Adverse event SOP

TITLE: Adverse Event Reporting	
VERSION: 1.2	
Prepared by: Catherine Arundel Date: 11.12.15	Approved by: Emily Peckham Date: 17.12.15
PURPOSE: To describe the process of adverse event reporting and follow up of adverse events for all staff involved in the SCIMITAR+ Study	

1) **PURPOSE**

To describe responsibilities and procedures for identifying, collecting, recording and reporting of Serious and Non Serious Adverse Events occurring in the SCIMITAR+ trial.

2) **DEFINITIONS**

The definitions listed comply with ICH GCP guidance (1996)

SERIOUS ADVERSE EVENT – Any untoward medical occurrence that results in one of the following criteria:

- Life threatening (i.e. event in which patient is at risk of death at the time of the event occurring).
- Is fatal (i.e. results in death).
- Requires unplanned or prolonged hospitalisation*.
- Results in persistent or significant disability or incapacity.
- Results in a congenital abnormality or birth defect.
- Any other medical condition not listed above, which may require medical or surgical intervention to prevent the above criteria occurring.

*Unplanned refers to emergency hospitalisations resulting in an inpatient stay. Prolonged hospitalisation is deemed to be where a patient's stay is longer than expected (e.g. patient is operated on as day case but remains in hospital overnight).

NON SERIOUS ADVERSE EVENT – This is any untoward medical occurrence in a participant to whom an intervention has been administered, including occurrences not necessarily caused by or related to that intervention.

EVENT OUTCOME - For any adverse event the outcome of the event must be detailed. Events may be:

- **RECOVERED:** e.g. Participant is no longer experiencing any unfavourable symptoms related to the event.

- **RECOVERED PARTIALLY:** Participant is still experiencing some unfavourable symptoms related to the event however the impact of these has improved since the event.

- **DEATH:** Participant is deceased as a result of the event.

- **ONGOING:** Participant continues to experience unfavourable symptoms which currently remain unresolved.

3) SCIMITAR+ REPORTING PROCEDURE

WHO

1) All trial staff that are in contact with patients are responsible for noting adverse events that are reported by the patient and making them known to York Trials Unit in a timely fashion. Patients entered into SCIMITAR+ must be encouraged from the outset to contact their researcher at the time of an event occurring.
2) The Trial Coordinator at York Trials Unit is responsible for the processing and reporting of serious and non-serious adverse events in line with procedure detailed below.
3) Clinical staff members at the University of York are responsible for the reviewing of Serious Adverse Events.
4) The Chief Investigator (Professor Simon Gilbody) is responsible signing off all Serious Adverse Events. Any events deemed to be related **and** unexpected will be reported to the REC and Sponsor by the Chief Investigator.

WHEN

- At each visit adverse events that might have occurred since the previous visit or assessment should be elicited from the patient. In many cases this will be captured at the point of data collection and further elaboration by the participant may be required to assist with recording.
- Adverse Events reported at any other time should also be reported to York Trials Unit within the time frames set out below.

- Adverse events which are **related to the research** and are **'On-going'**, when a participant completes their study involvement, should be followed up as required by the protocol and as clinically indicated.
- Adverse Events which are not related to the research and remain 'On-going' do not need to be followed up after study completion.

HOW

STUDY SITE

1) Document details of the event clearly, using the **SCIMITAR+ Adverse Events form**. Please ensure that the following are clearly documented;
- Date of Event. (*If the participant cannot remember please indicate as closely as possible*)
- Action taken including treatment and/or medication and dates that this commenced and/or stopped or was changed.
- Whether the event is deemed to be Serious or Non Serious (using the criteria as detailed in Section 4).
- The outcome of the event.

Please ensure that no patient identifiable detail is provided on the Adverse Event Form.

2) Events that are **serious** must be reported to York Trials Unit **within 24 hours** of study staff being made aware of the event.

   Events that are **non-serious** must be reported to York Trials Unit **within 5 days** of study staff being made aware of the event.

   Reporting of adverse events should be completed by sending the Adverse Event form to York Trials Unit by fax on [redacted] or via the University of York Drop Off. Events should be marked for the attention of/sent to Catherine Arundel [redacted] and Emily Peckham [redacted].

