**Research Protocol**

**FULL PROJECT TITLE**

**SHORT TITLE OR ACRONYM**

**LAY DESCRIPTION OF THE PROJECT (2-3 LINES ONLY)**

**WORDING TO STATE THE PROJECT WILL BE CONDUCTED IN COMPLIANCE WITH RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS IS RECOMMENDED HERE**

**PROJECT INVESTIGATOR(S)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Phone** | **Email** | **Institution** | **Study Role (e.g. Principal Investigator, Associate Investigator, Research Assistant)**  |
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**SUGGESTED RESEARCH PROTOCOL TEMPLATE HEADINGS***(delete those not applicable)*

1. **INTRODUCTION**
2. **BACKGROUND**
3. **AIM(S) OF PROJECT**
4. **OBJECTIVE(S)**
	1. Primary objective(s)
	2. Secondary objective(s)
5. **HYPOTHESIS (HYPOTHESES)**
	1. Primary hypothesis (hypotheses)
	2. Secondary hypothesis (hypotheses)
6. **PROJECT DESIGN AND METHODOLOGY**
7. **PROJECT SITE(S) / LOCATION(S)**
8. **PROJECT DURATION / TIMELINE**
9. **PROJECT POPULATION**
	1. Recruitment process
	2. Inclusion criteria
	3. Exclusion criteria
	4. Potential for risk, burdens and benefits
10. **PROJECT OUTCOME(S)**
	1. Primary outcome(s)
	2. Secondary outcome(s)
11. **PROJECT PROCEDURES**
	1. Recruitment and consent of participants
	2. Withdrawal of participants from a project
* *Participant withdrawal from project procedures*
* *Participant withdrawal from a project*

* 1. Randomisation
	2. Measurement tools used
	3. Project involvement by participants
	4. Data management and storage
	5. Safety considerations / patient safety
	6. Data monitoring
1. **SAMPLE SIZE AND DATA ANALYSIS**
	1. Sample size and statistical power
	2. Data analysis plan
2. **ETHICAL CONSIDERATIONS**
3. **DISSEMINATION OF RESULTS AND PUBLICATIONS**
4. **OUTCOMES AND SIGNIFICANCE**
5. **GLOSSARY OF ABBREVIATIONS**
6. **REFERENCES**