About the Case Report Form Template

The case report form (CRF) is a data collection tool used to capture the required data, as defined by the protocol, for each individual subject during their participation in the study. It is also a tool to guide the researcher through each study visit and can be used to document Investigator oversight of study conduct.

The design of the CRF must ensure that:

* Data will be captured and entered into the CRF in a chronological order, reflective of the protocol.
* The order of study visits and procedures will be taken into account, in order to make data entry as easy as possible for users and minimise the risk of missing data capture.
* Where data will be transcribed into the CRF from source documents, the layout and content of the CRF will be structured to minimise transcription errors (i.e. ensure units match).
* Raw data will be collected, where this is practical, to minimise unnecessary manual calculations and reduce risk of error.

This CRF template is designed to give a general basis on which to build a study specific CRF and therefore all sections may not be relevant and all study specific sections may not be present. Use the study protocol to add, remove and adapt sections of the CRF template to produce a study specific data collection tool. Highlighted text should be replaced with study specific details. Guidance text is included as a prompt and should be removed once appropriate text has been entered if required.

The CRF can be designed as one booklet for the study or as a collection of separate visit level documents. Decide what works best for your study design. If one booklet is to be produced, you can use the attached front page to start the CRF. The footer documenting the version of the CRF should be made continuous throughout for a single booklet where as individual visit specific CRFs can be updated independently of each other and each requires its own unique version in the footer.

Please see SOP CR013 for additional guidance on CRF design and responsibilities for implementation. For studies which have undergone combined risk assessment (GS002) the CRF must be reviewed by the lead ACCORD monitor prior to implementation.

Insert trial logo here

Insert full study title here

REC no.(optional):

**Case Report Form**

Chief Investigator: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Principal Investigator:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Site:** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Participant ID:** |  |
| **Participant Initials:** |  |