3) Study sites should respond promptly to any requests made for further information.

4) Copies of all correspondence and notes relating to an adverse event should be retained in the individual patient's research records or master site file. Reasons for late reporting must be documented on the SAE form and in the patient's research records or the master site file.

YORK TRIALS UNIT

Upon receipt of completed adverse event form(s), the form will be processed as described below.

1) The adverse event forms will be reviewed by trial staff at York Trials Unit. In the event that the event is deemed to be 'Serious' this will be provided to Professor Ian Watt for initial review.

2) All correspondence about the adverse event will be saved and held securely at York Trials Unit.

   Should a site provide patient identifiable details on any adverse event form (other than participant date of birth), this will be destroyed upon receipt at York Trials Unit. The site will be contacted to inform them of this breach of Data Protection and the need to destroy any copy that they have and to recomplete and resend the Adverse Event form removing any patient identifiable information.

3) The frequency of all adverse events will be reported internally to the DMEC and TSC at regular meetings. The DMEC will be responsible for completing immediate review of serious, unexpected **and** related events. They will then see unrelated SAE and NSAE at the next scheduled meeting. Details of serious and non-serious adverse events will also be reported externally to the HTA in regular progress reports.

4) YTU, in conjunction with the Chief Investigator, will complete an NRES SAE form for any related AND unexpected SAEs and will notify the REC, Sponsor and Funder **within 15 days.**

CHIEF INVESTIGATOR/DELEGATED CLINICIAN

1) The Chief Investigator will, upon receipt of a copy of a Serious Adverse Event form, review the event and complete a **CI Sign Off Form.**
2) A signed copy of the CI Sign Off Form should be returned to York Trials Unit.

Appendix 1: SCIMITAR+ Adverse Event Reporting Guidelines

Is the event serious?

	SITE	CHIEF INVESTIGATOR	YTU	
	Site to report to YTU within*:	Chief Investigator to report to REC	YTU to report to DMEC /TSC	YTU to report to Funder
SERIOUS	24 hours of being made aware of the event.	Only if event is related AND unexpected. Within 15 days.	Event is related AND unexpected: To be reported and reviewed immediately. All other events to be reported at next scheduled meeting.	YTU to provide details for routine funder progress reports.

Is the event non serious?

	SITE	YTU		
	Site to report to YTU within:	Chief Investigator to report to REC	YTU to report to DMEC/TSC	YTU to report to Funder
NON SERIOUS	5 days of being made aware of the event.	Not required.	To be reported at next scheduled meeting.	YTU to provide details for routine funder progress reports.

Appendix 2: SCIMITAR+ – Site Adverse Event Reporting Flowchart

Study site receives notification that SCIMITAR+ participant has experienced an adverse event.

EVENT IS SERIOUS

- Results in death.
- Is life threatening.
- Requires unplanned or prolonged hospitalisation.
- Results in persistent or significant disability or incapacity.
- Is a congenital anomaly or birth defect.
- Any other medical condition requiring medical or surgical intervention to prevent the above.

Adverse Event form to be completed, clearly documenting all necessary information.

Please ensure that no patient identifiable detail is provided on the Adverse Event Form

Event to be reported to York Trials Unit within 24 hours of the site being made aware of the event.

The Serious Adverse Event form should be faxed to York Trials Unit ([redacted]) or sent via University of York Drop Off to Catherine Arundel and Emily Peckham

YORK CTU

SAEs processed within 24 hours of receipt of notification.

All SAEs deemed to be related and expected/ unrelated and expected or unexpected to be sent to the CI for sign off within 14 days.

DMEC and TSC to be immediately informed of the event.

All related **and** unexpected SAEs to be notified to REC, Sponsor and Funder within 15 days.

CHIEF INVESTIGATOR

SAEs to be signed off and copy of form sent to YTU.

EVENT IS NON SERIOUS

Event does not fulfil 'Serious' criteria.

Adverse Event form to be completed, clearly documenting all necessary information.

Please ensure that no patient identifiable detail is provided on the Adverse Event Form

Event to be reported to York Trials Unit within 5 days of the site being made aware of the event.

