Plan Overview

A Data Management Plan created using DMPonline

Title: Identifying Mechanisms of Failure of Cartilage Repair Surgery

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Template: University of Manchester Generic Template

Project abstract:

This project will collect tissue from failed cartilage surgery. Tissue samples will be collected from a number of selected NHS Trusts and sent to the University of Manchester to be analysed. The aim will be to identify mechanisms of failure. The analyses carried out on these tissues may help identify why some surgical approaches are unsuccessful and could be used to inform future research into improving the success of cartilage repair surgery. It may also be possible to identify factors that contribute to an unsuccessful surgery, leading to guidelines about what sorts of approaches are best used with which kinds of patients.

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Identifying Mechanisms of Failure of Cartilage Repair Surgery

Manchester Data Management Outline

1. Is this project already funded?

- Yes

Will you be applying for funding from any of the following sources? If your funder isn't listed, please enter in the free text box provided.

This project has enough money to start using the PIs existing consumables money. We will seeking further financial support from the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine once the study begins.

3. Is The University of Manchester the lead institution for this project?

- Yes - only institution involved

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

- Acquire new data

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

- University of Manchester Research Data Storage Service (Isilon)

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

- 1 - 8 TB

7. If you have a contractual agreement with a 3rd party data provider will any of the data associated with this project be sourced from, processed or stored outside of the institutions and groups stated on your agreement?

- Not applicable

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

- 5 - 10 years

The consent forms (hard copies) will be kept in secure locked storage in a research office at each hospital site for 10 years. The research team will not gain access to these.
Pseudo-anonymous electronic data sent to the University of Manchester from the clinicians will be stored as a non-patient

identifiable database on encrypted University of Manchester computers for 10 years. The University of Manchester RDS will be used.

Pseudo-anonymous samples of tissue donated to the University of Manchester will be destroyed on site once analysis has completed. The tissue will not be kept longer than 10 years.

The principle investigator, sponsor representative and study monitors will have access to the data if required.

It will be carefully explained to patients that their data will be retained for up to 10 years (as opposed to the usual 5) to complete the analyses on their donated tissue and to answer research questions that arise from the analyses.

Questions about personal information

Personal information or personal data, the two terms are often used interchangeably, relates to identifiable living individuals. Special category personal data is more sensitive information such as medical records, ethnic background, religious beliefs, political opinions, sexual orientation and criminal convictions or offences information. If you are not using personal data then you can skip the rest of this section.

Please note that in line with data protection law (the 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.

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

- Personal information
- Pseudonymised personal data

Patient Information:

Clinicians who recruit patients for this study will be asked to submit the following pseudo-anonymous details about the patient via a Request Form:

Sex, age, clinical diagnosis, date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the tissue which will be donated.

The above information and sample will be pseudo-anonymised as follows: SurgeonSurname_Hospital_Date(of revision surgery) - Thus no identifiable information about the patient will be communicated to the research team at The University of Manchester.

If a clinician wishes to send more than one donation from different patients on the same day, the data and samples will be formatted as follows: Surname of Surgeon_Hospital_Date_1, Surname of Surgeon_Hospital_Date_2 etc.

Surgeon Information:

A report on each tissue sample will be created by study researchers once all laboratory assessments have been completed. This pseudo-anonymous report will be sent to the consultant surgeon from an NHS email account to an NHS or Spire Healthcare email account. The surgeon will be able to identify the patient by looking through their surgical lists and comparing this information to the clinical information and date of surgery detailed in the report (i.e. the pseudo-anonymisation key). The surgeon will be responsible for communicating the information in the report to the patient.

For this system to work, the research team will need to collect the following information about the consultant surgeon:

Name, hospital, NHS/Spire Healthcare email address.

10. Please provide details of how you plan to store, protect and ensure confidentiality of the participants' information as stated in the question above.

Patient information:

Only pseudo-anonymous patient data will be collected: Sex, age, clinical diagnosis, date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the tissue which will be donated.

This information will be provided by the orthopaedic surgeon via a Request Form which will be emailed to the research team at the University of Manchester. The researchers at the University will then be able to organise for containters labelled with the pseudo-anonymous ID to be sent to the hospital for sample collection.

The consent forms, completed on hospital-site with clinicians will be kept in locked cabinets in a locked research office at each hospital. Only the clinicians will have access to the room and cabinet.

The digital information in the Request Form will be digitised by a member of the research team. This will be in Microsoft Excel format and will be saved in a folder in a digital trial master file, which will be organised as per current GCP guidelines. Filenames will also follow current GCP guidelines, and the document will be checked by a second member of the research team to reduce the risk of data entry errors. The Excel document will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.

Samples of tissue removed during the revision treatment will be labelled using the format 'SurgeonSurname_Hospital_Date'. Thus, researchers at the University will be able to match the anonymised information in the Request Form to the sample itself using this ID. The researchers will be unable to determine the identity of the individual who dontated the sample from the information available to them.

Surgeon information:

The following personally identifiable information will be retained: Name, hospital, NHS/Spire Healthcare email address.

This information will be provided by the clinician via a Request Form which will be emailed to the researchers at the University of Manchester. Only members of the research team will have access to this information.

The information will be digitised by a member of the research team. This will be in Microsoft Excel format and will be saved in a folder in a digital trial master file, which will be organised as per current GCP guidelines. Filenames will also follow current GCP guidelines, and the document will be checked by a second member of the research team to reduce the risk of data entry errors. The Excel document will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.

11. If you are storing personal information will you need to keep it beyond the end of the project?

- No

We will not be storing any identifiable personal information of patients, but identifiable personal information of clinicians will be retained for 10 years.

12. Sharing person identifiable information can present risks to participants' privacy, researchers and the institution. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester? This includes using 3rd party service providers such as cloud storage providers or survey platforms.

- No

13. 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?

- Not applicable

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

- No

No personal information collected for this study will be kept for future purposes.

15. Who will act as the data custodian or information asset owner for this study?

Leela Biant

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

30/07/2019

Project details

What is the purpose of your research project?

This study will collect and analyse samples of tissue from failed cartilage repair surgery with the aim to determine mechanism of failure. This information could aid clinicians in future to identify which surgical approaches in cartilage repair are most successful.

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

project?

The General Data Protection Regulation (GDPR) will be adhered to, as will policies of the research group, department, and institution including The University of Manchester Records Management Policy, The University of Manchester Data Protection Policy, The University of Manchester Research Data Management Policy and the University of Manchester IT Policies and Guidelines. The University guidelines which will be adhered to are as follow:

The University of Manchester Research Data Management Policy
http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=33802%20
The University of Manchester Records Management Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14916
The University of Manchester Data Protection Policy
http://documents.manchester.ac.uk/display.aspx?DocID=14914
The University of Manchester Publications Policy
http://documents.manchester.ac.uk/display.aspx?DocID=28526
The University of Manchester Intellectual Property Policy
http://documents.manchester.ac.uk/display.aspx?DocID=24420
The University of Manchester IT policies and guidelines
http://www.itservices.manchester.ac.uk/aboutus/policy/

The University of Manchester Research Data Storage Policy

http://www.library.manchester.ac.uk/using-the-library/staff/research/research-data-management/working/storage/

The University of Manchester Records Retention Schedule

http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=6514

The Human Tissue Act will also apply to this study as it will involve the storage and analysis of human tissue. Guidelines on management, storage and security of the cells used in this study published by the Human Tissue Authority will be adhered to.

Responsibilities and Resources

Who will be responsible for data management?

The Principle Investigator, Professor Leela Biant will be responsible for data management. She will delegate day to day data management tasks to members of the research team.

Ultimately, all members of the research team will be responsible for digitising and securely storing the pseudo-anonymous (patients)/personal identifiable (clinicians) digital copies of Request Forms. They will also be responsible for quality control and organisation of the data collected.

The research team at The University of Manchester will also be responsible for collecting and securely storing the pseudo-anonymous tissue samples. They will also be responsible for collecting data from the pseudo-anonymous tissue samples obtained in the laboratory, as well as securely storing this data, checking its quality and organising it in an appropriate manner.

The clinicians who wish to send tissue samples for this research will be responsible for obtaining informed consent from patients. Consent forms will be kept at each hospital site and will not be made available to the research team to protect patient anonymity.

What resources will you require to deliver your plan?

