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FORM 01

Screening Log

Screening number

- **This CRF is used to record the screening activity at each site. It should be completed by either a member of the healthcare team or the research nurse**
- **One individual screening log should be completed for each patient that is screened**

General

Recruitment site [redacted]

CRF competed by ☐ CNS ☐ CRN

Name of person completing screening log

Screening date Day Month Year

Sex of patient ☐ Male ☐ Female

Age of patient Years

Patient referral status ☐ New referral ☐ Existing patient

Patient Eligibility

Please tick yes / no / missing. If any shaded boxes are ticked, the patient is ineligible.

Inclusion Criteria

	Yes	No
1. Is the patient >18 years old?	☐	☐
2. Is the patient living at home	☐	☐
3. Has the patient been prescribed opioid analgesia?	☐	☐
4. Is the patient cared for by specialist palliative care services?	☐	☐
5. Is the patient considered by their clinical team likely to survive beyond six weeks of follow up?	☐	☐
6. Does the patient have capacity to provide informed consent to participate?	☐	☐

Exclusion Criteria

	Yes	No
1. Does the patient have insufficient literacy, or proficiency in English, to contribute to the data collection required for the research?	☐	☐
2. Does the patient lack capacity to provide informed consent to this trial?	☐	☐

Eligibility screening outcome ☐ Failure → Reason

☐ Eligible

Completed by Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 01
Page 2 of 2

Screening Log

Screening number

For Eligible Patients Only

Has the patient been approached by the CNS or CRN and given an information pack? ☐ Yes ☐ No

Date patient given information sheet and consent form Day Month Year

Is the patient interested in the SMART study? ☐ Yes ☐ No

Does the patient think the SMART study is acceptable in principle? ☐ Yes ☐ No
☐ Other, please specify

Has the patient agreed for Research Fellow to contact them? ☐ Yes ☐ No

If no, reason

If yes, have contact details been passed to Research Fellow? ☐ Yes ☐ No

Date patient asked about researcher contact Day Month Year

Was a carer information sheet and consent form given? ☐ Yes ☐ No

If yes, date carer given information sheet and consent form Day Month Year

If no, reason ☐ No carer
☐ Other, please specify

Completed by Date Day Month Year Last Page ■

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 03
Page 1 of 1

CNS Recruitment Log

CNS Initials		CNS Study Number	

- **This CRF is used to document the recruitment process of CNSs to take part in end of study interview**
- **Completed by Research Fellow or CRN**

Name of CNS

Site [redacted] [redacted] [redacted] [redacted]

Sex ☐ Male ☐ Female

Age ☐☐ Years

Length of time working in specialist palliative care services ☐☐ Years ☐☐ Months

Independent prescriber? ☐ Yes ☐ No

Current grade/band

Has CNS been given an information sheet and consent form? ☐ Yes ☐ No

Date CNS given information sheet and consent form Day Month Year

Has a CNS consented to talking part in an interview? ☐ Yes ☐ No

Date CNS consent given Day Month Year

Has the CNS been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Did the CNS complete the interview? ☐ Yes ☐ No

Study numbers of patients linked to this CNS

Completed by Date Day Month Year

Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

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FORM 02

Patient (and Carer) Recruitment Log

Date of Birth	Day Month Year	Patient Study Number	

- **This CRF is used to record the recruitment and retention of all patients (and carers where appropriate) who are given a recruitment pack**
- **Completed by Research Fellow or CRN**

Patient Details

Screening log number

Patient sex ☐ Male ☐ Female

Consent

Has the patient consented to participate? ☐ Yes ☐ No

If no, reason

If yes, date patient consent obtained Day Month Year

Has the patient been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Has the patient given consent to GP contact? ☐ Yes ☐ No

Date GP letter sent Day Month Year

Completed by Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date Initials	*Verified/Checked* Date Initials

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FORM 02

Patient (and Carer) Recruitment Log

Date of Birth Day Month Year | Patient Study Number

Recruitment

Day 1

Date of baseline visit with Research Fellow or CRN Day Month Year

Has the patient completed the baseline questionnaire? ☐ Yes ☐ No

If yes, how has baseline questionnaire been completed?
- ☐ With the patient (face to face)
- ☐ Over the phone (with patient)
- ☐ By carer

Location of patient when completed baseline questionnaire
- ☐ At home
- ☐ Hospice
- ☐ Other, specify

If yes, patient is **recruited**; study number is

Has the CNS responsible for the patient been informed to commence the first SMART visit? ☐ Yes ☐ No

If yes, date of first SMART visit with CNS Day Month Year

Name of CNS completing SMART visits

Date of randomised interview Day Month Year

Did the interview take place? ☐ Yes ☐ No

If yes, date of interview Day Month Year

If no, reason

Withdrawal

Has the patient made a withdrawal within the 6 weeks study period? ☐ Yes ☐ No

If yes, date patient withdrawn from study Day Month Year

What has patient withdrawn from? *(Tick all that apply)*

	Date	Reason
☐ Questionnaire follow-up	Day Month Year	
☐ SMART intervention	Day Month Year	
☐ Final data collection	Day Month Year	

Completed by | Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date	Initials	*Verified/Checked* Date	Initials

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FORM 02

Patient (and Carer) Recruitment Log

Date of Birth: Day Month Year | Patient Study Number

Study completion or Loss to Follow-up

Did the patient complete six weeks of follow-up? ☐ Yes ☐ No

If yes, date patient completed six weeks follow-up: Day Month Year

If no, how may weeks follow-up did the patient complete? ☐ Weeks

Reason for loss to follow-up
- ☐ Death
- ☐ Deteriorating health
- ☐ Withdrawal
- ☐ Other, please specify

Has the patient been sent a thank you letter at the end of 6 week study period? ☐ Yes ☐ No

Carer Recruitment Interview

Has a carer consented to talking part in an interview? ☐ Yes ☐ No

If yes, date carer consent given: Day Month Year

Has the carer been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Carer study number *(Linked to patient)*

Carer initials

Carer date of birth: Day Month Year

Carer sex ☐ Male ☐ Female

Relationship to patient
- ☐ Spouse/partner
- ☐ Other relative
- ☐ Child
- ☐ Friend
- ☐ Other, please specify

Does the carer live with the patient? ☐ Yes ☐ No

Date of interview: Day Month Year

Did the carer complete the interview? ☐ Yes ☐ No

Completed by | Date: Day Month Year | Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 04
Page 1 of 1

Patient Contact Details

Date of Birth	Day Month Year	Patient Study Number	

The CRF is used to record the patient's contact details

Patient Details

Patient name | Title | First Name | Last Name

Postal address

House number/ name

Street

City

Postcode

Telephone number

Home

Mobile

Email address

What is the best method for contacting the patient?

- ☐ Call home phone
- ☐ Call mobile phone
- ☐ Text mobile phone
- ☐ Email
- ☐ Other, please specify

Have contact details been passed to the appropriate Research Fellow? ☐ Yes ☐ No

GP Details

If patient has consent to GP contact, enter GP name and postal address

GP name

Practice name

Street

City

Postcode

Completed by | Date Day Month Year | Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

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FORM 05

Baseline Assessment

Date of Birth	Day Month Year	Patient Study Number	

- **This CRF is used to record the baseline contact visit between the patient and the researcher or CRN prior to the first CNS SMART visit**
- **Completed by RF or CRN**

General

Date of baseline visit: Day Month Year

Clinical Characteristics

Disease Characteristics

Type of advanced disease

Date of original/clinical diagnosis: Day Month Year

Date of diagnosis of advanced disease: Day Month Year

Date referral to palliative care services: Day Month Year

Reason for referral to palliative care services

Current or Recent Treatments

Is the patient currently (or within the past month) receiving palliative treatment? ☐ Yes ☐ No

If yes, please list current **palliative treatments**

1.
2.
3.
4.
5.
6.

Completed by | Date: Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

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FORM 05
Page 2 of 2

Baseline Assessment

Date of Birth	Day Month Year	Patient Study Number	

Current or Recent Treatments *(Continued)*

Please give details of medications for pain, constipation and nausea

Name of medication	Type of pain medication *(Please use code list below)*	Dose & units	Frequency of dose *(Please use code list below)*
1.	☐		☐
2.	☐		☐
3.	☐		☐
4.	☐		☐
5.	☐		☐
6.	☐		☐
7.	☐		☐
8.	☐		☐
9.	☐		☐
10.	☐		☐
11.	☐		☐
12.	☐		☐

Type of pain medication code
1 = Strong opioid
2 = Weak opioid
3 = Non-opioid
4 = Adjuvant (pain)

Frequency of dose code
1 = OD
2 = BD
3 = TDS
4 = QDS
5 = PRN

Future Randomisation

If the study had been designed so that those taking part would be randomly selected to receive either the intervention or standard care would you *(the patient)* have taken part? ☐ Yes ☐ No

If no, reason for not taking part in a randomised study

Completed by		Date	Day Month Year

Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

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FORM 06
Page 1 of 2

CNS SMART Visits (Weeks 1–6)

Date of Birth	Day Month Year	Patient Study Number	

- **This CRF is used to document visits between the patient and their CNS using the SMART toolkit**
- **Completed by CRN**

General

Date of visit — Day Month Year

Location of visit
- ☐ Patient's home
- ☐ Hospice
- ☐ Other, specify

Length of visit — ☐☐☐ Minutes

Type of patient contact
- ☐ Face-to-face
- ☐ Telephone
- ☐ Other, specify

Who was present?
- ☐ Patient only
- ☐ Patient and carer
- ☐ Patient and other person (not main carer), specify relationship to patient

Today's SMART Visit

Disease Characteristics

What needs were identified?

What self-management information was discussed verbally?

Which fact sheets were given, discussed or revisited?
- ☐ Managing pain with opioids
- ☐ Contact and further information
- ☐ Getting prescriptions and obtaining medicines
- ☐ Organising opioid medicines
- ☐ Fitting pain control around my daily routine
- ☐ Checking opioids are managing pain
- ☐ Common concerns when taking opioid medicines
- ☐ Keeping on top of side-effects
- ☐ Pain diary
- ☐ Medication chart
- ☐ Goal setting sheet ("Things I Would Like To Achieve Over The Next Week")
- ☐ None

Were the video podcasts given? ☐ Yes ☐ No

Which video podcasts have been watched since the last visit?
- ☐ Patient
- ☐ Healthcare professional
- ☐ Neither
- ☐ N/A, visit 1

Completed by _____ Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date	Initials	*Verified/Checked* Date	Initials

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FORM 06
Page 2 of 2

CNS SMART Visits (Weeks 1–6)

Date of Birth (Day Month Year)	Patient Study Number

Were the goals and action plan from previous visit reviewed? ☐ Yes ☐ No ☐ N/A, visit 1

If no, reason

Have any changes been made to the patient's analgesic medications since the last visit? ☐ Yes ☐ No ☐ N/A, visit 1

If yes, describe changes to analgesic medications

Who made the changes to analgesic medications?

- ☐ GP
- ☐ Palliative care doctor
- ☐ Palliative care nurse
- ☐ Other, specify

Additional Contact With Patient

Has there been any contact with the patient between the previous SMART visit and today's SMART visit? ☐ Yes ☐ No ☐ N/A, visit 1

If yes, date of additional contact (Day Month Year)

Type of patient contact

- ☐ Face-to-face
- ☐ Telephone

Reason for additional contact with patient

Completed by | Date (Day Month Year) | Last Page ■

Return the completed form to SMART Research Fellows

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FORM 07

Fortnightly Follow-up Visit (Weeks 2, 4 and 6)

Date of Birth	Day Month Year	Patient Study Number	

- **This CRF is used to document the follow-up visit conducted by the RF or CRN**
- **Completed by RF or CRN**

General

Date of visit: Day Month Year

Visit Details

Has the patient completed the follow-up questionnaire? ☐ Yes ☐ No

If yes, who completed it?
- ☐ Patient
- ☐ Patient with Research Fellow or CRN
- ☐ Patient with carer

Where was it completed?
- ☐ Patient's home
- ☐ Hospice
- ☐ Over telephone
- ☐ Other, specify

If no, why was it not completed?
- ☐ Patient withdrew
- ☐ Patient died
- ☐ Unable to contact patient
- ☐ Unable to rearrange visit
- ☐ Other, specify

Have the carbon copies of goal setting sheets been collected from the patient folder for the previous week and this week?

Previous week ☐ Yes ☐ No

This week ☐ Yes ☐ No

Has the patient watched the video podcasts? ☐ Yes ☐ No

If yes, which ones? *(Tick all that apply)*
- ☐ Patient
- ☐ Healthcare professional

At what point in the past two weeks did they watch the pocast?

Completed by Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date Initials	*Verified/Checked* Date Initials

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FORM 07

Fortnightly Follow-up Visit (Weeks 2, 4 and 6)

Date of Birth	Day Month Year	Patient Study Number	

What factsheets does the patient have in their toolkit folder?
(Tick all that are present)

- ☐ Managing pain with opioids
- ☐ Contact and further information
- ☐ Getting prescriptions and obtaining medicines
- ☐ Organising opioid medicines
- ☐ Fitting pain control around my daily routine
- ☐ Checking opioids are managing pain
- ☐ Common concerns when taking opioid medicines
- ☐ Keeping on top of side-effects
- ☐ Pain diary
- ☐ Medication chart
- ☐ Goal setting sheet ("Things I Would Like To Achieve Over The Next Week")
- ☐ None

Is the patient still using the SMART toolkit? ☐ Yes ☐ No ☐ N/A, visit 1

Completed by _____ Date Day Month Year

Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

Version 1.0 06/11/2015

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FORM 08

Final Data Collection

Date of Birth	Day Month Year	Patient Study Number	

- **This CRF is used to gather together the final data on patients healthcare resource use, medications and date of death**
- **Completed by Research Fellows**

General

Date of final data collection: Day Month Year

Death

At end of the patient's 6 week study period, is the patient known to have died? ☐ Yes ☐ No

If no, date last known alive: Day Month Year

At the **end of the SMART study**, is the patient known to have died? ☐ Yes ☐ No

If no, date last known alive: Day Month Year

If yes to either question above, please record details of death:

Date of death: Day Month Year

Place of death:
☐ Home ☐ Hospice ☐ Hospital ☐ Care home ☐ Other, specify ☐ Unknown

Preferred place of death:
☐ Home ☐ Hospice ☐ Hospital ☐ Care home ☐ Other, specify ☐ Unknown

Primary cause of death:

How were you informed that the patient had died?
☐ Informed by health professional, please specify
☐ Informed by family member
☐ Clinical notes
☐ Other, specify

- **Return to SMART Research Fellows within 5 days of becoming aware of participant's death**
- **Where death is the result of an ongoing Related Unexpected Serious Adverse Event (RU SAE), ensure F10 RU SAE Report is updated and faxed to SMART Research Fellows within 24 hours**

Completed by: Date: Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date Initials	*Verified/Checked* Date Initials

smart

FORM 08

Final Data Collection

Date of Birth	Day Month Year	Patient Study Number	

Healthcare Resource Use – Collected up to 6 Weeks After Study Entry

Date of contact	Type of contact	Reason for attendance	Name of person conducting visit
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		

Completed by ______________________ Date Day Month Year

Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	*Computerised*		*Verified/Checked*	
	Date	*Initials*	*Date*	*Initials*

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FORM 08
Page 3 of 3

Final Data Collection

Date of Birth	Day Month Year	Patient Study Number	

Analgesic Medication Prescriptions – Collected up to 6 Weeks After Study Entry

Please give details of medications for pain, constipation and nausea

Name of medication	Date of prescription	Type of pain medication *(Please use code list below)*	Dose & units	Frequency of dose *(Please use code list below)*
1.	Day Month Year			
2.	Day Month Year			
3.	Day Month Year			
4.	Day Month Year			
5.	Day Month Year			
6.	Day Month Year			
7.	Day Month Year			
8.	Day Month Year			
9.	Day Month Year			
10.	Day Month Year			
11.	Day Month Year			
12.	Day Month Year			
13.	Day Month Year			
14.	Day Month Year			
15.	Day Month Year			
16.	Day Month Year			
17.	Day Month Year			
18.	Day Month Year			
19.	Day Month Year			
20.	Day Month Year			
21.	Day Month Year			

Type of pain medication code
1 = Strong opioid
2 = Weak opioid
3 = Non-opioid
4 = Adjuvant (pain)

Frequency of dose code
1 = OD
2 = BD
3 = TDS
4 = QDS
5 = PRN

Completed by | Date Day Month Year | Last Page

Return the completed form to SMART Research Fellows

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

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FORM 09

Page 1 of 1

Participant Withdrawal Request

Date of Birth	Day Month Year	Patient Study Number	

- **Complete this form for any participant who requests to withdraw consent to the trial interventions/ follow-up, as detailed in the categories below**
- **Ensure that the form is returned to the CTRU within 7 days of the date of withdrawal**

Date of withdrawal request Day Month Year

Has the participant withdrawn consent to the trial interventions?

☐ Yes ☐ No

Has the participant withdrawn prior to receiving the trial interventions?

☐ Yes ☐ No ☐ Not known

Has the participant withdrawn consent for questionnaire completion **via researcher contact**?

☐ Yes ☐ No

Is the participant still willing for further data to be collected from their medical records during the trial follow-up period?

☐ Yes ☐ No

Has the participant given a reason for their withdrawal? ☐ Yes ☐ No

If yes, please provide details *(Please specify if the participant was too unwell)*

Form completed by

☐ CNS
☐ CRN
☐ Research Fellow
☐ Other, please specify

Completed by Date Day Month Year

Last Page ■

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date Initials	*Verified/Checked* Date Initials

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RUSAE Report
Relevant Medical History Supplemental Page

Date of Birth	Day Month Year	Patient Study Number	

ONLY RECORD THE PARTICIPANT'S RELEVANT MEDICAL HISTORY

Name of condition, including dates where relevant:

Page ☐ **of** ☐ **Relevant Medical History Supplemental Page**

Completed by | Date Day Month Year

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials	SAE code

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Form 10
Page 1 of 2

Related and Unexpected Serious Adverse Events (RUSAE) Report

Date of Birth (Day / Month / Year)	Patient Study Number

Complete this form for RUSAEs occurring within the SMART trial. Fax immediately to the SMART Research Fellows

Report type: ☐ Initial ☐ Follow-up

a) Serious Adverse Event Information

a1) Date of SAE (Day / Month / Year)

a2) Date study team first aware of SAE (Day / Month / Year)

b3) **Main diagnosis/symptom**	
b4) **Associated symptoms** that caused the main event to become serious *(if applicable)*	

b5) **Brief description** of the SAE *(Including signs/symptoms and any other relevant information)*

a6) Place where SAE started ☐ Hospital ☐ Outpatient clinic ☐ Home ☐ Other *(specify)*

b) Seriousness criteria *(tick all that apply)*

- ☐ c1) Participant died
- ☐ c2) Life threatening
- ☐ c3) Required/prolonged hospitalisation
- ☐ c4) Persistent or significant disability/incapacity
- ☐ c5) Congenital anomaly/birth defect
- ☐ c6) Other important medical event

c) Outcome *(at the time of this report)*

- ☐ d1) Recovered → Date of recovery (Day / Month / Year)
- ☐ d2) Recovered with sequelae
- ☐ d3) Condition improving
- ☐ d4) Condition still present and unchanged
- ☐ d5) Condition deteriorated
- ☐ d6) Ongoing at time of death
- ☐ d7) Death *(only applicable if participant died due to the SAE)*

Date of death (Day / Month / Year)

Post-mortem undertaken? ☐ Yes ☐ No

***If yes**, please send in an anonymised copy of the report*

d) Participant's relevant medical history

d1) Does the participant have any other relevant medical conditions? *(Such as diseases, allergies or similar experiences)* ☐ Yes *(please give details)* ☐ Unknown ☐ No *(go to Section f)*

Name of condition, including dates where relevant:

Additional medical history may be provided on the RELEVANT MEDICAL HISTORY SUPPLEMENTAL PAGE ☐ *Tick if using*

Completed by | Date (Day / Month / Year) | *Form continues on next page ▶▶*

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

For office use only	Computerised: Date / Initials	Verified/Checked: Date / Initials	SAE code

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Form 10
Page 2 of 2

Related and Unexpected Serious Adverse Events (RUSAE) Report

Date of Birth Day Month Year | Patient Study Number

e) Study Procedures, Treatment and Action

e1) Was the participant undergoing any study procedures at the time of the SAE? ☐ Yes *(Please give details)* ☐ No

Trial procedure	Was any action taken/ treatment given? Yes*	No	*If yes, provide details
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

f) Relatedness and Expectedness

f1) Is the SAE suspected to be related to the study procedures? ☐ Yes → Please specify

☐ No

Expectedness ☐ Expected *(If this is ticked then this is not an RU SAE)*

☐ Unexpected *(= RU SAE)*

THE SAE MUST BE REVIEWED AND THIS SECTION COMPLETED BY THE INVESTIGATOR OR AN AUTHORISED DELEGATE.

Reviewer name _____ Reviewer position _____

Reviewer signature _____ Date Day Month Year

g) Is there any additional information not reported above? ☐ Yes ☐ No

Completed by _____ Date Day Month Year

Last Page ■

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

h) Report Handling (CTRU USE ONLY)

Is this event a RU SAE? ☐ Yes ☐ No

Date of initial report Day Month Year

SAE code *(Please also add to footer of previous and supplemental pages)*

Date this report received Day Month Year

Date reported to main REC Day Month Year

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials