|  |  |
| --- | --- |
|  | **<< Short Project Name/Acronym >>**  **Case Report Form Completion Guidelines** |



**Trial Logo**

(if applicable)

Protocol Version Number: XXXX

Chief Investigator: XXXX

This research project uses a <<specify e.g. MACRO/REDCap>> database to capture the data remotely.

**Where required: post/e-mail <<specify CRFs e.g. SAE forms>> CRFs to the <<XXXX>> Trial Manager at the following address**

**<<XXXX>> Trial Manager**

Swansea Trials Unit,

Swansea University Medical School

Institute of Life Science 2, Singleton Park

Swansea SA2 8PP

<<xxxx>>@swansea.ac.uk

Data should be submitted within <<xxxx>> weeks of the end of a visit.

**Eligibility, SAE and pregnancy forms have more urgent timelines, detailed in Section 4.11.**

**Remember any research project related documentation sent to the trial manager MUST NOT contain any patient-identifiable data.**

*Instructions please delete on completion.*

*Instructional text – requires you to complete the information. Prior to finalising the guidelines, ensure all text is black.*

*Optional text – requires you to choose one of the options and delete the other as applicable to your trial, prior to finalising the guidelines, ensure all text is black.*

*Standard wording – not to be removed or changed without prior consultation with the Swansea Trials Unit*

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# List of *Add short trial name* Case Report Forms

*Amend as necessary – this is an example of the generic CRF forms only*

|  |  |
| --- | --- |
| **Number** | **Title** |
| FORM XX | Inclusion Criteria |
| FORM XX | Exclusion Criteria |
| FORM XX | Eligibility review |
| FORM XX | Randomisation/Enrolment |
| FORM XX | Patient Details |
| FORM XX | Lifestyle |
| FORM XX | Medical History |
| FORM XX | Baseline Medical Conditions |
| FORM XX | Baseline Vital Signs |
| FORM XX | Baseline Physical Exam |
| FORM XX | ECG |
| FORM XX | Vital Signs |
| FORM XX | Physical Examination |
| FORM XX | Haematology Results |
| FORM XX | Biochemistry Results |
| FORM XX | *Insert Assessment delete if not required* |
| FORM XX | Initial Treatment |
| FORM XX | Treatment |
| FORM XX | Concomitant Medications |
| FORM XX | Adverse Events |
| FORM XX | Adverse Events of Special Interest |
| FORM XX | Serious Adverse Events |
| FORM XX | Pregnancy |
| FORM XX | Research Blood Samples |
| FORM XX | End of Treatment |
| FORM XX | Follow-Up Visit |
| FORM XX | Details of Death |
| FORM XX | Consent Withdrawal |
| FORM XX | *Any other required information delete if not required* |
| FORM XX | Infection |
| FORM XX | PI Declaration |
| QUESTIONNAIRES | *[List all questionnaires]* |
|  |  |
|  |  |

# Abbreviations

*Add or delete as required*

|  |  |
| --- | --- |
| **Abbreviation** | **Full Term** |
| AE | Adverse Event |
| BMI | Body Mass Index |
| CRF | Case Report Form |
| CT | Computerised Tomography |
| MedDRA | Medical Dictionary for Regulatory Activities |
| ECG | Electrocardiogram |
| MRI | Magnetic Resonance Imaging |
| ND | Not Done |
| PD | Progressive Disease |
| SAE | Serious Adverse Event |
| SD | Stable Disease |
| NK | Not Known |
|  |  |

# Visit Schedule and CRF Overview

*List all visits and all forms used at each visit*

|  |  |  |
| --- | --- | --- |
| **Visit** | **Form Number** | **Form Title** |
| e.g. Screening Visit -2 |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

| **Form**  **Number** | **Form Title** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** | **Visit x** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FORM XX | Inclusion Criteria |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Exclusion Criteria |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Eligibility Review |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Randomisation/Enrolment |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Patient Details |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Lifestyle |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Medical History |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Baseline Medical Conditions |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Baseline Vital Signs |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Baseline Physical Exam |  |  |  |  |  |  |  |  |  |  |
| FORM XX | ECG |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Vital Signs |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Physical Examination |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Haematology Results |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Biochemistry Results |  |  |  |  |  |  |  |  |  |  |
| FORM XX | *INSERT ASSESSMENT add or delete* |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Initial Treatment |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Treatment |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Concomitant Medications |  | As appropriate | | | | | | | | |
| FORM XX | Adverse Events |  | As appropriate | | | | | | | | |
| FORM XX | Adverse Events of Special Interest |  | As appropriate | | | | | | | | |
| FORM XX | Serious Adverse Events |  | As appropriate | | | | | | | | |
| FORM XX | Pregnancy |  | As appropriate | | | | | | | | |
| FORM XX | Research Blood Samples |  |  |  |  |  |  |  |  |  |  |
| FORM XX | End of Treatment |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Follow-Up Visit |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Details of Death |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Consent Withdrawal |  |  |  |  |  |  |  |  |  |  |
| FORM XX | *Any other required information or delete* |  |  |  |  |  |  |  |  |  |  |
| FORM XX | Infection |  |  |  |  |  |  |  |  |  |  |
| QUESTIONNAIRES | *List all questionnaires or delete* |  |  |  |  |  |  |  |  |  |  |

