Study plan for a Quality Assurance (QA) activity

### FULL QA STUDY TITLE

### SHORT TITLE OR ACRONYM

### LAY DESCRIPTION OF THE STUDY (2-3 LINES ONLY)

### WORDING TO STATE THE PROJECT WILL BE CONDUCTED IN COMPLIANCE WITH RELEVANT LEGISLATION AND GUIDANCE DOCUMENTS

## STUDY INVESTIGATOR(S)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Phone** | **Email** | **Institution** | **Study Role (e.g. Principal Investigator, Associate Investigator, Research Assistant)**  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

SUGGESTED QA STUDY PLAN HEADINGS (delete those not applicable)

## **INTRODUCTION**

## **BACKGROUND**

## **AIM(S) OF QA ACTIVITY**

## **OBJECTIVE(S)**

## **HYPOTHESIS**

## **QA DESIGN AND METHODOLOGY**

## **QA SETTING(S) / SITE(S)**

## **QA DURATION / TIMELINE**

## **QA POPULATION**

####   9.1 Inclusion criteria

####  9.2 Exclusion criteria

####  9.3 Potential for risk, burdens and benefits

## **QA OUTCOME(S)**

####  10.1 Primary outcome(s)

####  10.2 Secondary outcome(s)

# **QA PROCEDURES**

####  11.1 Recruitment and consent of participants

####  11.2 Withdrawal from a study / project

####  11.3 Randomisation

####  11.4 Measurement tools used

####  11.5 Study involvement by participants

####  11.6 Data management and storage

####  11.7 Safety considerations / Patient safety

## **SAMPLE SIZE AND DATA ANALYSIS**

####  12.1 Sample size and statistical power

####  12.2 Data analysis plan

## **ETHICAL CONSIDERATIONS**

## **DISSEMINATION OF RESULTS AND PUBLICATIONS**

## **OUTCOMES AND SIGNIFICANCE**

## **GLOSSARY OF ABBREVIATIONS**

## **REFERENCES**