## Supplementary material: Protocol deviation from SHC Study



**Protocol Deviation Reporting Form**

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| **Study title** | Evaluating the potential unintended impacts of minimum unit pricing of alcohol: A study in sexual health clinics in Scotland and England |
| **R&D Reference Number** | *GN12AL396 (Glasgow)* |
| **Site Name** | All sexual health clinic research sites for the study in Glasgow, Edinburgh, Tayside, Leeds, Manchester, and Sheffield |
| **Principal Investigator** | Prof Alastair Leyland, SPHSU |
| **Date of report** | 20.02.2018 |
| **Date of deviation** | 1-2, 5-9, 12-16, 19-23 February 2018 |
| **Date the Chief Investigator was informed of the deviation** | 15.02.2018 |
| **Date reported to the Sponsor** | 20.02.2018 |

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| 1. Please provide a full description of the deviation |
| The previous unapproved version (with version id and filename ‘submit v2c’) of the questionnaire was printed and used in all sites for the first wave baseline data collection. The correct version, ethically approved in August 2017, had the same version number and filename, and this version control error, in combination with high project complexity, regulatory and technical requirements, and extreme time pressures particular, but not unique, to this project, was how the wrong file was sent for printing, and the error arose. |

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| 2. Specify the impact of the deviation on patient safety | |
| None | |
| Was the deviation related to a specific patient(s)? | |
| Yes, all patients. |  |
| If yes, please provide the patient(s) subject number(s):  The study data are anonymous – there are no study IDs. The numbers at each site so far returned for the pilot data are:  Glasgow 26, Dundee 45, Edinburgh 111, Sheffield 120, Leeds 88, Manchester 99. | |

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| 3. Specify the impact of the deviation on the integrity of the study data |
| Data are still complete, but an adjustment will need to made to the analysis.  These will involve mapping of answer categories about highest educational level on to the revised answer categories. Otherwise all the questions and other information in the unapproved version were present in the approved version, although there was a timeframe of 6 months for change in alcohol and drug use, compared to 1 year in the final version. |

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| 4. Please specify what corrective actions have been taken (give details) |
| *e.g. patient to attend for repeat assessment / bloods, re-consent patient, remove patient from study*  A correct version will be used for waves 2 and 3 |

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| 5. Please specify what preventive actions have been taken (give details) |
| *e.g. re-training on protocol, better scheduling of study visits to ensure they take place within permitted timeframe*  Retraining on version control methods for SPHSU staff, Drew Millard and Ross Forsyth, will be delivered by the CI. Specifically this will include the need to keep a version control sheet recording the versions and dates of each study document. |

Were affected patient(s) informed of this deviation? Yes No N/A

x

x

Have the affected patient(s) remained in this trial? Yes No N/A

All patients. It is important we retain them as they form the baseline for the study measurement of change.

If yes, which patients?

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| Reported by | | | |
| Name | Andrew Millard | | |
| Designation | Research Lead | | |
| Signature |  | Date | 20/02/2018 |

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| Reviewed by (*Principal Investigator or Authorised Designee (as specified on the Site Staff Responsibilities Log)* | | | |
| Name | Professor Alastair Leyland | | |
| Designation | Principal Investigator & Associate Director | | |
| Signature |  | Date | 20/02/18 |

**Once complete, please send to the Clinical Trial Monitors:**

**RandD.MonitoringGroup@ggc.scot.nhs.uk**

***P.T.O for form completion guidelines***