# General Completion Guidelines *Amend as necessary*

## General Principles for CRF Completion

* Data should be complete, without omissions
  + - Missing data should have an explanation in the source documents
* CRFs should be completed only by those delegated the task to do so, who have received trial-specific training and are competent in CRF completion. They should also have completed and signed the site’s trial Delegation Log
* CRFs should be completed as soon as possible after each participant’s assessment
* The correct version of the CRF must be completed
* Data reported on the CRF must be accurate and verifiable against documented source data
* Values outside normal, or expected, reference ranges shall have a file note completed
* All CRF pages must be clear, legible and completed in black ball point ink

Important as 1 and 7 can be misrepresented if the writing is not clear

e.g. 1 or I and 7 or ~~7~~

* Where selection boxes indicate a selection of Y or N or numerical options (i.e. 1, 2, 3), only ONE entry should be recorded per box
* The CRFs must be completed, dated and initialled by an Investigator or delegate as soon as the requested information is available

**For trials not using an eCRF:**

* + - The **ORIGINAL** CRF pages must be returned promptly to the Trial Manager
    - The investigator site should always retain a copy of each completed form
* Any changes made to the CRF pages once the original has been uploaded to the database must be sent to the Trial Manager within XX days/months (*see section 4.9 Correcting Errors)*
* Data queries shall be addressed quickly and an audit trail exist to detail outcome
* The timely completion, legibility and accuracy of the CRFs remain the responsibility of the Principal Investigator (PI) at site
* The PI should retain regular oversight and timely sign off of the CRFs
* PIs should sign off the eligibility CRF

## Header Boxes

* The following data must be completed in the header of every completed CRF:
* Patient Initials: First and last initials only
* Patient Date of Birth: Enter using the DD/MM/YYYY format (e.g. 22/03/2017)
* Site Code: The site number allocated at site initiation (e.g. N07)
* Participant ID number: Each participant will receive a unique XXXX-digit trial number upon randomisation/enrolment (e.g. 0261)

## Footer Boxes

* The following data must be completed in the footer of every completed CRF:
  + Completed By: Initials of person completing the form
  + Date Completed: Enter using the DD/MM/YYYY format (e.g. 22/03/2017)

## Patient Data

* CRFs (and any other study-related documentation) sent to the Trial Manager **MUST NOT** contain any patient-identifiable information
* Please use ONLY the participant ID number when communicating with the STU team

## Completion of Dates

* All dates are to be completed in the sequence day/month/year (DD/MM/YYYY)
* If the day or month is unknown complete the boxes with NK

## Entering numbers

* Enter a digit in each box provided, if three boxes are provided but only two are required please enter a preceding 0

0 2 3

e.g.

## Unavailable Data

* **All** applicable questions must be answered
* Where data are not available **please do not leave the answer blank** as this will create unnecessary data queries
* Please include one of the following abbreviations instead:
* NK = Not known
* NA = Not available
* ND = Not done

## Completion of Time

* Time should be completed in a consistent manner in 24 hour format (e.g. 14:00)

## Correcting Errors

For Paper CRFs:

* Errors should be crossed out with a single line (i.e. ~~mistake~~), the correction inserted and the change initialled and dated by the investigator or delegate
* Typing correction fluid should **NOT** be used
* If it is not clear why a change has been made, an explanation should be written next to the change

For eCRFs:

* Corrections should be entered directly over the values in the eCRF
* Reason for the amendment should be entered on to the system
* The database system will record an audit trail of amendments. There is no need to initial or date the amendment

## Sending paper CRFs to the Trial Manager

* Please send **ORIGINAL** CRF forms to:

Trial Manager name

Trial ID

ADD ADDRESS

* Ensure that the form is copied, with the original sent to the manager and a copy kept at your site
* Once a patient has been registered, please send the following IMMEDIATELY:

FORM XX: ELIGIBILITY (EXCLUSION/INCLUSION CRITERIA)

Anonymised supporting documents as required by the protocol

## Sending SAE and Pregnancy forms to the Trial Manager

* Completed **SAE/PREGNANCY** forms should be sent to the trial manager by email/fax **within 24 hours** of becoming aware of the event

# Completion Guidelines *Amend as necessary*

Note: Guidelines are only provided for questions on the Case Report Form (CRF) where guidance will be of benefit to support completion. Therefore, not all questions on the CRFs are covered by these guidelines. Contact the Trial Manager if you require clarification on any questions.

