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**