieve in the longer-term? For example, this might be*

- *To improve outcomes for patients with colon cancer in south-western Sydney*
- *To improve efficiency of operating theatre utilisation at Liverpool Hospital*
- *To improve the quality of speech therapy services for stroke patients.*
- *To develop a better test for predicting outcomes of surgery*
- *To assess the quality of our service delivery*

Protocol Requirements

STUDY AIMS/OBJECTIVES

The study **objective**, research question or hypothesis describes exactly what the study is designed to achieve. When the study is completed you should be able to directly answer the study question (respond to the objective or test the hypothesis). Usually, it should include a description of:

- The population or patients who are the target of the study
- The risk factor, intervention, exposure, study factor (and comparator or counter-factual) that is being assessed
- The outcome, disease or endpoint.

Please note the study aims and objectives should NOT include the study design (“to conduct a survey”, “to conduct a trial”) and it should NOT include the career or vocational objectives of the researcher (“to complete an assignment”).

Protocol Requirements

PARTICIPATING SITES

- Please ensure that all sites where the study will be conducted are listed in the protocol this includes where the recruitment, data collection, analysis, intervention etc will take place.
- For sites that are external to NSW Health and are a private organisation an external entity agreement is required for each private site.

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Protocol Requirements

STUDY DESIGN/PLAN OF INVESTIGATION/STUDY TYPE:

- Describe the study design for example: A randomized controlled trial, observational, cohort study, cross sectional, focus groups, in depth interviews etc.
- Describe the study type, i.e. retrospective, prospective, qualitative, quantitative, involving access to data linkage etc.

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EXPECTED STUDY DURATION/DATA SOURCES AND POPULATION

- Duration: Describe the study start and end date, and if applicable, the expected duration of the recruitment phase.
- Population: Describe the study groups and numbers in each group and in each participating site.
- Population: Outline the total number of participants expected.
- Sample Size: Ensure you justify your sample size or power calculation and include relevant reference i.e. how will you measure, manipulate and/or analyse the information that you collect/gather? Matching and sampling strategies, accounting for potential bias, confounding factors and missing information, statistical power calculation.
- Outline the data variables collected for the purpose of the research and provide justification for the collection and Provide a data collection form or list of the data variables to be collected.

Protocol Requirements

RECRUITMENT AND SCREENING

Participant recruitment strategies and timeframes: Explain how potential participants will be identified for the study and where?

Examples include the following:

•Review of databases (please identify the database and the custodian)

•Retrospective audit of medical records (please include who will be reviewing the notes e.g. research coordinator). What data will be extracted (identifiable, re-identifiable, de-identified?

•Advertisements (include where the advertisement will be e.g. newspaper, poster in outpatients' area or hospital foyer, radio announcements)

•Information Letter to clinicians

•Explain how potential participants will be screened for the study

•For prospective studies, describe how you will recruit (flyers, email invitation, online only, focus groups, interviews, etc), who will be sending the email / putting up the flyers, where will flyers be put up, will there be any follow up emails (who will send?)

Protocol Requirements

INCLUSION/EXCLUSION CRITERIA

Exclusion Criteria
List criteria, for example:

- *Sex, Age range, Weight, Height, Disease status, Concomitant disease status, Laboratory parameters*
- *Others: radiograms, electrocardiograms, CT-scan, ultrasound, etc.*
- *Willingness to give written or oral informed consent (either written or oral, as appropriate) and willingness to participate to and comply with the study*

Exclusion Criteria
List criteria, for example:

- *Women lactating, pregnant or of childbearing potential who are not willing to avoid becoming pregnant during the study.*
- *Patients with a history of XXXX disease(s) that is (are) likely to interfere with the metabolism or excretion of the test medication.*
- *Patients with a history of a psychological illness or condition such as to interfere with the patient's ability to understand the requirements of the study.*
- *The following medication(s) can have interactive effects and may interfere with the patient's ability to meet the study requirements; they cannot be administered during the clinical study: list any prohibited concomitant medications*

Protocol Requirements

CONSENT PROCESS

- Describe how informed consent will be obtained, how will it be assured that consent is voluntary i.e. study participation is free of coercion and pressure (see National Statement Chapters 2.2.9, 4.3 for guidance)
- Explain the process and how the process will be documented and whether there are any site specific requirements (e.g. in NSW Clinical trials with delegation of consent may require review by the Guardianship Tribunal)
- **NOTE:** If a **retrospective** study, please provide **justification for a waiver of consent** in accordance with Chapter 2 of the National Statement. I.e., a waiver of consent if justified in this study as it would be impractical to obtain the consent of each participant, de-identified data will be used in the study, there is minimal risk to participants, participants will not be contacted for the study, etc.
- If necessary, the type of consent provided to different participant groups, when and where, and any arrangements to confirm that consent. If necessary, details of who will be confirming or re-negotiating consent with participants and the process/es that will be undertaken.