The Adverse Event form should be faxed to York Trials Unit ([redacted]) or sent via University of York Drop Off to Catherine Arundel and Emily Peckham

Adverse Events Contacts

York CTU

Fax: [redacted]

Catherine Arundel

Tel: [redacted]

Email: [redacted]

In the absence of Catherine, please contact:

Emily Peckham, [redacted]

Email: [redacted]

Appendix 4: How to use University of York Drop Off

1) To access the University of York Drop Off service go to: https://dropoff.york.ac.uk

2) To access the system, click on 'Drop Off'

3) Enter your name, your organisation and email address and enter the numbers/letters displayed

4) You will receive an email from University of York Drop Off. Click on the link which will take you to the following page

5) Enter Catherine and Emily's email addresses in the 'To' box

6) Select the files you need to upload using the 'Choose File' button. This will allow you to browse to access the relevant files. *NB: please ensure files are password protected/encrypted before uploading.*

Please note the system can only upload one file at a time.

7) Once all relevant files have been uploaded, click the 'Drop Off Files' button. This will send the files back to York Trials Unit.

Suicide Protocol

If at any time you believe that there is significant suicide risk with a patient who is participating in the study that has not been recently communicated to their GP, psychiatrist or care coordinator/CPN, you must contact the relevant designated centre psychiatrist or health professional or Prof Simon Gilbody (Consultant psychiatrist) if the relevant designated centre psychiatrist or health professional is unavailable.

Contact numbers can be found on the back page of this protocol.

The designated psychiatrist/ health professional or Prof Gilbody, will then assess the patient and if it believed necessary, and if there is a significant risk,

Suicide risk identified during face-to-face or telephone interview

The PHQ-9 questionnaire asks if the patient has had '**Thoughts that you would be better off dead or hurting yourself in some way**' **(Question 9).**

If the participant indicates a response of 3 for this item, then you should ask whether the patient has talked to their GP, psychiatrist or care coordinator/CPN about these feelings. **If the patient has spoken of these thoughts to their GP or psychiatrist, then no action is required.**

If not, you should ask the patient whether it is OK for you to contact their GP and inform them of the situation. If the patient refuses, contact the relevant designated psychiatrist/health professional. If the patient agrees, you should immediately get in touch with the patients GP or psychiatrist.

If unable to contact the patients GP or psychiatrist contact any of the designated centre psychiatrists/health professionals, if unable to contact any

of the designated centre psychiatrists/health professionals contact Prof Gilbody, if unable to contact Prof Gilbody, contact the Trial manager, Emily Peckham or the Trial Intervention Co-ordinator, Della Bailey. If unable to contact any of the above contact any other of the co-investigators who will advise further.

Please also complete the attached Suicidal Intent Form, if the patient agrees to you contacting their GP/psychiatrist and inform the Trial Manager. If relevant, Professor Gilbody or the relevant designated centre psychiatrist/health professional should also complete the Suicidal Intent Form: Psychiatrist/ Health Professional. These forms should be stored with the patient's trial records and a copy faxed to York Trials Unit on [redacted].

If any other responses during the face-to-face or telephone interview give you cause for concern, raise this with the relevant designated psychiatrist/health professional.

Suicide risk identified on a postal questionnaire

At 6 month and 12 month follow up points, some patients can choose to receive and return questionnaires by post. If you receive a PHQ-9 in which the patient has indicated a score of 3 for question 9, you will need to follow the suicide protocol.

Contact the patient by phone and say that you are concerned with their response to this question. Ask if they have discussed these feelings with their GP or psychiatrist. **If the patient has spoken of these thoughts to their GP or psychiatrist, then no action is required.**

If not, you should ask the patient whether it is OK for you to contact their GP and/or psychiatrist and inform them of the situation. If the patient refuses, contact the relevant designated psychiatrist/health professional or if unable to contact the relevant designated psychiatrist/health professional contact Prof Gilbody. If the patient agrees, you should immediately get in touch with the appropriate GP and/or health professional.

If unable to contact the patients GP or psychiatrist contact any of the designated centre psychiatrists/health professionals, if unable to contact any of the designated centre psychiatrists/health professionals contact Prof Gilbody, if unable to contact Prof Gilbody, contact the Trial manager, Emily Peckham or the Trial Intervention Co-ordinator, Della Bailey. If unable to contact any of the above contact any other of the co-investigators who will advise further.

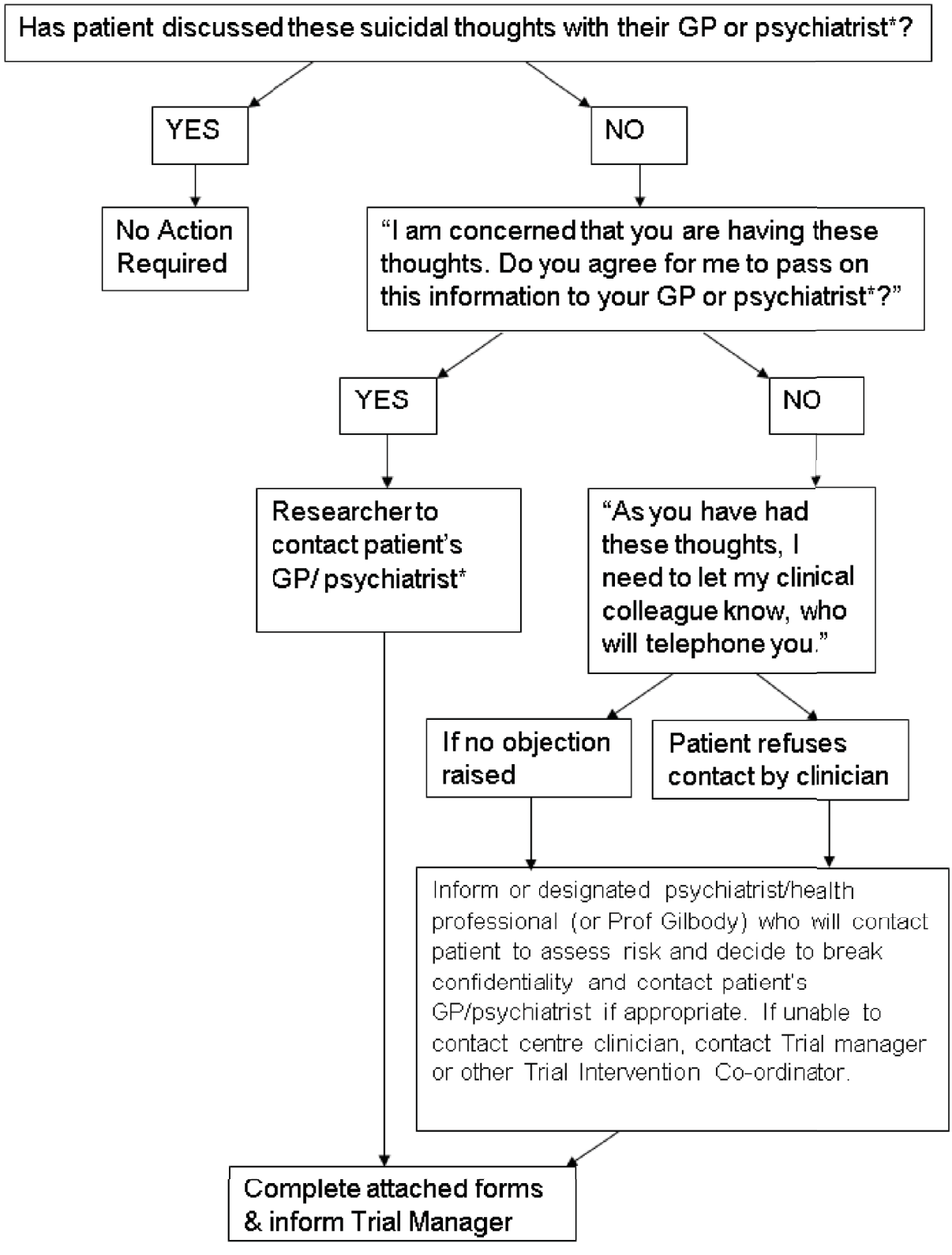
If any other written responses on the questionnaires give you cause for concern, raise this with the relevant designated psychiatrist/health professional.

