STUDY TITLE

**CONFIDENTIAL**

This document is confidential and the property of \_\_\_\_\_\_\_\_\_\_

No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the Institution.

**STATEMENT OF COMPLIANCE**

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

**NOTE: Guidance for completing this template: Some sections may apply to your study. You should delete those sections that are N/A. Delete all guidance text (marked in RED or highlighted yellow) and margin comments prior to submission.**

**PROTOCOL SYNOPSIS**

|  |  |
| --- | --- |
| Title |  |
| Objectives | Primary:  Secondary: |
| Study Design |  |
| Planned Sample Size |  |
| Selection Criteria |  |
| Study Procedures |  |
| Statistical Procedures | Sample Size Calculation:  Analysis Plan: |
| Duration of the study |  |

# Study Management

* 1. **Principal and Associate Investigators**

Please include the name of the Principal Investigator and all Associate Investigators with their title, telephone number, department they work in and their primary email.

* 1. **Statistician (if applicable)**

Please include the name and title, address and telephone number(s)

**1.3 Sponsor**

|  |  |
| --- | --- |
| Investigator-Initiated | |
| Site: Royal North Shore Hospital | Sponsor: Northern Sydney Local Health District |
| Site: North Shore Private Hospital | Sponsor: North Shore Private Hospital |

The study sponsor is not necessarily the same as the funding body.

**The sponsor is the company, institution or organisation that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports the clinical trial**. The sponsor usually owns the study protocol and study data. For example, in the following situation - *an employee of NSLHD who is conducting a study with an NHMRC project grant* – NSLHD is the study sponsor, NHMRC is the funding body.

**1.4 Funding and resources**

Please explain all sources of funding/resources for this project. (e.g. Department funds etc).

# INTRODUCTION AND BACKGROUND

* 1. **Background Information**

Include information based on literature review and investigators’ experiences, brief history of the disease including prognostic factors. All references must be listed at the back of the protocol.

* 1. **Research Question**

Clearly state the question the study intends to answer (e.g. *‘In infants born prematurely, compared to those born at full term, what is the lifetime prevalence of sensory deafness?'*).

* 1. **Rationale for Current Study**

The rationale specifies the reasons for conducting the research in light of current knowledge. It should include a well-documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. It is the equivalent to the introduction in a research paper and it puts the proposal in context. It should answer the question of why and what: why the research needs to be done and what will be its relevance.

# STUDY OBJECTIVES

* 1. **Primary Objective**
  2. **Secondary Objectives**

Your research question needs to be further refined into one or more study *objectives*. The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research question. Objectives should be simple, specific, and stated in advance (*e.g. to determine if socioeconomic status is associated with childhood asthma in Istanbul).*

# STUDY DESIGN

* 1. **Type of Study**

For example a randomised control trial, qualitative study, case control study, retrospective record review etc.

* 1. **Study Design**

The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The methodology section is the most important part of the protocol. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study

* 1. **Number of Participants**

XXX participants will be recruited OR the data of XXX patients will be collected

* 1. **Expected Duration of Study**

Expected start and stop date

Include the expected time period for the recruitment phase of the study

Include the expected time period for the follow up phase of the study

* 1. **Primary and Secondary Outcome Measures**

The **primary outcome** should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic, or other) of the study. This is the measure used to answer your study aim. It is also the outcome used to calculate study sample size and power (e.g. caesarean/no caesarean; blood loss ≥500mL/blood loss <500mL; weight – kg; pain - mild, moderate, severe; time to event (e.g. survival); and counts (e.g. number of infections).

**Secondary outcome(s)** are measures of additional or less important research interest. They may include additional clinical, psychological, economic, or safety outcomes (e.g. treatment related side effects/adverse events). However, as these endpoints are not used to calculate study power and sample size it is often not possible to draw robust conclusions from the results.

1. **PARTICIPANT ENROLLMENT AND RANDOMISATION**
   1. **Recruitment**

Explain how potential participants will be identified for the study and where. For record review, explain how records will be identified.

Please note that it is not acceptable to ‘cold call’ participants for research unless they have previously provided consent. Please contact the Research Office for advice on how to handle recruitment when follow-up is required for patients who have not consented to be contacted for research.

