

	<div style="text-align: right;">   <b>University Hospitals Plymouth</b>  <small>NHS Trust</small> </div> <p style="text-align: center;"><b>STANDARD OPERATING PROCEDURE</b></p>
---	--

**DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION**


The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website:

<https://www.plymouthhospitals.nhs.uk/research-sops>

## Case Report Forms Design

SOP No: P15  
 Version No: 2.1  
 Effective Date: Jan 2019  
 Supersedes: Version 2.0, Sep 2019  
 Page: 1 of 23

Last Review Date: Jan 2019                      Next review date: Aug 2022

	<b>APPROVED BY</b>
Name:	Chris Rollinson
Job Title:	Research Governance Manager
Signature:	
Date:	21 <sup>st</sup> Jan 2019

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 2 of 23
Title: Case Report Forms Design	Version: 2.1

## 1 Purpose and Scope

The purpose of this guide is to give assistance in the design of paper Case Report Forms (CRFs). CRFs are the official instrument to collect data from clinical trials and are a key component of quality assurance and control.

CRFs are used to collect data generated for a trial subject, during the course of their participation in a trial. They should be designed to collect data in accordance with the approved study protocol. A well designed CRF also helps to ensure compliance with regulatory requirements. Collaboration with a trial statistician is recommended when designing a study CRF.

Standard CRFs usually include the following forms:

- Randomisation/registration form
- Entry form (collects baseline data)
- Treatment form (doses, AEs, toxicity)
- Concomitant medication (if applicable)
- Adverse Events & Serious Adverse Events
- End of Treatment form (end result of study?)
- Follow-ups

In scope: research sponsored by UHPNT, particularly Chief Investigators (CIs), Statisticians, co-researchers, trial coordinators / managers and research nurses.

### **Definitions**

PI	Principal Investigators
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
REC	Research Ethics Committee
RD&I	Research Development & Innovation

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 3 of 23
Title: Case Report Forms Design	Version: 2.1

RO	Research Office
SOP	Standard Operating Procedure
UHPNT	University Hospitals Plymouth NHS Trust

## 2 Who should read this document?

Research staff involved in the designing and implementation of the CRF.

## 3 Procedure to Follow

### 3.1 General Principles

Each CRF should be dated and have a clear version number. Any changes to the final CRFs used during a trial should be documented.

The CRF layout should have a logical ordering that follows the schedule of clinic visits and should be consistent with the protocol. Thought should be given in advance as to whether any data collected on the CRF can be validated through monitoring of the original source document if required or if the CRF is the source document.

CRFs should be reviewed and signed off by the Chief Investigator and Trial Statistician, if available before they are used in the trial. It is good practice for data managers, monitors, CRAs and research nurses to view the CRFs prior to sign off as they will have a clear perspective of any practical issues that need to be considered in the capture of the study data.

Ideally a well-designed CRF will remind the Principal Investigators (PIs) at local sites to perform specific evaluations. Research nurses can use it easily to enter data, monitors can check data quickly as the CRF has a logical flow to it, and the database developer will be able to build in edit checks to help with data management and analysis.

The CRF package that is circulated to all local sites should include:

- General instructions
- Use permanent ink when completing
- Complete all items
- Provide glossary of abbreviations
- Contact information
- Procedure for corrections and amendments
- CRF study schedule
- Checklist and section dividers, preferably by visit

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 4 of 23
Title: Case Report Forms Design	Version: 2.1

## 3.2 Design Guide

For ease of completion:

- Provide definitions
- Specify units if appropriate
- Avoid requesting unnecessary calculations
- Consider grading visual analogue scales

For ease of understanding:

- Ask explicit questions
- Use absolute questions, e.g.:  
Use: None Rather than: Better  
Mild Same  
Moderate Worse  
Severe
- Give constant baselines for comparisons
- Avoid compound questions. This is a question that actually asks several things which might require different answers (more than one question is combined in what seems to be a single question). For example:  
"Are you still taking illicit drugs?" The argument is phrased as a single question requiring a single answer (yes or no), but actually involves two or more issues that cannot necessarily be accurately answered with a single response. By combining the questions "Are you currently taking illicit drugs?" and "Have you ever taken illicit drugs?" it is impossible for someone who has never taken illicit drugs to effectively answer the question, as phrased with a simple "no".