If you are unable to contact the patient within 24 hours, contact the patient's GP or psychiatrist. Inform them of the patient's questionnaire response and that you have been unable to contact the patient to assess the situation further.

At this point also check the patient's contact telephone number is correct. It may be that the telephone number on the database is out of date. If an alternative number is provided and the GP/ health professional agrees, attempt to contact the patient again.

If still unable to contact the patient and if no alternative contact details are available, confirm with the GP/ health professional that they will follow up with the patient as they feel appropriate based on their clinical knowledge of the patient.

Inform the relevant designated psychiatrist/health professional or Prof Gilbody of the patient's questionnaire response and details of resultant contacts with the patients GP/psychiatrist.


Has patient discussed these suicidal thoughts with their GP or psychiatrist*?
YES
NO
No Action Required
"I am concerned that you are having these thoughts. Do you agree for me to pass on this information to your GP or psychiatrist*?"
YES
NO
Researcher to contact patient's GP/ psychiatrist*
"As you have had these thoughts, I need to let my clinical colleague know, who will telephone you."
If no objection raised
Patient refuses contact by clinician
Inform or designated psychiatrist/health professional (or Prof Gilbody) who will contact patient to assess risk and decide to break confidentiality and contact patient's GP/psychiatrist if appropriate. If unable to contact centre clinician, contact Trial manager or other Trial Intervention Co-ordinator.
Complete attached forms & inform Trial Manager

Non- Suicide risk

If any other areas of risk arise in the interviews that are not related to suicide or self-harm but that give cause for concern please complete the non-suicide risk form.

If a non-suicide risk is identified check whether the participants care coordinator/ GP/ psychiatrist is aware of the risk and document this on the non-suicide risk form. If the none of the above are aware contact the site PI for advice and complete the non-suicide risk form. Note the Site PI only needs to sign the non-suicide risk form if the researcher/ mental health smoking cessation practitioner has contacted the site PI.

If a participant has a very high CO reading (above 100ppm), they should be given advice about possible acute CO poisoning, and should be advised to attend their local Accident and Emergency department. A non-suicide risk form should be completed.

If a participant has a reading between 51ppm and 100ppm please recommend that they get their car and home appliances etc serviced in order to check they are not being exposed to CO via other means and advise them to speak to their GP.

Suicidal Intent Form

The patient below has shown thoughts of suicidal intent on the PHQ-9 Questionnaire and has agreed for their GP and/or psychiatrist to be contacted by the researcher.

Date of birth: _____/_____/_____

SCIMITAR Participant ID: __ __ __ __

Action taken

Name of GP/Psychiatrist contacted: _____

Date of contact: _____/_____/_____ Time: ___:___ am/pm

Outcome of contact/Action/Comments:

Suicidal Intent Form: Psychiatrist/Health Professional

Name of Participant: _____

Date of birth: _____/_____/_____

Name of Psychiatrist/trial health professional notified: _____

Date notified: _____/_____/_____

Action taken

Patient contacted: Yes ☐ No ☐

GP/Psychiatrist contacted Yes ☐ No ☐

If yes, GP/psychiatrist contacted with Patient's consent?

Yes ☐ No ☐

Name of GP contacted:_____

Date: __/__/___

Name of Psychiatrist contacted: _____

Date: __/__/___

Outcome of contact/Action/Comments:

Non-Suicide Risk Form

The participant below has been identified as being a risk other than self-harm/ suicide during a SCIMITAR+ follow up or meeting with a mental health smoking cessation practitioner (MH-SCP).

Participant ID Code:

Date of Assessment:

Assessment: Baseline / 6 month follow up / 12 month follow up / meeting with MH-SCP

Risk identified and how:

Summary of how risk protocol implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact GP/mental health professional – name of practice/team, name of GP/mental health professional spoken to, date of contact)

Researcher Name: ……..... Study Site: ☐ ..... ☐

Research Signature: …… Date: ……...

Name of Clinical Contact: …….....

Clinical Contact Signature **Date**