## Supplementary material: Letters to NIHR

### Letter to NIHR re SHCs protocol dated 23.10.17 change to v2.3

**Your ref: 12-SS-0121**

**Evaluating the potential unintended impacts of minimum unit pricing of alcohol: A study in sexual health clinics in Scotland and England**

Dear Dr XXXXXXX,

I write to you to request a major amendment to this project. The changes have arisen as a consequence of delays to the implementation of Minimum Unit Pricing of alcohol, following legal challenges. We explain the changes that are being requested below.

During the implementation delays, the host organisation (the MRC/CSO Social & Public Health Sciences Unit, SPHSU) has become a formal part of the University of Glasgow and the previous Chief Investigator has moved to Australia. This has resulted in a change in the sponsorship arrangements (from the SPHSU to the NHS) and the Chief Investigator (Prof. Alastair Leyland has taken over this position from Prof. Lyndal Bond). In addition, changes have been made to the questionnaire (question 7) in order to update the drug types listed and the names commonly used for them. This has been done to ensure the question is relevant within the context of current patterns of drug use and language within the UK and has been adapted under the guidance of the Scottish Drugs Forum and Crew (providers of information relating to drug use).

We feel that the substantive science remains unchanged and in our view, the alterations do not raise important additional ethical issues that have not been previously considered.

We therefore request the approval of A-REC for the changes, and enclose a notice of substantial amendment.

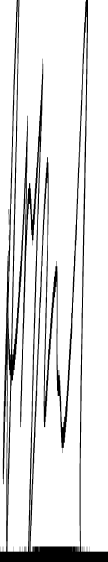
We have also updated the protocol document. This is mainly to provide greater detail than included in the previous version and to meet the requirements of new governance arrangements following the Unit becoming a formal part of the University of Glasgow. All changes to the research conduct are noted within the cover letter and appendix.

The implementation of the Scottish legislation on the minimum unit price (MUP) for alcohol has been long delayed as a result of alcohol industry-funded legal challenges. However, in October last year, this policy was emphatically assessed as legal, though now subject to a further appeal to the UK Supreme court. If that fails, the policy will be implemented after April 2018, depending on the Supreme Court’s workload. As the legislation contains a sunset clause it may lapse after six years unless evidence is given of its value. There is therefore a need to establish a baseline to measure the effect and directly inform policy in this area.

We were awarded funding from NIHR in 2012 to evaluate the policy, with one of the components being to study the potential unintended impacts of minimum unit pricing of alcohol.

The separate study of emergency departments which is mentioned in the protocol has a separate ethical approval (IRAS number 99791). A separate notice of substantial amendment for that linked study will be submitted.

Regards,



Prof. Alastair Leyland (on behalf of the study team),

Chief Investigator, and Associate Director MRC/CSO Social & Public Health Sciences Unit.

### Letter to NIHR re ED protocol change dated 21.08.17

Date 21.08.17

**Your ref: 12-SS-0120**

**Evaluating the impact of minimum unit pricing of alcohol on Emergency Department attendances (Short title: Evaluation of Minimum Unit Pricing of Alcohol in Emergency Departments)**

Dear Dr XXXXX,

Since 2012 there have been a number of changes to this project including the Chief Investigator, sponsor, and use of iPads by researchers rather than paper questionnaires, but otherwise no changes to the research tools or procedures. We therefore request the approval of A-REC for the changes, and enclose a notice of substantial amendment.

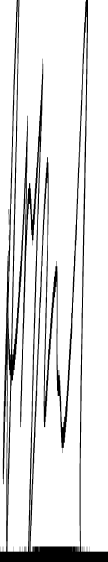
The modifications to the protocol are mainly to provide greater detail than in the previous version and to meet the requirements of new governance arrangements following the Unit becoming a formal part of the University of Glasgow. All changes to the research conduct are noted within the cover letter and appendix.

The implementation of the Scottish legislation on the minimum unit price (MUP) for alcohol has been long delayed as a result of alcohol industry-funded legal challenges. However, in October last year, this policy was emphatically assessed as legal, though now subject to a further appeal to the UK Supreme court. If that fails, the policy will be implemented after April 2018, depending on the supreme court’s workload. As the legislation contains a sunset clause it may lapse after 6 years unless evidence is given of its value. So there is a need to establish a baseline to measure the effect.

We were awarded funding from NIHR in 2012 to evaluate the policy, with one of the components being to estimate prevalence of alcohol-related attendance within Emergency Departments.

The separate study of sexual health clinics which is mentioned in the protocol has another separate ethical approval, but will also be amended. We will complete a notice of substantial amendment for that and send it shortly.

Regards,



Alastair Leyland,

Chief Investigator, and Associate Director MRC/CSO Social & Public Health Sciences Unit.