### 3.2.1 Layout

Keep adequate amounts of free space on the CRF page. Ensure alignment, margins, spacing and fonts are consistent throughout the CRF booklet. Margins should be large enough to accommodate hole punching/binding.

As much as possible, align text to the right with boxes to the left or centred so it is easily understood which tick box is associated to which question:

	Yes	No
Married?	<input type="checkbox"/>	<input type="checkbox"/>
Driving licence?	<input type="checkbox"/>	<input type="checkbox"/>
Any children?	<input type="checkbox"/>	<input type="checkbox"/>
Good health?	<input type="checkbox"/>	<input type="checkbox"/>

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 5 of 23
Title: Case Report Forms Design	Version: 2.1

Layout of CRF should allow for ease of completion, as well as ease of data entry. Things to look for with data entry include adding dropdown choices onto a database, grouping same type of data together on the same form, e.g. dropdown answers together, numeric together and alpha numeric together.

## 3.2.2 Header

The header of each CRF should include:

- Name of study or study number
- Participant identification number
- Participant's Initials
- Site/centre number (if not included in the subject number),
- Name of form
- If CRF goes to 2 pages, indicate page 1 of 2 and 2 of 2

It is easier to access this vital information when looking through a stack of CRFs if located in the upper right hand corner

<Name of study>	<subject ID number>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
<Name of form> (page 1 of 2)				Initials	<input type="text"/>	<input type="text"/>

## 3.2.3 Footer

Signatures and dates should be included at the bottom of each CRF. Each CRF should include the address to return form to on the bottom of the form

Completed by: .....	Date completed: .....
<i>Please return to: &lt;trial&gt; Coordinator, UHPNT, address</i>	

## 3.2.4 Data Collection

For data analysis purposes, avoid unnecessary textual data, pictorial data and obtaining data from diary cards. Provide choices for each question, this makes it easier at analysis.

Provide units to ensure comparable values and provide instructions to reduce misinterpretations.

Collect raw data rather than calculated data, e.g. for age, collect birth date and visit date. When collecting toxicity data, it is more valuable to have the exact value of the blood result, e.g. haemoglobin 5.2 g/dl rather than a Common Terminology Criteria for Adverse Events (CTCAE) toxicity grade of 3.

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 6 of 23
Title: Case Report Forms Design	Version: 2.1

There are different types of data collection responses:

- Open: text, number, alpha numeric
- Closed: Check box, multiple choice
- Combination: open and closed
- Analogue / rating scales

### 3.2.4.1 Open

Avoid free text if possible as it is almost impossible to analyse. For date / time, add characters to boxes to ensure that the dates are collected in a uniform fashion (DD / MMM / YYYY). This is especially important with international trials.

### 3.2.4.2 Closed

Provides a list of options e.g. yes/no. Checkbox is the clearest option. If using coding, be consistent across all CRFs, e.g. 'Yes' is always 1, 'No' is always 2.

This is the best choice for collecting and analysing data.

### 3.2.4.3 Combination

Generally used with closed type questions when one of the possible responses is 'Other', or 'Specify'. This information could be used for future studies as it gives the investigator additional options.

### 3.2.4.4 Analogue/rating scales

Use only validated instruments, e.g. Quality of Life. They are used to measure one's perception of a situation.

Text boxes should have a consistent design throughout, e.g. utilise box combing, box dividing or free text areas (avoid if possible).

Box combing:

Box dividing:

Free text:

Use a standardised answer mode throughout all the CRFs, e.g.:

Married?	Yes / No	By circling
Driving Licence?	<u>Yes</u> / No	By underlining
Any children?	Yes / No	By deletion
Good health?	Yes <input type="checkbox"/> / No <input checked="" type="checkbox"/>	By ticking a box
Do you take regular exercise?	Yes <input checked="" type="checkbox"/> / No <input type="checkbox"/>	By cross
Smoker?	Yes (1) / No (2)	By code

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 7 of 23
Title: Case Report Forms Design	Version: 2.1

Tick boxes tend to be the easiest to complete and utilise for data entry.

