University of Bristol Tobacco and Alcohol Research Group
Standard Operating Procedures

SOP - 15

REPORTING AND HANDLING ADVERSE EVENTS

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Table of Contents	**Page**
1. PURPOSE	2
2. REFERENCES	2
3. PERSONNEL REQUIRED AND LEVEL OF EXPERTISE	2
4. MATERIALS AND EQUIPMENT REQUIRED	2
5. PROCEDURE	2
5.1 Handling an adverse event	2
5.2 Reporting an adverse event	3
6. TROUBLE SHOOTING	3

SOP - 15

REPPORTING AND HANDLING ADVERSE EVENTS

Definitions/Abbreviations	
RED	Research Enterprise and Development
R&D	Research and Development
SAE	Serious Adverse Event
UoB	University of Bristol
SOP	Standard Operating Procedure

1. PURPOSE:

To provide step-by-step instruction for handling and reporting adverse events.

2. REFERENCES:

R&D Adverse Event Reporting Guidelines: http://www.bristol.ac.uk/red/research-governance/registration-sponsorship/specific-advice/adverseevent.html

3. PERSONNEL REQUIRED AND LEVEL OF EXPERTISE:

- Investigator, research team, or trained first aider.

4. MATERIALS AND EQUIPMENT REQUIRED:

- Laboratory phone (mandatory)
- Adverse Event Form (Appendix A)
- TARG Adverse Event Report (Appendix B)

5. PROCEDURE:

5.1 Handling an adverse event

If you have witnessed an adverse event or received a call notifying you of an adverse event:

- Establish the severity of the event. Does the participant require an ambulance?

- Serious adverse events (SAE): If the participant requires an ambulance, replace the handset and call 999. Provide the address:

  School of Psychological Science,
  University of Bristol
  12a Priory Road,
  Bristol,
  BS8 1TU
  Lab Phone Number: 07957334265

- Notify reception on Tel: 01179288450 that an ambulance has been called and ask them for support.
- Contact the relevant PI or work stream lead to notify them of the event.

- If the participant does not require an ambulance:
    - Assess the participant's health and wellbeing. Call a first aider if necessary (see contact sheets posted in all laboratories and on z-drive 'approved personnel for lab support').
    - Once you have ensured the participant is in a comfortable state, contact the school reception so that they can notify the student health service or school porters if further attention is required.

5.2. Reporting an adverse event

After the event has occurred, and the necessary steps have been followed to support the participant, complete an adverse event report form (see steps below).

Your study protocol should document the procedures for reporting an adverse event. All researchers should know the AE procedures for their study, which should adhere to UoB guidelines: http://www.bristol.ac.uk/red/research-governance/registration-sponsorship/specific-advice/adverseevent.html

All AEs should be recorded in the study or project file with a note that will identify when the event occurred, the details of the AE, any potential study relation, action taken and resolution / closure of the AE. An assessment of seriousness needs to be made by the researcher and SAEs need to be reported in line with legislation and university guidance. At the end of the study a safety report will be compiled and sent to the Principal Investigator (PI) listing all adverse events and adverse reactions.

6. TROUBLE SHOOTING:

Problem	Solution
Any problems	**TARG Laboratory phone:** 07957334265 **Prof Marcus Munafò** (0117) 954 6841 internal 46841 Marcus.Munafo@bristol.ac.uk **Dr Angela Attwood** (0117) 331 7450 internal 17450 Angela.Attwood@bristol.ac.uk
Reporting guidance or advice	**Mr Adam Taylor** (Head of Research Governance) (No phone number on website) Adam.Taylor@bristol.ac.uk **RED Reception and General Enquires** (0117) 928 8676 internal 88676 Red-Office@bristol.ac.uk

SOP - 15

REPPORTING AND HANDLING ADVERSE EVENTS

UNIVERSITY OF BRISTOL

School of Experimental Psychology
12a Priory Road
University of Bristol
Bristol
BS8 1TU

Adverse Event Report

Study:

Ethics Number:

Date of Report:

Principal Investigator:

Investigators:

Researcher making report:

SOP - 15

REPPORTING AND HANDLING ADVERSE EVENTS

ADVERSE EVENTS

List below and record any additional details on Comment page

AE no.	Symptom	Date / time of onset	Date / time resolved	Outcome	Intensity/Seriousness	Treatment required/Action taken (Tick all that apply)	Relationship to study drug
		_ _ / _ _ _ / _ _ d d m m m y y _ _ : _ _ 24 hr clock	_ _ / _ _ _ / _ _ d d m m m y y _ _ : _ _ 24 hr clock Frequency : Intermittent ☐ Continuous ☐	☐Resolved ☐Partially recovered ☐Persisting ☐**Lost to follow-up*** ☐Death ☐Unknown *add last contact date and details to comments page	☐Mild ☐Moderate ☐Severe ☐Serious ↳***Complete SAE form***	☐None ☐Dose adjusted ☐Temporary stop ☐Permanent stop ☐Hospitalisation ☐Other_____ (Please specify) ☐Medication ↳**Complete 'concomitant medication' form**	☐Very likely ☐Probably related ☐Possibly related ☐Doubtful ☐Not related
		_ _ / _ _ _ / _ _ d d m m m y y _ _ : _ _ 24 hr clock	_ _ / _ _ _ / _ _ d d m m m y y _ _ : _ _ 24 hr clock Frequency : Intermittent ☐ Continuous ☐	☐Resolved ☐Partially recovered ☐Persisting ☐**Lost to follow-up*** ☐Death ☐Unknown *add last contact date and details to comments page	☐Mild ☐Moderate ☐Severe ☐Serious ↳***Complete SAE form***	☐None ☐Dose adjusted ☐Temporary stop ☐Permanent stop ☐Hospitalisation ☐Other_____ (Please specify) ☐Medication ↳**Complete 'concomitant medication' form**	☐Very likely ☐Probably related ☐Possibly related ☐Doubtful ☐Not related

SOP - 15
REPORTING ADVERSE EVENTS

COMMENT PAGE

Comment														
Time (24 hr format)			:											
Date (dd/mm/yyyy)			/			/					CRF page no.		Initials	
Comment														
Time (24 hr format)			:											
Date (dd/mm/yyyy)			/			/					CRF page no.		Initials	

SOP - 15
REPORTING ADVERSE EVENTS

Appendix B: TARG Adverse Event Report

Adverse Event Report

Title of Study:

Study Site:
Ethics Number:

Participant ID:
Participant Initials:

Description of Event:

Intensity:
Onset Date:
Onset Time:
Duration:
Related to study medication:

Action Taken:

Sequelae:

Date Reported:

Person making report: **Signature:**

Role in study: