|  |  |
| --- | --- |
| SOP Number | Insert Number |
| SOP Title | Design and Development of Case Report Forms |
|  | NAME  | TITLE | SIGNATURE | DATE |
| Author |  |  |  |  |
| Reviewer |  |  |  |  |
| Authoriser |  |  |  |  |

|  |  |  |
| --- | --- | --- |
|  | Effective Date: |  |

|  |
| --- |
| READ BY |
| NAME | TITLE | SIGNATURE | DATE |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

This SOP has been written as an example which can be adapted for use in any department conducting clinical research where there are no SOPs in place. The contents of the SOP should be reviewed in conjunction with the procedures which take place within the department and the text should be altered accordingly.

Delete highlighted text before finalising the document.

# purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the standard procedures to be followed when designing and developing Case Report Forms (CRFs) in clinical research sponsored by the University of Oxford.

# introduction

Case Report Forms (CRFs) are printed, optical or electronic document designed to record all of the protocol required information on each trial subject.

# Scope

This SOP applies to paper CRFs used in clinical research where the University of Oxford has accepted the role of ‘Sponsor’, in the INSERT NAME department/ for the INSERT NAME/NUMBER trial (delete as appropriate).

This SOP does not apply to commercially sponsored research or research sponsored by an external non-commercial organisation.

# responsibilities

Chief Investigator (CI) or delegate

The Chief Investigator or delegate is responsible for the design and development of CRFs. The CI is also responsible for ensuring that there are adequate CRFs for use in the study in all participating sites. Instructions should be given to all participating sites on how to complete the CRFs to ensure data is collected in a standardized fashion. A CRF completion guide may be useful in a multicenter study.

# SPECIFIC PROCEDURE

A CRF should be designed to ensure that it captures all the information which is required according to the protocol. It should not capture information which is not specified in the protocol. Clinical Trials and Research Governance have a CRF template, which can be adapted to suit the study requirements.

## CRF design

The way the CRF is designed depends on the type of variables that are collected.

Generally the following guidelines should be followed:

* The arrangement of the data fields should be clear, logical, and user friendly.
* When possible, provide tick box options and free text kept to a minimum. Tick box options should be exhaustive e.g. provide an option for “other” or “NA” if appropriate.
* For variables where the actual value is captured, the number of boxes required should be adequate and if appropriate reflect the number of decimal places desired.
* The unit of measurement should be specified.
* Consideration should be given as to how the CRF will relate to the database.

## What data should the CRFs capture?

CRFs should have study identification (study code, title, sponsor). If possible, all pages should have the subject ID and initials. The date of each subject visit should be captured. There should be a place, preferably at the end of the CRF for the Principal Investigator’s signature to verify that all data is complete and accurate.

Typically, CRF pages are arranged in order of subject visits and should include the following:

* Inclusion/exclusion criteria checklist with tick boxes
* If informed consent had been taken or date informed consent taken
* Subject demographics (e.g. age, gender, ethnicity)
* Relevant medical history
* Results of physical exam
* Baseline data
* Primary and secondary endpoints
* Laboratory data, ECG etc.
* Dosing and compliance data
* Adverse events
* Concomitant medications
* Withdrawal/Off study form
* Serious Adverse Event Reporting Form (if available)

# forms/Templates to be used

# Internal AND EXternal references

This section is used to list all controlled internal references (e.g. SOPs) and external references referred to within the text of the SOP only.

Where Forms/Templates are referenced in the text, the numbers and titles are listed under this section.

## Internal References

## External References

ICH Harmonised Tripartite Guideline for Good Clinical Practice.

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of medicinal products for human use.

# CHANGE HISTORY

Where the SOP is the initial version:

* SOP No: Record the SOP and version number
* Effective Date: Record effective date of the SOP or “see page 1”
* Significant Changes: State, “Initial version” or “new SOP”
* Previous SOP no.: State “NA”.

Where replacing a previous SOP

* SOP No: Record the SOP and new version number
* Effective Date: Record effective date of the SOP or “see page 1”
* Significant Changes: Record the main changes from previous SOP
* Previous SOP no.: Record SOP and previous version number

| SOP no. | EffectiveDate | Significant Changes | PreviousSOP no. |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |