

						-			
--	--	--	--	--	--	---	--	--	--

## WOLVERINE: Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery

An international audit and cohort study

### PATIENT INFORMATION SHEET

Version 3.0, [16<sup>th</sup> October 2023]

We would like to invite you to take part in the **WOLVERINE** research study. Joining the study is completely voluntary. Before you decide, we would like you to understand why the research is being done and what it would involve for you. A member of the local research team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have.

Part 1 of this Participant Information Sheet (PIS) tells you the purpose of the study. Part 2 gives more detailed information about what will happen to you if you take part and about the conduct of the study. Please do take the opportunity to talk to others about the study if you wish, and to ask any questions you might have if anything is unclear.

#### **Part 1**

##### What is the purpose of the WOLVERINE study?

**WOLVERINE** stands for Wound Closure and Surgical Site Infection Prevention Strategies in Abdominal Surgery. The overall aim is to assess the different practices of wound closure techniques and surgical site prevention strategies around the world. The study will also look the effect of wound closure and surgical site infection prevention practices on the rate of abdominal wound failure from 30 days to 1 year after surgery. The data collected will be used to help design a future interventional trial on wound closure and surgical site infection prevention.

##### What is a surgical site infection?

A surgical site infection (SSI) is an infection related to a surgical procedure that occurs near the surgical wound on your abdomen (tummy).

##### What are patient reported outcomes?

Patient reported outcomes (PROMS) are questionnaires that measure the patient's view of their own recovery from surgery. Questionnaires are completed at different time points after treatment so we can see how the treatment has affected you.

##### Who is organising and funding the research?

**WOLVERINE** was developed by the European Society of Coloproctology (ESCP) and has been funded by ESCP. The study is being coordinated by the ESCP team based at the University of Birmingham, UK. A company, Ethiconm are supporting ESCP in developing educational material to help surgeons prevent surgical wound problems.

### What are the possible benefits of taking part in WOLVERINE?

While there is no direct benefit to you in taking part in **WOLVERINE**, you will be helping surgeons across the world to improve patient recovery from abdominal surgery.

### How have patients and the public been involved in this study?

Patients have developed the questionnaires in the study, and this Participant Information Sheet.

## **Part 2**

### Why have I been chosen?

Your surgeon feels the **WOLVERINE** study is important and are inviting all their patients that are undergoing abdominal surgery to take part in the study. **WOLVERINE** will include patients from across the world.

### Who is eligible to take part in WOLVERINE?

Patients aged 18 or over, undergoing abdominal surgery can eligible to take part in **WOLVERINE**.

### What would taking part in WOLVERINE involve?

If you agree to take part in the study you will be asked to complete questionnaires about how you are feeling after your surgery. These questionnaires will be collected at 30 days after surgery, at 60 days, 90 days, 6 months and at 1 year.

### How will you collect the information from me?

If you wish to participate in this study, you will be provided with a unique **WOLVERINE** identification number by your surgeon or care team. You will only ever be identified in the study by the unique **WOLVERINE** identification number.

Once you have been provided with the identification number, you will then be asked to access the **WOLVERINE** patient website. On the website, you will be asked to log in securely and give your consent to answer questions about your health, this will be done via a secure UK based online database system called REDCap, which is hosted by the University of Birmingham. We will need to collect your email address and mobile phone number so that we can send you a link to your questionnaires. This information will be kept secure on the University of Birmingham system and only the study administrators will be able to access this. Your surgeon may help you access the **WOLVERINE** patient website to give your consent, if required.

The questionnaires you will need to complete will then be sent to you via email. You can answer the questionnaires using the web browser on your phone or on a computer.

### How long will the WOLVERINE study last?

**WOLVERINE** will start in 2023 and we plan to recruit patients for 5 months. Your participation will be for 12 months.

### Do I have to take part?

No. Taking part in research is always voluntary. If you decide to take part you will be asked to sign a consent form but you are still free to withdraw at any time and without giving a reason. If you decide

not to take part, you don't have to give any reason why and no-one will think badly of you for not wishing to take part. Your care will not be affected in any way. Your surgeon or local study investigator will be happy to talk you through any questions you may have regarding **WOLVERINE**.

#### How we will use information about you

We will need to use information from you, and from your medical records for this research project. This information will not include any identifiable data. You will be assigned a unique study ID when you agree to take part in **WOLVERINE**. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Researchers outside your hospital 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. Your email address and mobile phone number will be deleted once your involvement in the study has ended.

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. Data will be stored securely for up to 10 years.

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

You can find out more about how we use your information

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- the University's Data Protection Officer at [dataprotection@contacts.bham.ac.uk](mailto:dataprotection@contacts.bham.ac.uk)

#### What will happen with the results of the study?

Once **WOLVERINE** has finished we will publish the results in a medical journal so that other patients can benefit. Results will also be presented at international conferences such as the European Society of Colorproctology annual conference. No individual patients will be identifiable in any publications or presentations.

#### Who has reviewed the study?

This study has been looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Health and Care Research.

#### Complaints

If you have any concerns, please speak to a member of the research team in the first instance, email [wolverine@contacts.bham.ac.uk](mailto:wolverine@contacts.bham.ac.uk) and we will do our best to answer your questions. If your concerns are not addressed and you wish to make a formal complaint then please contact Dr Birgit Whitman, email: [researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk).

#### Chief Investigator on behalf of ESCP:

Associate Professor Gabrielle van Ramshorst, Associate Professor of Surgery, Ghent University Hospital (Belgium)  
Email - [wolverine@contacts.bham.ac.uk](mailto:wolverine@contacts.bham.ac.uk)

Where can I get further information?

If you have any further questions about your treatment or this study, please discuss them with your surgeon or local study investigator:

Name: .....

Tel No: .....

Position: .....

## How to register for the **WOLVERINE** study

If you are happy to contribute to the study by answering our questionnaires, please scan the QR code or enter the following web address into your web search bar to gain access: <https://redcap.link/WOLVERINEconsent>.



And use the following unique study identification number:

					-			
--	--	--	--	--	---	--	--	--

- You will be asked to confirm you give consent to complete the questionnaires.
- You will also be asked to provide an email address to send the questionnaires to.

**Thank you for taking the time to read this Patient Information Sheet**