CRFs should be designed so that they are clear, concise and easy to complete. They can have brief instructions but must be intuitive. Instructions shall only be provided for CRFs that are complicated and will be of benefit to completion.

Please document completion guidelines for necessary forms below. Add or remove forms as necessary.

FORM XX: Eligibility Criteria

Complete this form at the following point in the trial:

* Screening
* Tick the box confirming that the patient meets all inclusion and exclusion criteria
* Please ensure this form is signed and dated by the INVESTIGATOR prior to sending to the Trial Manager
* *Provide a copy of the anonymised pathology report/CT scan report as required*

FORM XX: Medical History

Complete this form at the following point in the trial:

* Screening
* Ensure all questions are completed as baseline measurements are **MANDATORY**. If any information is not known, please mark as NK, clearly stating the reason on the CRF

FORM XX: Baseline Medical Conditions

Complete this form at the following point in the trial:

* Baseline visit
* *Use agreed format <<e.g. MedDRA* [*http://www.meddra.org*](http://www.meddra.org)*>>*

FORM XX: Baseline Physical Examination

Complete this form at the following point in the trial:

* Baseline visit
* Sex and Height are only mandatory at screening visit
* If the patient presents any physical abnormalities, please give details of these in the table

FORM XX: ECG

Complete this form at the following point(s) in the trial:

* XXX
* XXX
* XXX
* If the ECG result is abnormal, details of how the result is abnormal must be provided
* In the case of abnormal ECGs, the PI or Co-investigator MUST confirm that the patient can receive the trial treatment

### 

FORM XX: Haematology Results

Complete this form at the following point(s) in the trial:

* XXX
* XXX
* XXX
* Check units of values entered to ensure these match the units listed on the form. Enter ‘ND’ for those tests that were not done

FORM XX: Concomitant Medications

Complete this form as appropriate at the following points in the trial:

* Baseline visit
* During Treatment
* End of Treatment
* XXX
* XXX
* Complete ALL fields on the form (using the codes provided)
* Enter only ONE value per field (e.g. do not enter a range such as ‘100-200’ for Dose)
* If the medication is on-going, enter ‘1’ in the ‘On-going’ field
* If the medication is NOT on going, enter ‘0’ in the ‘Ongoing’ field AND PROVIDE THE STOP DATE

FORM XX: Adverse Events

Complete this form as appropriate during the trial.

* Use the agreed format e.g*. MedDRA/CTCAE*
* Complete ALL fields on the form (using the codes provided)
* If the event is on-going, enter ‘1’ in the ‘on-going’ field
* If the event is NOT on going, enter ‘0’ in the ‘Ongoing’ field AND PROVIDE THE END DATE
* Each form should contain details of a single AE. Complete the same form at each visit. When the AE has been resolved send the original form to STU

FORM XX: Adverse Events of Special Interest

Complete this form as appropriate during the trial.

* Use the agreed format e.g*. MedDRA/CTCAE*
* Complete ALL fields on the form (using the codes provided)
* If the event is on-going, enter ‘1’ in the ‘on going’ field
* If the event is NOT on going, enter ‘0’ in the ‘Ongoing’ field AND PROVIDE THE END DATE.
* Each form should contain details of a single AESI. Complete the same form at each visit and send a copy of the updated form to the Trial Coordinator
* When the AESI has been resolved send the original form to the CCTU-CTC.

FORM XX: Serious Adverse Events

Complete this form as appropriate during the trial:

* Use the agreed format e.g*. MedDRA/CTCAE*
* Complete all sections of the form
* Report the SAE to the Trial Coordinator as defined in the protocol

The form should be sent to the trial coordinator **within 24 hours** of becoming aware of the event by fax/email.

FORM XX: Pregnancy

Complete this form at the following point in the trial:

* If the patient becomes pregnant
* If the patient’s partner becomes pregnant

The form should be sent to the trial coordinator **within 24 hours** of becoming aware of the pregnancy by fax/email.

FORM XX: Follow-Up Visit

Complete this form at the following point(s) in the trial:

* Follow-up
* To be completed every XXX (Add frequency e.g. 4 weeks)
* If answered “Dead” for survival status, please ensure FORM XX: Details of Death is completed

FORM XX: Details of Death

Complete this form at the following point in the trial:

* Patient death

FORM XX: Consent Withdrawal

Complete this form as appropriate during the trial if:

* The patient withdraws consent for any reason
* Return this form to the Trial Manager as soon as possible after the patient has withdrawn consent

QUESTIONNAIRE(S): EORTC QLQ-C30, QLQ-PAN26, EQ-5D-5L (etc.)

Ensure these forms are completed by the patient at the following point(s) in the trial:

* XXX
* XXX
* XXX
* Complete the header of the questionnaires before releasing the documents to the patient
* Review the completed form to ensure all questions have been answered

# Appendix 1 – XXXXXXXXX Amend as necessary - Included as an example