Common errors in Protocol submission

The following document outlines common errors and omissions noted by the DRC:

General

1. Contact details of the corresponding investigator is not supplied
2. A standardized protocol format is not followed (HREC recommended format)
3. The study timeline is omitted or the date of planned collection of data has already passed
4. Investigator does not address when s/he plans to do with the data on completion (reporting and implementation)

Introduction

1. The introduction / literature review is not referenced
2. The introduction does not address the research question / aims of the study
3. The literature review is recommended to be between 300 and 1000 words
4. Grammatical and spelling errors

Objectives

Primary (and secondary) objectives are not clearly defined

Methods

1. The study design is not documented
2. The time period for the study is vague
3. A sample size analysis or power calculation has not been performed where appropriate
4. Inclusion and exclusion criteria are omitted
    a. Note exclusion criteria are not the opposite of inclusion criteria, but exclusions for those participants that fulfil the inclusion criteria
5. Recruitment and enrolment are not addressed
6. A datasheet with proposed variables to be collected is not supplied

7. Researchers often indicate that a statistician will be consulted following collection of the data. The role of the statistician/ stats analyst is to plan the design of the study. It is therefore essential that the planned statistical analysis is presented in the protocol. This also applies to descriptive studies and audits.

Ethics

Although it is not the mandate of the DRC to assess the ethical integrity of the protocol, obvious ethical concerns will be address.

1. Consent forms (where required) should be submitted as supplemental documentation
2. If telephonic consent is required, a description of the method of acquiring consent should be supplied
3. Confidentiality in the management of data is not addressed
4. Risks/inconveniences to participants in the study are not documented
5. Specific patient/participant benefits are not addressed