

## STANDARD OPERATING PROCEDURE:

### Case Record Form Completion (Electronic and Manual)

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<b>SOP SUMMARY</b>		
This SOP describes the procedure for completing, signing and correcting case report forms.		
<b>The Trust monitors the implementation of and compliance with this policy in the following ways:</b>		
Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.		
<b>Services</b>	<b>Applicable</b>	<b>Comments</b>
Trustwide	✓	
Essex MH&LD		
CHS		

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(Electronic and Manual)**

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## CLPG19 SOP4 Case Record Form Completion (Electronic and Manual)

### 1. BACKGROUND

ICH Good Clinical Practice Guidelines define a Case Report Form (CRF) as:

*“A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject”*

The rationale for using CRFs in a study is to collect the necessary information about:

- The patient
- Study interventions
- Administration of the Investigational Product (if applicable)
- Study procedures
- Outcome of assessments/tests
- Adverse events

CRFs are the official documentation of the trial for both sponsors and regulatory authorities, and together with the source documents contained in the Study File, will be closely examined during audits and inspections.

The data collected on the CRF is therefore used directly as the basis for the trial report and any publications, as well as making up part of the data for regulatory approval of a new drug.

### 2. PURPOSE

To describe the procedure for completing, signing and correcting case report forms.

### 3. PROCEDURE

Prior to study initiation/start-up, it is the responsibility of a designated member of staff to ensure there is an adequate supply of CRFs at the research site. If the study requires electronic data entry, the designated member of staff should ensure that there is access to the electronic data entry system. The delegation of responsibility of CRF completion by the Investigator should be documented on the Study Delegation Log/ Site Responsibility Log and only these individuals may enter data in a CRF.

CRFs should be completed according to the specifications of each study. CRFs should be completed prospectively in a timely fashion, where possible.

### 3.1 Manual CRF completion

Always use a **black** ink ballpoint pen as the ink is less likely to fade and photocopies are clearer.

If the CRFs are printed on carbonless duplication paper, always make sure that a suitable separator is inserted under the form being completed.

Ensure data entry is as complete as possible without omissions. It is impossible for personnel doing the data entry to interpret blank spaces. If data is unavailable write, for example, '*unknown*', '*missing*', '*test not done*', etc. as defined by CRF Completion Guidelines (if applicable) and explain by use of file note why data is unavailable. Avoid using the ambiguous phrase, 'not available'.

Ensure all entries are accurate, legible and verifiable with the source data in the medical record. Do not invent data.

Any discrepancies with source data should be explained and the significance noted in the CRF and/or patients medical records. For laboratory values outside the laboratory's reference range or some other range defined within the protocol, or if a value shows significant variation from one assessment to the next, this should be commented on and the significance noted in the CRF and/or patients medical records.

Never over-write an entry. Corrections should be made as follows:

- Cross out the incorrect entry with a single line so that the incorrect entry should still be readable. Never use correction fluid or obliterate entries made on the CRF.
- Enter the correct data.
- Initial and date the correction, and give an explanation of the correction if required by protocol.

The procedure to be followed for the resolution of data queries should be agreed with the coordinator or the designated person for data queries and completed by site staff in a timely fashion.

Unless otherwise agreed, laboratory values should be entered without conversion from printed reports even if in multi-centre study units of measurement differ from centre to centre.

The patient's identity should remain confidential at all times, for this reason it is imperative that the patient is identified by a study number and/or initials only on the CRF (some exceptions may apply). A record must be kept by the Principal Investigator of patients in the study consisting of the patient's full name and study number; this is the Subject Identification Log and can be found in the Study File.

The CRF must be signed where indicated, by the Principal Investigator or designee (as appropriate) to assert that he/she believes they are complete and correct.

CRFs should be kept in a secure location during the course of the study. CRFs should then be archived when the study has finished.

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### 3.2 Electronic CRF completion

The designated member of staff must ensure that access to the electronic system has been obtained, including usernames and passwords.

Once all the data has been entered, the individual should ensure the file is accurately submitted to the sponsor company or CRO (Contract Research Organisation) in accordance with trials centre guidance.

Never disclose a password to another member of the team – this represents an electronic signature.

### 4. CONFIDENTIALITY

To ensure patient confidentiality the computer should not be left unattended whilst the data is being entered and should be accurately closed down once all the data has been submitted.

If a laptop has been provided for this purpose it should only be used for study specific data. Normal arrangements relating to Data Protection must be adhered to.

### 5. REFERENCES

National Cancer Research Network (2004) Case Record Form Completion

ICH-GCP, Good Clinical Practice Guidelines,  
<http://ichgcp.net>