

**Participant Information Sheet**

**Clinicians views of ambulatory care provision**

**for adults with congenital heart disease.**

Principal Investigator: Dr Louise Coats

**Introduction:**

We would like to invite you to take part in our research study. It is important to understand what the study entails before you decide to take part. Please read the following information carefully and if anything is unclear, please do not hesitate to ask. If you decide to participate in this study, we will ask you to sign a consent form.

**Background:**

1 in a 100 babies is born with congenital heart disease. Due to successes in infant surgery, over 95% now survive to adulthood. The adult congenital heart disease (ACHD) population is therefore growing in size and complexity. In the present healthcare system, many of those with ACHD fail to attend clinic or become lost to follow up and this is associated with worse outcomes. Ambulatory care for those with ACHD is almost universally provided by the tertiary centre and outcomes when managed elsewhere are presently worse. Healthcare provision for other chronic conditions originating in childhood, eg diabetes mellites, adopt a more patient centred model of care in line with recommendations for chronic care provision. The purpose of this study is to explore the views of clinicians (specialists, other cardiologists and primary care physicians) caring for those with ACHD about present arrangements for ambulatory care and what changes may be possible to enable more patient centred care delivery.

**Why was I chosen, and do I have to take part?**

You have been chosen to take part in this study because you are a clinician with either experience in or interest in the ambulatory care of those with ACHD or a clinician who may occasionally care for those with ACHD.

**What will happen to me if I take part?**

If you agree to take part, you will be asked to complete a consent form that relates to information provided in this participant information sheet. We will ask you send this back to us with any questions you may have. We will then organise a date and time for the interview. At the beginning of the interview we will run through the consent form again and check whether you have any questions. The interview will then last between 30-60 minutes and take place over Zoom. The interview will be recorded. The visual recording is not essential to the research therefore if you wish you are welcome to disable or cover your camera. The interview will be transcribed and anonymised by a member of our research group so that it can be analysed alongside other interviews at a later date. You are free to withdraw from the study at any time without providing a reason.

**What are the risks and benefits of taking part?**

## The risks of this study are low. All interview transcripts will be discussed amongst the research team to ensure agreement on coding and categorisation of comments and minimise the risk of misrepresentation. You will not be identified by your location of work or gender or ethnicity in any arising publication. If you wish, following the interview you may a request a copy of your interview transcript and make any edits you feel necessary to ensure the effectiveness of this agreement about confidentiality.

**Will my taking part in the study be kept confidential?**

All information collected about you during this study will be kept strictly confidential. The recording of the interview will be stored in a folder with access limited to Dr Louise Coats and direct members of the research team. The research folder will be located on a Newcastle University server. Transcribed interviews will be anonymised prior to analysis. Only fully anonymised information will leave the research folder. Your participation in the research (written and oral consent) will be recorded in the electronic site file which will also be located on the Newcastle University server and may be accessed by the University R&D department if the study is chosen for audit

**How will we use information about you?**

We will need to use information from you for this research project. This information will include your name, age, ethnicity, profession and level of experience with ACHD. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### **What are your choices about how your information is used?**

### You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information by asking one of the research team (details below).

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (details below). If you wish to complain formally, the researchers will guide you as to the process

**Who is organising and supporting this study?**

This study is being organised by a team of researchers at Newcastle University. This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee.

**Contact and further information:**

**If you have any questions please contact:**

This research has been reviewed and approved by the Newcastle University Research Ethics Board. If you have any further questions or concerns about this study, please contact:

Name of researcher: Dr Louise Coats

Full address: Population Health Sciences Institute, Newcastle University
E-mail: louise.coats@newcastle.ac.uk

**What if I have concerns about this research?**

If you are worried about this research, or if you are concerned about how it is being conducted, you can contact the Chair of the Faculty of Medical Sciences Ethics Committee, Newcastle University or email at  fmsethics@ncl.ac.uk