Access to a lockable filing cabinet and room for storage of the consent forms at each hospital, and access to the University of Manchester Research Data Storage service will be required to deliver this plan. There will be no storage costs associated with this plan, nor will research staff be required to undergo any relevant training.

The samples of tissue provided by patients will be stored securely in laboratories at the University of Manchester. All equipment, staff and technical support necessary for the analysis of the tissue is already available at the University of Manchester. Once the study is running, the PI will seek additional funding so that additional NHS sites can be involved.

Data Collection

What data will you collect or create?

Online Request Form:

1. Pseudo-anonymous patient information: Sex, age, clinical diagnosis, date of initial cartilage repair surgery, details on the failed surgical approach, date of the revision surgery, and details of the tissue which will be donated. A sample ID will also be generated on the form in the format of 'SurgeonSurname_Hospital_Date'.

2. Clinician information: Name, hospital, NHS or Spire Healthcare email address
This sheet will then be sent to The University of Manchester by secure email.
Pseudo-anonymous issue Sample: Sample ID written in the form of 'SurgeonSurname_Hospital_Date' by researchers.
Histological, Immunohistochemical and proteomic analyses will be carried out on the samples at The University of Manchester.

How will the data be collected or created?

Clinicians will identify patients who are undergoing a revision procedure for a cartilage repair surgery from their surgical lists.
Prior to the procedure, the clinician will be responsible for discussing the option to donate the tissue to The University of Manchester with the patient. The clinician will give the patient a Patient Information Sheet to read. If the patient gives written consent at a later date, the clinician will complete a Request Form obtained directly from the research team and send it back to the researchers by email. The University of Manchester will then send pseudo-anonymised labelled containers to the hospital before the operative date. The tissue which would routinely be removed and destroyed post-operatively will then be retained and sent to The University of Manchester for analysis. The pseudo-anonymous samples will be transported by courier from the hospital to the University of Manchester. No other data or patient information will be transported with these samples.
The sample and data in the online form will be pseudo-anonymous and the identifier on both will be used by researchers to link the sample to the form. The clinician who sent the sample will be the only person who will have access to the pseudo-anonymisation key.
Members of the research team will securely store the sample and digitise the Patient Data form in the University of Manchester RDS. The data entry will be validated by another clinical member of the research team at a later date to minimise human error in transcribing the paper data to the electronic spreadsheet.
The electronic copies of the data will be stored in an electronic master file which will be organised as per current Good Clinical Practice (GCP) Guidelines. File names will also follow reccomendations by GCP (including filename conventions). The data collected from each individual will be stored in an excel file.
The hard copies of consent forms will be stored in a locked filing cabinet in a locked research office at each hospital site.
A hard copy of the study master file will also be created and stored under lock and key at the University of Manchester. This will be maintained by the research team, and will also be organised as per current GCP guidelines and recommendation.
Histological, immunohistochemical and proteomic analyses will be carried out on the samples at The University of Manchester. Repeated tests will be carried out on these samples to ensure reliability. All instruments will be calibrated as per the manufacturers guidelines before use, and standardised methods will be used to collect the data. The data will be peer reviewed.

Documentation and Metadata

What documentation and metadata will accompany the data?

An explanation of how researchers can access the data collected during this study will be given in the master file. This file will include all essential information on the study including the names of researchers involved (and who has access to the data), the aims and background of the study, the methods used (protocol) and information on how to interpret the data collected. Once the study is complete, an overview of the results will also be added to the study master file. Metadata will also be provided, which will describe the file names and formats. This will follow current GCP guidelines.

Ethics and Legal Compliance

How will you manage any ethical issues?

