Note to Users

This Protocol Template is designed to be generic and to be used as a guide. Investigators should amend the protocol contents to meet the needs of their study. It is recommended that you keep all headings in this template – but respond with N/A as required..

Once you have finished your template, don't forget to highlight and right hand click on the contents page and select "update all", this will automatically update the page and section numbers that have change.

Links

Other protocol templates may provide additional information more relevant to your study. Please consider:

Mater Research:	**Guide to writing a research protocol / QA project plan - Mater Research**
Royal Melbourne:	https://www.thermh.org.au/research/researchers/ethics/submit-ethics-application
CFAHR:	https://www.health.qld.gov.au/cfahr/html/proposal
WHO:	**http://www.who.int/rpc/research_ethics/format_rp/en/**
Western Australian Govt:	
	WA Health Research Protocol Template for Non-Clinical Trials
	WA Health Research Protocol Template for Clinical Trials (Word 181KB

PROTOCOL

[Insert Full study Title]

Version:
Date: DD/MM/YYYY

Author/s:
<<List Author/s>>

Sponsor/s (for clinical trials only)
<<Insert Sponsor/s>>

CONFIDENTIAL

Statement of Compliance

This study will be conducted in compliance with all stipulation of this protocol, the conditions of the 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).

STUDY SYNOPSIS

(please provide brief information)

Title:			
Short Title:			
Design:			
Study Location/s:	☐ MSAMHS All Sites ☐ MSAMHS Community Sites ☐ MSAMHS Inpatient Units ☐ PAH Inpatient Unit ☐ Redlands Inpatient Unit ☐ Logan Inpatient Unit ☐ Beenleigh Community Site ☐ Inala Community Site ☐ Browns Plains Community Site ☐ Woolloongabba Community ☐ Evolve Therapeutic ☐ Bayside Community ☐ Logan Community ☐ Coorparoo CCU ☐ Logan CCU ☐ Bayside CCU ☐ Other		
Study Question:			
Study Aims & Objectives:			
Is there any specific assistance required from the RAC? (eg power calculations)			
Anticipated Start Date		Anticipated Duration	
Principal Investigator Name:		ACU	
Phone		Email	
Signature		Date	
Study Support			
Team Leader Name		Professional Leader Name	
Signature/Approval		Signature/Approval	
Date		Date	
ACU Clinical Director Name			
Signature/Approval		Date	

Study Title

Study Short Title

Study Research Team

<<Names, affiliations, positions, designation and responsibilities of investigators and other key project team members >>

Principal Investigator

- Position
- Designation
- Contact Details
- ACU
- Address
- Roles and responsibilities

Co Investigator/s

- Position
- Designation
- Contact Details
- ACU
- Address
- Roles and responsibilities

Rationale and Background

<<Background Information>>

- Literature review
- Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved clinical practice)

Study Objectives

Research Question/ Hypothesis

- Significance
- Aims and objectives
- Expected outcomes

Study Setting

- Single site
- Multiple sites

Study Design & Methodology

- method/s (linked to project aims/objectives)
- How does it address the different hypothesis research questions
- Social inclusion – review of design/information to population by peer workforce/consumer carer

Study Population

Population:

- Description and rationale
- Recruitment methods/ Source
- Inclusion/exclusion procedure/ criteria
- Participant safety
- Risk management & Safety
- Handling withdrawals
- Impact of and response to participant withdrawal (not required for qualitative studies)

Sampling Issues:

- Size of study group appropriate – statistical power appropriate
- Justification for size
- Reasonable representativeness of population

Bias minimisation measures

- Methods to minimise bias & confounding included (not required for qualitative studies)
- Randomisation (not required for qualitative studies)

Interventions/ Research Activities

<<What you are going to do?>>

- justifications for interventions/activities
- procedures
- assessments/outcome measures (measurements, observations, lab investigations)
- description of sequence and duration of techniques or assessments to be performed
- Study termination criteria

Data Collection/ Outcome Measures

<<What information are you going to collect/gather? >>

- Data collection/gathering techniques: How will you collect/gather the information?
- Tools to be used - (questionnaire, interview questions/prompts, data collection tool)

Data analysis plan

- Types of analysis and description
- Data analysis software used
- Presentation of demographic and outcome data summaries

Data management & Storage

- Data management systems
- Confidentiality and security
- Details of where records will be kept & how long they will be stored/archived Re-use, destruction plans
  Note: MSAMHS procedure on data storage is currently in progress

Resources

Physical Resources
All resources that will be used (even if already available)– eg meeting rooms, PC, whiteboards

Item	**Length of Time Required**	**Frequency during study**
Eg Conference room for training	*3 hours*	*2*

Human Resources

Personnel ***(Role, Position, Designation): Please include each member of the study team separately***	**Hours Required / week or per month (please indicate)**	**Timeframe required**
Eg1 *Jo Researcher (PI)* *Team Leader* *HP5*	*4/ week +* *2/week*	*12 months* *6 months*
Eg 2 *30 survey respondents (staff)* *Various roles (Av: 5 x HP3; 5 x HP4; 5 x CNC)*	*.5 hours / week*	*1 week*

- All costs/ including in-kind resources (eg time)
- If study entails cooperation by individuals other than the investigators, or use of equipment or resource, then permission for use of services should be obtained from the relevant manager

Timescale

- The timetable/schedule of the research
- list all the tasks and estimate duration, be generous/realistic
- Project closure processes

Ethical Considerations

<<Matters relevant to and the methods by which the study population interests will be safeguarded should be described Ethical principles **do good** (known as **beneficence**) and **(b) do no harm** (known as **non-malfeasance**). **(a)** obtain **informed consent** from potential research participants; **(b)** minimise the **risk of harm** to participants; **(c)** protect their **anonymity** and **confidentiality**; **(d)** avoid using **deceptive practices**; and **(e)** give participants the **right to withdraw** from your research. http://dissertation.laerd.com/principles-of-research-ethics.php >>

- Potential for undue influence and how relationships might affect the voluntariness of consent should be considered
- Justification of treatments/interventions
- Permissible medications/treatments
- Procedures for monitoring participant compliance
- Risk mitigation
- Frequency of monitoring for adverse events
- Methods of checking for and dealing with potential adverse events/side effects

Population study information

- Information provision
- Method of obtaining informed consent
- Confidentiality of data
- Potential issues addressed
- Risks to participants minimised

Assessment of Efficacy

- Specification of parameters
- Methods for timing for assessing, recording

Assessment of safety

- Known risks and benefits to participants
- Procedures for assessing and responding to potential participant safety events
- Procedures for eliciting reports and reporting of adverse events
- Type & duration of follow-up of participant/s for adverse events

Outcomes and significance - Dissemination

- Benefits of the study
- Contribution to clinical practice
- Contribution to knowledge
- Plans for return of results of research to participants
- Plans for dissemination and publication of study outcomes
- Other potential uses of the data at the end of the project - How results will be used- likely affect to health care, systems/policies
- Plans for sharing and/or future use of data and/or follow-up research
- Anticipated secondary use of data

References

<<Sources of information referred to in the research protocol should be listed>>