

DATA INFORMATION LEAFLET

STRAP ACL: A study testing if adding a strong tape during knee ligament surgery helps people more than surgery without the tape.

You can read this information online at the study website
www.warwick.ac.uk/strapacl/public or by scanning the QR
code:



How will we use information about you?

We will need to use information from you and your medical records for this research project.

This information will include your:

- Initials
- Name
- NHS number (or equivalent in Scotland known as Community Health Index/Northern Ireland known as Health & Care Number)
- Date of birth
- Contact details (address, telephone number, and email address)
- Sex
- Ethnicity
- Imaging (e.g. x-rays, MRI scans and surgical images)

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.

The University of Warwick is the Sponsor of this research. The University of Warwick is responsible for looking after your information. Warwick Clinical Trials Unit is part of The University of Warwick.

We may use information from your GP for this research project.

Who will we share your data with?

We will share your information related to this research project with the following types of organisations:

- The Chief Investigator and research partners at other universities or NHS organisations including the University of Warwick, University Hospitals Coventry and Warwickshire NHS Trust, the University of Oxford and the University of Cambridge
- A third-party company to send you study updates and follow-up questionnaires
- Your GP (General Practitioner), to share relevant information about your participation in the study for your care or safety
- The staff at the NHS site where you take part
- The study sponsor, who is responsible for overseeing the research
- Regulatory bodies that ensure research is safe and properly conducted
- Independent monitors or auditors who check that the study meets required standards
- Data management or IT service providers who securely store or process study data on our behalf for sending images (x-rays, MRI scans and surgical images), for example SharePoint.
- Trusted academic or research partners who help analyse the study data.

How will we keep your information safe and secure?

We will keep all information about you safe and secure by:

- Keeping any paper records in locked filing cabinets in secure areas that only authorised staff can enter
- Storing electronic information on secure, password protected systems used only for this research
- Allowing access to your information only to trained members of the research team who need it to run the study
- Encrypting data when it is stored or sent, so it cannot be read by anyone who should not see it
- Following UK data protection laws and regularly checking that our systems meet required security standards
- Removing your name and other details that identify you wherever possible and replacing them with a study ID number.

International Transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- notify you via text message when questionnaires are ready to complete and when study results are ready to be shared with you.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Twilio is a cloud communications company that provides tools for sending automated text messages, phone calls and other digital communications.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law.

We will make sure your data is safe outside the UK by doing the following:

- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

How will we use information about you after the study ends?

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.

We will keep your study data for up to 20 years. The study data will then be fully anonymised and securely archived or destroyed.

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
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- Our leaflet: www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to infocompliance@warwick.ac.uk
- By visiting:
<https://warwick.ac.uk/services/legalandcomplianceservices/dataprotection/otherprivacynotices/research/>
- By visiting: <https://www.twilio.com/en-us/legal/privacy>

Next of Kin

The University of Warwick will collect your name, email address and phone number for use in this research project. We will only use these if we are unable to get in touch with the study participant to complete their study questionnaires, and ask you to help re-establish contact with them.

Only people who need to know will be able to see your name and contact details. We will store your information on secure, password protected systems.

We will not consider you to be a participant in this research study, and you will not receive marketing communication or routine contact from us.

Your information will be destroyed at the end of this research study.

If you do not wish us to hold or use your details, please contact the study team at strapacl@warwick.ac.uk, or the University's Data Protection Officer following the link below.

You can find out more about how we use your information by visiting
<https://warwick.ac.uk/services/legalandcomplianceservices/dataprotection/otherprivacynotices/research/>