Plan Overview

A Data Management Plan created using DMPonline

Title: Characterising Pregnancies Complicated by Chronic Histiocytic Intervillositis

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Project abstract:

The placenta, the organ which supplies the developing fetus with oxygen and nutrients during pregnancy, is made up of half of the mother's genes and half of the father's. Normally, a foreign organ (like a transplant) would trigger the mother's immune system, however in a healthy pregnancy the placenta is protected. In a condition known as chronic histiocytic intervillositis (CHI), this protection appears to fail, and the mother's immune cells build up in the placenta, preventing the growth of the baby, or in severe cases causing fetal death. During the recent COVID-19 pandemic, CHI was also found in some placentas from stillbirths where the mother had been infected with the virus.

Currently, CHI can only be diagnosed by specialist doctors who examine the placenta under a microscope after a pregnancy has been affected, and there are no treatments proven to prevent it. The cause of CHI is unknown, though it has been suggested that the mother's immune system reacts inappropriately towards the semi-foreign placenta. CHI is rare (0.17% of all pregnancies), but returns in 25-100% of future pregnancies.

This study, funded by Tommy's Baby Charity, aims to investigate the behaviour of the mother's immune cells in CHI by collecting blood and placental samples from women with the condition attending Saint Mary's Hospital, Manchester, UK over a period of five years. Participant questionnaires and medical records will also be used to identify possible risk factors associated with the development of CHI, for example change in paternity or autoimmune disease. By better understanding the cause of CHI and how immune cells cause poor outcomes, more specific treatments may be developed in future to increase the chance that women will go on to have a healthy baby after their first diagnosis. Investigation of potential markers in the blood of affected women may also allow those at risk of developing CHI to be identified before they suffer a pregnancy loss.

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Characterising Pregnancies Complicated by Chronic Histiocytic Intervillositis

Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

- Yes - Part of a collaboration and owning or handling data

Project recruitment and sample and data collection takes place at Manchester University NHS Foundation Trust

3. What data will you use in this project (please select all that apply)?

- Acquire new data
- Re-use existing data (please list below)

Project involves issuing of participant questionnaires and collection of existing clinical data from medical notes

4. Where will the data be stored and backed-up during the project lifetime?

- Other storage system (please list below)

The consent forms, consent to contact forms and pseudonymisation key relating to study participants will be stored as paper copies in locked storage at the Maternal and Fetal Health Research Centre. Pseudonymised data from questionnaires and medical notes will be stored on REDCap for the duration of the study (5 years).

5. If you will be using Research Data Storage, how much storage will you require?

- < 1 TB

6. Are you going to be receiving data from, or sharing data with an external third party?

- Yes

There is potential for pseudoanonymised participant data held in REDCap to be shared with other researchers working on CHI. Data sharing will be facilitated by REDCap's external collaborator feature.

7. How long do you intend to keep your data for after the end of your project (in years)?

- 5 - 10 years

Guidance for questions 8 to 13

Highly restricted information defined in the Information security classification, ownership and secure information handling SOP is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more examples of highly restricted information.

If you are using 'Very Sensitive' information as defined by the Information Security Classification, Ownerships and Secure Information Handling SOP, please consult the Information Governance Office for guidance.

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with data protection law (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de—identified) as soon as practically possible. You must obtain the appropriate ethical approval in order to use identifiable personal data.

8. What type of information will you be processing (please select all that apply)?

- Special category personal data, or criminal offence data
- Personal information, including signed consent forms
- Pseudonymised personal data

Consent forms, consent to contact forms and the study pseudonymisation key will be stored as paper copies.

Data from NHS records will be accessible only to researchers working on the study who have prior access granted by Manchester University NHS Foundation Trust and have been issued a Letter of Access.

Special category data collected for this study includes ethnicity and health data (age, BMI, pregnancy history and outcomes, comorbidities and medication taken).

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

- Where needed, follow University of Manchester guidelines for disposing of personal data
- Access data hosted by the University of Manchester via its secure Virtual Private Network (VPN)
- Store data in buildings, rooms or filing cabinets with controlled access
- Store data on University of Manchester approved and securely backed up servers or computers
- Store data in encrypted files, folders, computers or devices
- Pseudonymise data and apply secure key management procedures
- Impose suitable data sharing and collaboration agreements

Consent forms, consent to contact forms and the pseudonymisation key will be stored as physical copies in a locked cabinet in the Chief Investigator's office accessible to the Chief Investigator and Co-Investigator only. Pseudonymised medical data and questionnaires will be stored using REDCap via the University of Manchester's license, and will be accessible only to researchers granted prior access by the Chief Investigator and the University of Manchester. NHS medical records will be accessible only to researchers who have been issued a Letter of Access by Manchester University NHS Foundation Trust.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

- Yes – Other

Where study participants have consented and specifically agreed to it, personal contact details will be retained so they can receive a report of the results of the study and copies of publications.

Consent forms will be kept for 5 years after the end of the study in accordance with University of Manchester Records Retention Schedule.

11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?

- Yes - Public institutions with contractual arrangements (e.g. NHS research sites or other higher education institutions)

Pseudonymised REDCap data including ethnicity and health data may be shared with researchers working on CHI at other medical or educational institutions via REDCap's external collaborator feature where participants have given consent for this. The pseudonymisation key will remain on paper in locked storage at the University of Manchester throughout the project and so will not be accessible to external collaborators and prevent identification of participants.

12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?

- Yes

As CHI is a rare disease, there is scope in future for collaboration with other medical or educational institutions to share pseudonymised research data, and these institutions may be outside of the EEA.

13. Are you planning to use the personal information for future purposes such as research?

- No

14. Will this project use innovative technologies to collect or process data?

- No

15. Who will act as the data custodian for this study, and so be responsible for the information involved?

Prof Alexander Heazell

16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).

2023-09-25

Project details

What is the purpose of your research project?

To identify risk factors and causes of chronic histiocytic intervillositis, a rare disorder of pregnancy.

What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

The University of Manchester Research Data Management Policy
University Records Retention Schedule
GDPR

Responsibilities and Resources

Who will be responsible for data management?

Professor Alexander Heazell - Chief Investigator

Dr Chloe Brady - Co-Investigator

What resources will you require to deliver your plan?

Physical storage space at the Maternal and Fetal Health Research Centre
Storage space on The University of Manchester Research Data Storage System
Use of the University's REDCap system

Data Collection

What data will you collect or create?

Data collected will include existing demographic, medical and pregnancy history (ethnicity, BMI, age, number of pregnancies and their outcome, comorbidities and medication taken) and new information on change in paternity between pregnancies, COVID vaccination/infection history, familial history of pregnancy loss or autoimmune disease, and contraception method used.

How will the data be collected or created?

Existing medical and pregnancy history will be collected from clinical notes (electronic or physical copies). New data will be collected using a questionnaire distributed to participants via REDCap online.

Documentation and Metadata

What documentation and metadata will accompany the data?

A document listing the definitions of each clinical data variable will be created. Data will be stored under clear categories in REDCap allowing easy understanding by future users.

Ethics and Legal Compliance

How will you manage any ethical issues?

To protect participant identity, participants will be issued with a study number to facilitate pseudonymisation of their data. The key to link personal and pseudonymised data will be securely kept under locked storage in the Chief Investigator's office in the department and be accessible to the Chief and Co-Investigator only. The department is accessible only to those with swipe card access by Manchester University NHS Foundation Trust.
Access to REDCap will only be granted to members of the research team following approval by the Chief Investigator and the University of Manchester. External collaborators will not have access to the paper pseudonymisation key to prevent identification of participants.
Consent to share pseudonymised data with other researchers will be requested during recruitment of participants.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The University of Manchester will own copyright and intellectual property of data as the sponsor.

Storage and backup

How will the data be stored and backed up?

Consent forms, consent to contact forms and the pseudonymisation key will be stored as physical copies in locked cabinets in the office of the Chief Investigator.
Pseudonymised study data from medical notes and questionnaires will be stored using the University's REDCap database for the duration of the study (5 years). At the end of the study, the pseudonymisation key will be destroyed, and data removed from REDCap before transfer to the University Research Data Storage system.

How will you manage access and security?

Access to physical consent forms, consent to contact forms and the pseudonymisation key will be managed by the Chief Investigator who will be in possession of the key for their locked storage.
REDCap and Research Data Storage system access will be controlled by the University of Manchester once approval is granted to the relevant research staff by the Chief Investigator. Data from questionnaires will be directly input into REDCap by participants or the research team for storage to eliminate the need to transfer data between systems.

Selection and Preservation

Which data should be retained, shared, and/or preserved?

Consent forms will be retained for 5 years after the end of the study in accordance with NHS Trust and University policy.
Contact details of participants who have consented to receive study findings will be retained for 5 years after the end of the study.

What is the long-term preservation plan for the dataset?

Upon completion of the dataset, study numbers and data will be removed from the REDCap database and anonymised data transferred to the Research Data Storage system.

Data Sharing

How will you share the data?

Figshare will be used as a data repository, and anonymised data in publications will be available by request.
Research will be registered in accordance with the HRA Make it Public strategy and written up into a layman's summary.

Are any restrictions on data sharing required?

Study participants have the choice on whether they consent to have their anonymised data shared with researchers from other institutions.