### 3.3 Completing CRFs

No fields should be left blank. ND (not done) should be used if data is unavailable either because a measure was not taken or test was not performed. N/A (not applicable) should be used if a measure was not required at the particular time point the form relates to. NK (not known) should be used if the data is unknown and every effort has been made to find the data. CRFs should be signed by all site personnel completing the CRF. The Principal Investigator at the local site is responsible for the accuracy of the CRF.

### 3.4 Amendments

As a general rule, amendments to data recorded on CRFs should always be handled at the local site. Exceptionally, the Chief Investigator or Trial Coordinator could amend a CRF if this is agreed in writing or verbally AND a copy of the changed CRF is then sent to the local site.

Corrections should be made by drawing a single line through the incorrect item and dating and initialling all corrections. Tippex should **not** be used.

When completing a query, attach an amended copy of the CRF and return either by post or fax to the coordinating centre

### 3.5 Electronic data capture

Electronic data capture (EDC) will allow the local sites to transcribe subject details direct onto a web-based database, thus saving time and trees. They also offer an advantage as it ensures a standardised format for data entry and can code events. Possible disadvantages include training of staff at local sites to complete online, ensuring that all staff have access to the internet and the need for a paper backup in case of system failure or transcription error and the need to validate computer systems and back-ups.

## 4 Document Ratification Process

The review period for this document is set as **default of three** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the **RD&I Manager or their Deputy**.

Non-significant amendments to this document may be made, under delegated authority from **a Senior RD&I manager**, by the nominated author. These must be ratified by **a Senior RD&I manager**.

Significant reviews and revisions to this document will include a consultation with **appropriately knowledgeable staff**. For non-significant amendments, informal consultation will be restricted to **staff** who are directly affected by the proposed changes.

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 8 of 23
Title: Case Report Forms Design	Version: 2.1

## ***Dissemination and implementation***

### **4.1. Dissemination of this SOP**

**4.1.1. New SOPs and new versions of existing SOPs:** The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

### **4.2. Training in this SOP**

**4.2.1.** All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

## **5 Reference material**

CRF template document has been freely provided by The Global Health Network. Please reference The Global Health Network if you use it. [www.theglobalhealthnetwork.org](http://www.theglobalhealthnetwork.org)



# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 9 of 23
Title: Case Report Forms Design	Version: 2.1

## Appendix: Generic CRF template

## Appendix 1

Study Code:	Subject study no:	<input type="text"/> <input type="text"/> <input type="text"/>	Subject initials:	<input type="text"/> <input type="text"/> <input type="text"/>
-------------	-------------------	--	-------------------	--

This Example CRF can be used as a starting point for designing a study specific CRF. The CRF should include all data which the protocol states will be collected.

<p style="text-align: center;"><b>CASE REPORT FORM</b></p> <p style="text-align: center;"><b>STUDY TITLE</b></p> <p style="text-align: center;"><b>Insert brief title</b></p> <p style="text-align: center;">Study reference number <b>insert</b></p>
---

<p style="text-align: center;">CLINICAL TRIAL SITE/UNIT:</p> <p style="text-align: center;">PRINCIPAL INVESTIGATOR:</p>
---

Subject Initials:	<input type="text"/> <input type="text"/> <input type="text"/>
Subject Study Number:	<input type="text"/> <input type="text"/> <input type="text"/>

*I am confident that the information supplied in this case record form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that written informed consent was obtained prior to the study.*

Investigator's Signature: .....

Date of signature:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
D	d	m	m	m	y	y	y	y	

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 10 of 23
Title: Case Report Forms Design	Version: 2.1

<b>Study Code:</b>	<b>Subject study no:</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<b>Subject initials:</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>
--------------------	--------------------------	----------------------	----------------------	----------------------	--------------------------	----------------------	----------------------	----------------------

## Inclusion Criteria

	<b>Yes</b>	<b>No*</b>
1 Is the subject a healthy male aged between 18 and 60 years?	<input type="checkbox"/>	<input type="checkbox"/>
2 Has the subject willingly given written informed consent?	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>

\*If any inclusion criteria are ticked no then the patient is not eligible for the study.

## Exclusion Criteria

	<b>Yes*</b>	<b>No</b>
1	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>
3	<input type="checkbox"/>	<input type="checkbox"/>
4	<input type="checkbox"/>	<input type="checkbox"/>
5	<input type="checkbox"/>	<input type="checkbox"/>
6	<input type="checkbox"/>	<input type="checkbox"/>
7	<input type="checkbox"/>	<input type="checkbox"/>
8	<input type="checkbox"/>	<input type="checkbox"/>
9	<input type="checkbox"/>	<input type="checkbox"/>

\* If any exclusion criteria are ticked yes then the patient is not eligible for the study.

