



## Privacy notice: CHAMPION (Alcohol Harm Prevention in pregnancy) Study.

### I have questions or want further information. Who do I talk to?

If you have any questions or concerns about how your data will be processed within this project please contact Hull Health Trials Unit (HHTU) in the first instance:

Email: [hhtuenquiries@hyms.ac.uk](mailto:hhtuenquiries@hyms.ac.uk)

Telephone: 01482 463444

Address: 3<sup>rd</sup> Floor, Allam Medical Building, University of Hull, Hull, HU6 7RX

If you would like further information, please contact the University of Hull, Data Protection Officer (DPO):

Email: [dataprotection@hull.ac.uk](mailto:dataprotection@hull.ac.uk)

Telephone: 01482 466594

Address: University of Hull, Cottingham Road, Hull HU6 7RX

### What is this project about?

Drinking too much alcohol can damage a woman's health and can also harm her baby. There is more chance that she might develop a serious illness such as breast cancer. It can affect a child's growth and development, including their physical and mental health and it is thought that up to 17 in 100 children in England might have symptoms. The national guidelines advise midwives to ask and advise women about their drinking and help women to access specialist support for alcohol problems. However, our recent research shows that not all midwives have this conversation at routine antenatal appointments.

In the first part of the study, we carried out co-design workshops, where the researchers worked together with maternity service users and midwives. We developed strategies to support midwives have conversations about alcohol with pregnant women. In this second part of the study, we will ask midwives to use these strategies during their usual clinical practice for 3 months. We will recruit a total of 30-40 midwives from two NHS Trusts in North East England. We will collect information from the maternity records of all women on the caseload of the midwives



to see whether drinking alcohol was discussed and written in the notes and what actions were taken.

After the 3 month period, we will recruit and interview 12-15 of the midwives and 12-15 women to find out how well the strategies were used, what was discussed and if they were acceptable to both the women and midwives.

If we can show that the study can be run, the information from this study will help us to plan a larger trial.

### What data are you using?

We will use data that is routinely collected in the maternity notes of pregnant women who are seen by midwives taking part in the study. This will include basic demographics and stage of pregnancy of women on their caseload, and whether conversations about alcohol consumption have taken place at routine antenatal appointments and recorded in the notes.

We will not collect any directly personal identifiable details (e.g name, date of birth or address). The data collected will be entered into a database by local research midwives. Personal details that would identify women will be removed and a unique pseudonymised Subject Identification Number will be assigned to each person.

If your data is included, the team responsible for analysing the data will not be able to identify you from any of the information in the database. Only your local research team will be able to link your data to the unique Subject Identification Number. Team members from HHTU and regulatory organisations responsible for monitoring the study for data quality and compliance may request permission to review your medical and research records to check the accuracy of the data collected.

### Am I in this dataset?

If you were pregnant between {insert dates} and were seen by a midwife at one of these NHS Trusts {insert names}, then your data may have been collected.

The NHS Trust where you received your ante-natal care are responsible for collecting your data and will know if you have been included. They should have made checks of the national opt-out repository (<https://digital.nhs.uk/services/national-data-opt-out-programme>) for any previous dissent to the use of your data in research you may have made. A number of methods have been used to highlight the study to women who are on the caseload of midwives taking part in the study with ways to opt-out of consent to use routine data for this research project. If you completed an opt-out, your data should not be included in the database.

If you would like to confirm you have not been included, in the first instance, please contact your midwife to confirm whether you have been included or not.



If you have previously opted out of your data being used for research purposes but have been included in error without your consent or wish to remove your consent, the HHTU research team will work with the research midwife and NHS Trust to meet any request or objection you might have, using your rights under GDPR 2018 as described below.

### How will you look after your information and have access to it?

Your data will be managed and stored by the Hull Health Trials Unit (HHTU) using their data capture system REDCap cloud and BOX Governance file storage system. Both systems have high levels of security and all data is stored within the EU. Only staff working on this study will have access to your data. Staff have individual logins and all activity is logged. The HHTU hold a Data Security and Protection Toolkit (DSP) which provides assurance that they are practising good data security and that personal data is handled correctly. More information about the DSP can be found [here](#).

### How long will you keep it?

The University of Hull will keep archived records of the information about you until 10 years after closure of the research project.

### What is the purpose of the General Data Protection Regulations (GDPR 2018)?

Under the GDPR 2018, there is a legal basis for processing personal data we collect about you during research as this is being done in the public interest (schedule 6) and for scientific research purposes (schedule 9).

The University of Hull is the data controller of the information it collects and processes as described in this Notice. This means that it has the core legal responsibility to safeguard the information and ensure it is processed lawfully. The law is set out in the EU General Data Protection Regulation (called “GDPR”) and a new UK law, the Data Protection Act 2018. In particular UOH must:

- Take steps to ensure that the data it processes is accurate and up to date;
- Give you clear information about its processing of your data, in one or more privacy notices like this one and the participant information sheet (referred to together in this section as a “Privacy Notice”);
- Only process your data for specific purposes described to you in a Privacy Notice, and only share your data with third parties as provided for in a Privacy Notice; and
- Keep your data secure.

The law states that we can only process your personal data if the processing meets one of the conditions of processing in Article 6 GDPR. As we are processing your special category data we also must meet one of the conditions in Article 9 GDPR. Special Category data includes personal data which relates to your ethnicity, sex life or sexual orientation, health or disability, biometric or genetic data, religious or



philosophical beliefs, political opinions or trade union membership. Under the data protection legislation we need to explain the legal basis for holding your data, i.e. which of these conditions apply.

For our research project the following conditions apply:

- Article 6.1(e) of the GDPR, i.e. our processing is necessary for the performance of a task carried out in the public interest. Research is a task that UoH performs in the public interest, as part of our core function as a university;
- Article 9.2(j) of the GDPR, i.e. our processing is necessary for research purposes or statistical purposes. This condition applies as long as we are applying appropriate protections to keep your data secure and safeguard your interests.

### Your rights as a data subject

Under the data protection laws you have a number of rights in relation to the processing of your data. These are limited by the lawful basis under which we hold your data. Your rights are:

- Right to request access to your data as processed by UoH and information about that processing
- Right to rectify any inaccuracies in your data
- Right to place restrictions on our processing of your data

If you would like to exercise any of your rights as outlined above, you can contact the DPO as above or visit the Data Protection page on our website

<https://www.hull.ac.uk/choose-hull/university-and-region/key-documents/data-protection.aspx>

We will always aim to respond clearly and fully to any concerns you have about our processing and requests to exercise the rights set out above. However, as a data subject, if you have concerns about our data processing or consider that we have failed to comply with the data protection legislation, then you have the right to lodge a complaint with the data protection regulator, the Information Commissioner:

Online reporting: <https://ico.org.uk/concerns/>

Email: [casework@ico.org.uk](mailto:casework@ico.org.uk)

Tel: 0303 123 1113

Post: Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF



