UNIVERSITY OF SUSSEX

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Ethical Review Audit Questionnaire

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Project Title

Primary Investigator

Funding Body

Department

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1. Brief Description of Research (in lay terms and in fewer than 300 words)

0/4000 used

2. Progress report (in fewer than 100 words) At what specific stage is the study? (i.e. preparation stage, collection of data, writing up of results, completed etc.)

3. Date a favourable ethical opinion was given by the C-REC/ SREO and date of approval of any amendments, with Sussex Direct reference numbers. If a Certificate of Approval (CoA) was provided this date should be attached. In the absence of a CoA please give the approved date showing in the Submission History section of the online form.

4. Have any aspects of the application, or procedures as agreed by the C-REC/ SREO changed in any way? i.e. processes not solely related to but including: recruitment/consent/survey/study team etc. Yes No

4.1. If Yes give details:

5. Does the study involve other ethical (external) approving bodies including 'gatekeeper' permission or similar? Please state the names of the approving bodies in 5.1.1 below Yes No

5.1. Did the external approving body specify any conditions as part of their approval? If Yes have their guidelines and conditions been adhered to? If No, please explain in 5.1.1 below. Yes No N/A

5.1.1. Give the names and details of external approving bodies and summary of any conditions. If relevant, please indicate why their conditions were not adhered to. Please attach relevant documents (as PDFs) to your audit response.

6. Has participant consent for the study been obtained as outlined in the original application that received approval from the C-REC/ SREO ? This includes whether there have been changes from the individuals previously identified as seeking participant consent. Yes No

6.1. If No, please describe and account for the deviation from the original application

7. Has the participant information sheet and / or the recruitment materials been revised from the versions approved by the C-REC/ SREO? Yes No N/A

7.1. If Yes, please describe and account for the deviation from the original application

8. What version numbers of consent form and participant information sheet have been used in participant recruitment?

9. Are the procedures undertaken to maintain participant confidentiality identical to those described in the original application? Yes No N/A

9.1. If No, please describe and account for the deviation from the original application.

10. Is the risk assessment checklist at the start of the online ethical application form still valid? Yes No

10.1. If No, please describe and account for the difference from the original risk assessment

11. Where and how are consent forms being stored (if applicable)? Please provide details of storage whether physical or digital. Is access restricted?

12. Where is research data being stored? (Please give web links of any open online surveys or the name of any online survey tools (such as Qualtrics) if they have closed. Please provide details of research data storage including any university systems and devices (PCs, laptops), filing cabinets etc., and whether encryption /password protection/ use of a keys is applied. Is access restricted?

13. Have any adverse incidents been observed? Yes/No Please provide details of the incidents in 13.1.1 below. Yes No

13.1. If Yes, have these incidents been reported? Indicate to whom they were reported in 13.1.1 below? Yes No N/A

13.1.1. If adverse events have occurred but not been reported, please give details:

14. Give a brief report on any unanticipated areas of ethical concern (for example unexpected risk to participants or researchers, failure of medical screening, uncovering of incidental or unintended findings) or difficulties in adhering to the approved application. Has anything been learned that may be of use to other researchers?

15. Describe any additional training or support needs in relation to research ethics and governance that have arisen in the course of the research (such as data management, anonymization techniques or consent training). You may also make any other comments or points that you wish to bring to the attention of the reviewer here.

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