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 11 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code:

Subject study no:

Subject initials:

## INFORMED CONSENT

Please note: written informed consent must be given before any study specific procedures take place or any current therapy is discontinued for the purposes of participation in this study.

Has the subject freely given written informed consent?

Yes

No

## VISIT 1 (SCREENING)

Date:

DD    MMM    YYYY

## DEMOGRAPHIC DATA

Age (yrs):

Sex:

Female

Male

Height (m):

•

Weight (Kg):

•

Body Mass Index (BMI = Wt (kg)/H<sup>2</sup> (M):

•

## SMOKING HABITS

Does the subject smoke or use tobacco products?

\*Yes

No

\* How many cigarettes per day?

Other, specify

.....

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 12 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_ Subject study no:    Subject initials:

**ALCOHOL CONSUMPTION**

Does the subject consume alcohol? Yes  No

If yes, how many units per week?

**MEDICATIONS TAKEN**

Is the subject currently or previously taking any medication including OTC, vitamins and/or supplements? Yes  No

\*Record **all** medication on Concomitant Medications page

**VISIT 1 (SCREENING)**

**PREVIOUS MEDICAL HISTORY**

**Is there any relevant medical history in the following systems?**

Code	System	*Yes	No		Code	System	*Yes	No
1	Cardiovascular				9	Neoplasia		
2	Respiratory				10	Neurological		
3	Hepato-biliary				11	Psychological		
4	Gastro-intestinal				12	Immunological		
5	Genito-urinary				13	Dermatological		
6	Endocrine				14	Allergies		
7	Haematological				15	Eyes, ear, nose, throat		
8	Musculo-skeletal				00	Other		

\*If **YES** for any of the above, enter the code for each condition in the boxes overleaf, give further details (including dates) and state if the condition is currently or potentially active. If giving details of surgery please specify the underlying cause. Use a separate line for each condition.



# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 14 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code:

Subject study no:

--	--	--

Subject initials:

--	--	--

**VISIT 1 (SCREENING)**

PHYSICAL EXAMINATION (to be carried out by medical staff only)			
Code	System	*Abnormal	Normal
1	General Appearance		
2	Heart		
3	Lungs		
4	Abdomen		
5	Extremities		
<p>* If <b>ABNORMAL</b> enter the code for each condition in the boxes below and give brief details. Please use a separate line for each condition.</p>			
Code	Details		

VITAL SIGNS							
Pulse rate	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Bpm						
Blood pressure (seated)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> mmHg						

ECG	
Is the ECG:	Normal <input style="width: 30px; height: 20px;" type="checkbox"/> Abnormal <input style="width: 30px; height: 20px;" type="checkbox"/> **
**Description	
Retain signed and dated trace in the plastic sleeve at back of CRF	

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 15 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_ Subject study no:    Subject initials:

**VISIT 1 (SCREENING)**

<b>LABORATORY ANALYSIS</b>	<b>Initials</b>
Blood for haematology and biochemistry	Taken by <input style="width: 80px;" type="text"/>

✓	Repeat Sample Required?	Date Taken (dd mmm yyyy)
✓	Haematology	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
✓	Clinical Chemistry	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

<b>Are all final results:</b> **Description _____ _____ _____	Normal <input style="width: 30px;" type="checkbox"/>	Abnormal NCS <input style="width: 30px;" type="checkbox"/>	** Abnormal CS <input style="width: 30px;" type="checkbox"/>
Does <u>any</u> result contradict study entry?		*Yes <input style="width: 30px;" type="checkbox"/>	No <input style="width: 30px;" type="checkbox"/>
		Initials: <input style="width: 100px;" type="text"/>	
* If YES, subject must not continue. Please complete off study page.			

**Add Study Specific Data, as relevant for the particular study**

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 16 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code:

Subject study no:

Subject initials:

## VISIT 1 (SCREENING)

### End of Visit Checklist: to be completed by Investigator

	Yes	No
1 Does the subject satisfy the inclusion and exclusion criteria to date?	<input type="checkbox"/>	<input type="checkbox"/>
2 Have all screening procedures been completed?	<input type="checkbox"/>	<input type="checkbox"/>
3 Has the concomitant medication page been completed?	<input type="checkbox"/>	<input type="checkbox"/>
4 Is the subject willing to proceed?	<input type="checkbox"/>	<input type="checkbox"/>

### Investigator

	Yes	No
Is the subject to continue?	<input type="checkbox"/>	<input type="checkbox"/>
Has medication been collected from Pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>
Have the dosing instructions been explained to the patient?	<input type="checkbox"/>	<input type="checkbox"/>

Signature: \_\_\_\_\_

Date:

d d m m m y y y y

If 'Yes' please:

Complete details of next visit and any other needed instructions on the instruction card.

Give the subject the instruction card



# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 17 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_

Subject study no: \_\_\_\_\_

--	--	--

Subject initials: \_\_\_\_\_

--	--	--

## VISIT 2 (WEEK 1)

Date: \_\_\_\_\_

DD    MMM    YYYY

<b>PHYSICAL EXAMINATION (to be carried out by medical staff only)</b>			
Code	System	*Abnormal	Normal
1	General Appearance		
2	Heart		
3	Lungs		
4	Abdomen		
5	Extremities		

\* If any changes from baseline, complete adverse event page.

<b>VITAL SIGNS</b>							
Pulse rate	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Bpm						
Blood pressure (seated)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> mmHg						

<b>LABORATORY ANALYSIS</b>		<b>Initials</b>																				
Blood for haematology and biochemistry		Taken by <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 40px; height: 20px;"></td></tr></table>																				
✓	Repeat Sample Required?	Date Taken (dd mmm yyyy)																				
✓	Haematology	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>																				
	Clinical Chemistry	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px;"></td> </tr> </table>																				

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

<b>Are all final results:</b>	Normal <input type="checkbox"/>	Abnormal NCS <input type="checkbox"/>	**Abnormal CS <input type="checkbox"/>
**Description:	----- -----		
Does <u>any</u> result contradict continuation in the study?	*Yes <input type="checkbox"/>	No <input type="checkbox"/>	
*If YES, subject must not continue. Please complete off study page.			

**Add Study Specific Data, as relevant for the particular study**

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 18 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_

Subject study no: \_\_\_\_\_

--	--	--

Subject initials: \_\_\_\_\_

--	--	--

## VISIT 3 (WEEK 26)

Date: \_\_\_\_\_  
DD    MMM    YYYY

<b>PHYSICAL EXAMINATION (to be carried out by medical staff only)</b>			
Code	System	*Abnormal	Normal
1	General Appearance		
2	Heart		
3	Lungs		
4	Abdomen		
5	Extremities		

\* If any changes from baseline, complete adverse event page.

<b>VITAL SIGNS</b>							
Pulse rate	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> Bpm						
Blood pressure (seated)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table> mmHg						

<b>LABORATORY ANALYSIS</b>		<b>Initials</b>													
Blood for haematology and biochemistry		Taken by <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 40px; height: 20px;"></td></tr></table>													
<input checked="" type="checkbox"/>	<b>Repeat Sample Required?</b>	<b>Date Taken (dd mmm yyyy)</b>													
Haematology	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>													<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 40px; height: 20px;"></td></tr></table>	
Clinical Chemistry	<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>													<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 40px; height: 20px;"></td></tr></table>	

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

<b>Are all final results:</b> Normal <input type="checkbox"/> Abnormal NCS <input type="checkbox"/> ** Abnormal CS <input type="checkbox"/>
<b>**Description:</b> _____ _____
Does <u>any</u> result contradict continuation in the study?      *Yes <input type="checkbox"/> No <input type="checkbox"/>
<small>*If YES, subject must not continue. Please complete off study page.</small>

**Add Study Specific Data, as relevant for the particular study**

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 19 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_

Subject study no: \_\_\_\_\_

--	--	--

Subject initials: \_\_\_\_\_

--	--	--

## VISIT 4 (WEEK 52)

Date: \_\_\_\_\_  
DD    MMM    YYYY

<b>PHYSICAL EXAMINATION (to be carried out by medical staff only)</b>			
Code	System	*Abnormal	Normal
1	General Appearance		
2	Heart		
3	Lungs		
4	Abdomen		
5	Extremities		

\* If any changes from baseline, complete adverse event page.