Examples include the following:

* review of databases (please identify the database and the custodian)
* review of outpatient clinic files, Emergency Department admissions, inpatients (please include who will be reviewing the notes e.g. research coordinator)
* advertisements (include where the advertisement will be e.g. newspaper, poster in outpatients area or hospital foyer, radio announcements)
* Information Letter to Medical practitioners

Explain how potential participants will be screened for the study.

* 1. **Eligibility Criteria**
     1. **Inclusion Criteria**

List each criterion, e.g. gender, age range, disease state, laboratory parameters

* + 1. **Exclusion Criteria**

List each criterion, e.g. Women lactating, pregnant or of childbearing potential who are not willing to avoid pregnancy during the study

# Informed Consent Process

Explain the process and how it will be documented.

The following fundamental conditions for a valid informed consent should be met for each participant: Disclosure of relevant information, comprehension of the information provided, voluntary agreement of the participant (free from coercion).

State who will obtain consent.

If the study does not involve obtaining consent, you must justify why you do not intend to gain consent, with reference to the National Statement, section 2.3.

**6.1 Waiver of Consent**

It is strongly recommended that you contact the Research Ethics team in the Research Office for guidance if you intend to use patient information for research without individual consent. There are specific requirements that must be addressed in your application in order to request that the Committee consider waiving the requirement of consent for your research.

Please also see [this information](https://www.nslhd.health.nsw.gov.au/AboutUs/Research/Office/Pages/Not-on-menu/Accessing-Patient-Information-for-Research.aspx) on the Research Office website regarding the use of personal health information in research (i.e. medical records).

* 1. **Participant Withdrawal**
     1. **Reasons for withdrawal**

What are the possible circumstances for early termination of the study and how will this be managed

# STUDY VISITS AND PROCEDURES SCHEDULE

Include all study visits and all study procedures conducted at each visit/time point. This information can also be displayed in a flow chart or table. For a record review describe the process (identification of records, data extraction etc)

# SAFETY REPORTING

This section may not be applicable. However, if your study involves contact with participants, for example via survey or interview, you should have processes in place to manage participant distress.

<https://www.nslhd.health.nsw.gov.au/Research/ResearchOffice/Pages/Safety-Reporting-for-Clinical-Trials.aspx>

1. **SERIOUS BREACH REPORTING**

Serious Breaches will be submitted to the HREC for review.

Serious Breach definition; A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree;

a) The safety or rights of a trial participant, or

b) The reliability and robustness of the data generated in the clinical trial.

Serious breaches must be reported by the sponsor through the CPI within 7 calendar days of the breach. The breach must be submitted as a general amendment via Regis.

# STATISTICAL METHODS

The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed.

* 1. **Sample Size Estimation**
  2. **Statistical Analysis Plan**
  3. **Interim Analyses (if applicable)**

# DATA MANAGEMENT

* 1. **Data Collection**

Details of how the data will be collected.

* 1. **Data Storage**

Outline where and how the data or database will be stored. Describe all procedures for handling data, how data are coded, who has access to the source data and database, by whom the key to the code is safeguarded, which steps will be taken to ensure data security, and how the participants’ privacy is protected, such as de-identification. If the research is multi-site and data storage methods may differ across sites, please include this detail here.

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* 1. **Data confidentiality**

Explain how participants’ privacy will be protected and how data confidentiality will be maintained **during the study, for archiving and storage, and for publication**. Specify if data/records will be identifiable, re-identifiable (ie. coded), or de-identified/anonymised. NB. Coded data is NOT de-identified.

* 1. **Study Record Retention**

The minimum period for retention of research data is 5 years for non-clinical research, (this includes health and social science research), 15 years for clinical research and until participants are at least 25 years of age for research involving children/adolescents under the age of 16.

# ADMINISTRATIVE ASPECTS

* 1. **Independent HREC approval**

This study has been approved by the Northern Sydney Local Health District HREC 202X/ETHXXXXX:

* 1. **Amendments to the protocol**

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

* 1. **Participant reimbursement**

Details of participant reimbursement, if any.

* 1. **Financial disclosure and conflicts of interest**

Please state if any.

# USE OF DATA AND PUBLICATIONS POLICY

The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.

# REFERENCES

This is the bibliography section for any information cited in the protocol.

List MUST INCLUDE: guidelines on the conduct of research in humans (eg National Statement).