No identifiable information about patients will be given to researchers at the University of Manchester. Each sample in this study will be given a unique ID to pseudo-anonymise the data. Only the clinicians who send the sample and are directly involved in the patient's care will have access to identifiable data. Only the clinician will have access to their pseudo-annoynimisation key.
The name, hospital and NHS or Spire Healthcare email addresses of the surgeons who send samples will be stored for the purpose of this centre. This will enable the researchers to communicate the results of the analyses on the tissues to the surgeon from whom the sample was sent. The digital Request Forms will be saved on the University of Manchester Research Data Storage Service (Isilon). All data will be backed up on this service. Only researchers involved in the project will have access to this document, via a password protected interface.
The study will be referred to a local NHS Research Ethics Committee for approval (via the Integrated Research Application System), as the samples will be coming from UK hospitals. The study will not commence until approval has been granted. A handful of NHS Trusts will be included in the first instance, but the project lead will seek to expand the study in future to include more sites. The study will also have HRA approval.
All potential participants will be given a Patient Information Sheet (PIS) by their clinician prior to their inclusion. Written consent by

the orthopaedic surgeon will be taken from each patient prior to their donation being sent to the University of Manchester. Participants will be free to withdraw from the study at any time by informing their clinician verbally or in written form. This will be made clear to the patients in the PIS and verbally. The clinician will be responsible for informing the research team of patients who wish to withdraw their sample. Participants will not be required to give a reason for withdrawing from the study. Their legal rights will not be affected by their withdrawal. Data already collected with consent would be retained and used in the study.

Consent from the surgeon to share their name, hospital and email address with the University of Manchester will be assumed by the fact that the surgeon will have completed the above information him/herself and organised for the sample to be analysed at the University of Manchester.

The study data will be kept for 10 years as a non-patient identifiable database on university servers. The master file and hard copies of data will be kept for 10 years in secure locked storage on site in a research office at the University of Manchester. The chief investigator, sponsor representative and study monitors will have access if required.

We intend to disseminate this work as personalised reports for surgeons, peer-reviewed scientific journals, conference presentations and by publications on websites. No patient or surgeon identifiable information will be published.

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

The University of Manchester own the copyright and IPR of any new and existing data.

Storage and backup

How will the data be stored and backed up?

The hard copies of consent forms will be stored in a locked filing cabinet in a locked room at each hospital site.

All electronic data will be stored on the University of Manchester Research Data Storage system which is backed up every day and is secure.

All human tissue will be stored in an appropriate laboratory and labelled in accordance with the guidelines and standards of the Human Tissue Authority. The tissue will be stored in its own area and will not be mixed with those of other projects.

How will you manage access and security?

Only those listed in the protocol as study researchers will be given access to the data.

Access to the pseudo-anonymous electronic data will be restricted to the involved researchers. This restriction will be put in place by the IT team at the University of Manchester who are responsible for granting access to staff members using the University of Manchester

Research Data Storage system. The PI will inform the IT team who can access the data. All those with access will be required to enter a password to access the data.

The data will not be shared with anyone outside the University of Manchester.

Selection and Preservation

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

The study data will be kept for 10 years on a database on encrypted university computers. This data will include all pseudo-anonymised results and the analysis and observations of these results. The pseudo-anonymised data will be shared with the clinician. Group analyses of anonymised data will be shared on Mendeley - the university recommended respository.

The master file and hard copies of data will be kept for 10 years in secure locked storage on hospital site. The chief investigator, sponsor representative and study monitors will have access if required.

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

The study data will be kept for 10 years on a database on encrypted university computers using the University of Manchester Research Data Storage Service. This data will include all pseudo-anonymised results and the analysis and observations of these results. The pseudo-anonymised data will be shared with the clinician. Group analyses of anonymised data will be shared on

Mendeley - the university recommended respository.
The master file and hard copies of data will be kept for 10 years in secure locked storage on hospital site. The chief investigator, sponsor representative and study monitors will have access if required.

Data Sharing

How will you share the data?

The pseudo-anonymous data from the analyses on each individual sample will be shared with the clinician who ordered the analyses. Only the clinician will be able to de-anonymise the data. Pseudo-anonymised group data will be made publicly available via the university recommended repository (Mendeley) at the end of the project. The GDPR will be adhered to with respect to data sharing. We will ensure it is adhered to by ensuring all researchers involved with the service have been trained in data protection, as is University of Manchester policy.
Research on multiple pseudo-anonymous samples will be reported through peer reviewed academic journals. The findings will be made public through public engagement events. There is no public database for registering this form of research.
To comply with the Open Access Policy (2016), all published research will be made publicly accessible via green or gold access and a Data Access Statement will be made available with the publication. Journal restrictions will be adhered to.

Are any restrictions on data sharing required?

Only anonymised data will be shared to the public.