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STUDY PROCEDURES

- Describe how the study procedures/interventions will be conducted, and the rationale for choices of method/s.
- Include details of all study visits and all procedures conducted per visit (including duration and location of visit) that are related to the research. It may be helpful to summarise these in a table (example below).
- Procedures that are not performed as part of routine practice should be clearly defined and a description of the procedure provided.
- Describe the statistical analysis and outcome measures in detail, and whether this has been reviewed by a biostatistician.
- Consider the impact of and response to participant withdrawal (will you keep the data, will you remove that data from the study. Ensure this is clearly outlined to participants when you create the Participant Information Sheet).
- **NOTE:** If the research methods involve the use of a validated instrument or tool, it is the research team's responsibility to seek the appropriate permissions before using the instruments or tools in this research project.

Protocol Requirements

STUDY PROCEDURES – FLOWCHART

To help the Ethics Committee understand complex studies, it is useful to include a flow chart illustrating what steps are involved throughout the study. See example below. Note that it is often easier to build a simple flow chart using PowerPoint, and paste it into the word document.

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ETHICAL CONSIDERATIONS

Ethical considerations focus on the ethical aspects of the design, review and conduct of the research. An excellent guideline to use when writing the ethical considerations section of your protocol is the ***National Statement on Ethical Conduct in Human Research (2007) - Updated 2018***

Risks and Benefits

Benefits:
- *Research will be ethically acceptable only if its potential benefits justify those risks.*
- Identify any benefits for conducting the project (include benefits to the individual participating in the research, the family members if relevant, wider community).

Risks:
- Identify any risk for distress (even if minimal) and outline mitigation strategy
- Identify and justify any dual relationships, coercion or inducement, and how this will be mitigated/avoided.
- Describe any risks relating to your consent method (even if minimal).

Note: *Even retrospective studies carry risk (e.g. privacy/confidentiality)*

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Risks and Benefits

Most research has benefits and risks. It is justifiable to undertake the research if the benefits outweigh risks:

- What are the benefits of undertaking this research project? These may be benefits for the individual participating in the research, for future patients or for the wider community.
- Identify any risk for distress or harm (even if minimal) that might arise from the conduct of the study
- Outline the proposed risk and harm mitigation strategy
- Summarise risk and harms, after mitigation, in terms of their
  - Likelihood
  - Impact
- Evaluate the balance between benefits

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Confidentiality and Privacy

- Describe how confidentiality, anonymity and the identity of participants will be maintained.
- Identify and justify any non-negligible risk or burden.
- Who is undertaking the data linkage if relevant?
- Whether identifying information will be provided to researchers and a rationale for this.
- Who has access to the identified / re-identifiable and/or de-identified data?

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Data Storage and Record Retention

- Where will the data be stored? State where the password protected computer and/or locked cabinet will be stored (i.e., at SWSLHD, university, other institute, etc.).
  Note: It is unacceptable to store research data on a laptop/USB/portable hard drives.
- Where will the hard copy consent forms be kept (i.e., stored in a locked filing cabinet in a specific office, or will they be destroyed after being electronically stored on a secure network/server?)
- What security steps are in place for the transfer of data?(Please contact your local ICT services to confirm requirements).
- Outline the NSW requirements for record retention of study data. I.e. 5 years for low risk projects, 15 years for clinical trials, if minors are participants the data must be retained for a minimum of 15 years for adult studies or 25 years for paediatric studies etc. Please check the relevant regulations applicable to your study.
- How will the data be disposed of at the end of the retention period?

Protocol Requirements

CONFLICT OF INTEREST

Please outline in this section whether any personnel involved in the study have any potential conflict of interest.

- Do the investigators have any potential duality or conflict of interest arising from their role in this study? For example,
- What benefits (financial or otherwise) flow to the investigators as a result of the conduct of this study?
- Do the investigators or the sponsor stand to benefit (financially or otherwise) from any particular outcome or finding from this study? If so, describe the nature of the benefits.

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FUNDING

- How is the research to be funded?
- What are the obligations of the investigator and the sponsor to the research funder?

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RESEARCH OUTCOMES

- Describe any plans for return of results of research to participants
- Describe plans for dissemination and publication of project outcomes
- Describe other potential uses of the data at the end of the project
- Describe the project closure processes (Detail process for archiving and destruction of research data)
- Describe plans for sharing and/or future use of data and/or follow-up research
- Describe any anticipated secondary use of data

Protocol Requirements

ADDITIONAL: CLINICAL TRIALS IF APPLICABLE

- Safety Reporting
- Data Safety and Monitoring Board
- Early Termination
- Randomisation
- Blinding and Unblinding
- Tissue Collection/Biobanking

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Who do I contact?

Research Directorate

For: for assistance with registration, applications, and post-approval/authorisation matters such as: information/documents you need to include, missing or incorrect dep't information (site-governance applications), and how to use REGIS (non-technical).
Location – Level 2 UNSW clinical School – Liverpool Hospital
E-mail: SWSLHD-Ethics@health.nsw.gov.au
Website: http://www.swslhd.nsw.gov.au/ethics/
Phone: 02 8738 8304

REGIS

For: technical queries such as system issues or faults, and account access issues. The Help desk is available 7am-7pm Monday-Friday, excluding ACT Public Holidays.
Email: support@f1solutions.com.au
Website: https://regis.health.nsw.gov.au/
Phone: 1300 073 447

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Questions

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