University of Bristol Tobacco and Alcohol Research Group
Standard Operating Procedures

SOP - 12
USE OF QUESTIONNAIRES and CRF Completion

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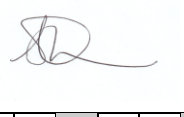
	Signature	
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Definitions/Abbreviations	
SOP	Standard Operating Procedure
CRF	Case Report Form

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1. PURPOSE:

- To provide step-by-step instruction to all persons using questionnaires in clinical trials to ensure consistent data.

2. REFERENCES:

- Questionnaires.

3. PERSONNEL REQUIRED AND LEVEL OF EXPERTISE:

- Investigator or research team (no training required).

4. MATERIALS AND EQUIPMENT REQUIRED:

- Questionnaires preferably formatted as part of a CRF.

5. PROCEDURE:

5.1 When:

When a measure of mood, personality, health etc. is required by the study protocol. This can be as a baseline measure, to give information about the disposition of your participants, or to evaluate changes to your participant during or after a test procedure, drug or challenge.

5.2 How:

The researcher should familiarise themselves with the questionnaires and their instructions. In addition, and applicable for all questionnaires, the researcher should be available to answer any further questions the participant may have. However, the participant should complete the questionnaire "**on their understanding of the questionnaire instruction**". There are never wrong answers.

Questionnaires should be completed in black or blue ink by the participant. During the session the researcher should check all questionnaires, for crossings out or missed pages/items.

All errors must be amended, initialled and dated by the participant.

6. TROUBLE SHOOTING:

Problem	Solution
Participant does not understand the question or the terminology	All instructions are detailed at the top of the questionnaire. Read the instructions with the participant and use your own interpretation to explain the instructions.
Participant has not encountered a situation questioned about in the questionnaire	Ask the participant to imagine being in that situation.
Any other 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