<b>VITAL SIGNS</b>							
Pulse rate	<table border="1" style="display: inline-table; width: 60px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> Bpm						
Blood pressure (seated)	<table border="1" style="display: inline-table; width: 60px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> / <table border="1" style="display: inline-table; width: 60px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> mmHg						

<b>LABORATORY ANALYSIS</b>		<b>Initials</b>												
Blood for haematology and biochemistry		Taken by <table border="1" style="width: 60px; height: 20px;"></table>												
<input checked="" type="checkbox"/>	<b>Repeat Sample Required?</b>	<b>Date Taken (dd mmm yyyy)</b>												
	Haematology	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> </tr> </table>												
	Clinical Chemistry	<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> <td style="width: 10px;"></td> </tr> </table>												

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

<b>Are all final results:</b>	Normal <input type="checkbox"/>	Abnormal NCS <input type="checkbox"/>	** Abnormal CS <input type="checkbox"/>
**Description: _____			
Does <u>any</u> result contradict continuation in the study?			
			*Yes <input type="checkbox"/> No <input type="checkbox"/>
*If YES, subject must not continue. Please complete off study page.			

**Add Study Specific Data, as relevant for the particular study**

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 20 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code: \_\_\_\_\_ Subject study no:    Subject initials:    |

## VISIT 5 (WEEK 56)

Date: \_\_\_\_\_  
DD    MMM    YYYY

<b>PHYSICAL EXAMINATION (to be carried out by medical staff only)</b>			
Code	System	*Abnormal	Normal
1	General Appearance		
2	Heart		
3	Lungs		
4	Abdomen		
5	Extremities		

\* If any changes from baseline, complete adverse event page.

**VITAL SIGNS**

Pulse rate    Bpm

Blood pressure (seated)    /    mmHg

<b>LABORATORY ANALYSIS</b>		<b>Initials</b>
Blood for U+Es		Taken by <input style="width: 80px;" type="text"/>
<input checked="" type="checkbox"/>	<b>Repeat Sample Required?</b>	<b>Date Taken (dd mmm yyyy)</b>
	Clinical Chemistry	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Please insert a copy of all results in the plastic sleeve at the back of the CRF.

**Are all final results:**      Normal       Abnormal NCS       \*\* Abnormal CS

\*\*Description: \_\_\_\_\_

---

Has renal function remained stable?      Yes       \*No

\*If No, record on adverse event page.

**Add Study Specific Data, as relevant for the particular study**



# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 22 of 23
Title: Case Report Forms Design	Version: 2.1

Study Code:

Subject study no:

--	--	--

Subject initials:

--	--	--

## Adverse Events

Has the patient experienced any Adverse Events since signing the Informed Consent?  Yes, specify below  No

AE no.	Adverse Event (diagnosis (if known) or signs/symptoms)	Start Date dd/mmm/yyyy (24 hour clock)	Stop Date dd/mmm/yyyy (24 hour clock)	Outcome 1=Recovered 2=Recovered with sequelae 3=Continuing 4=Patient Died 5=Change in AE 6=unknown	Severity 1=Mild 2=Moderate 3=Severe	Plausible relationship to Study Drug	Action taken with Study Drug 1=None 2=Dose Reduction Temporarily 3=Dose Reduced 4=Discontinued Temporarily 5=Discontinued	Withdrawn due to AE?	Serious AE (SAE)?	If SAE does it require immediate reporting? (see Protocol)?
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
		/ / :	/ / :			<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

# STANDARD OPERATING PROCEDURE

SOP No: P15	Page 23 of 23
Title: Case Report Forms Design	Version: 2.1

## 6

### Amendment History

Version Number: 2.1  
Date Of Amendment: Jan 2019  
Details Of Amendment: Updated Trust and Dept. name; Reduce signature requirement to single senior RD&I Manager.

---

Version Number: 2.0  
Date Of Amendment: Aug 2017  
Details Of Amendment: SOP reviewed and updated. SOP numbering system updated.

---

Version Number: 1.1 (minor amendment)  
Date Of Amendment: Mar 2012  
Details Of Amendment: Cover page - Change of SOP location address.

---