

SITU Privacy policy

The University College London Surgical & Interventional Trials Unit (SITU) conducts research using clinical trials and other studies. Our work includes measuring aspects of outcomes following treatments and results of diagnostic tests in patients. Our portfolio is diverse, we cover both cancer and non-cancer trials/studies, for a full list of studies/trials please see www.ucl.ac.uk/situ. Data is collected either via paper, clinical research forms, electronic forms and questionnaires or interviews.

Collection and use of personally identifiable and study data

- **If you consent to take part in one of SITU's trials or studies you will be asked to sign a consent form.** We may ask for your consent for us or one of our collaborators to hold your name, contact details, NHS number, date of birth and other study data classed as personal. Contact data (home address, email address, telephone number) will be used for the purposes of sending questionnaires, or other study related documents to you and to enable us to conduct telephone interviews or call you for any study related queries. Name, date of birth and NHS number will be used in some studies/trials for long term data linkage via NHS Digital. Data collected are survival, use of health resource and disease status from NHS Digital, the responses to paper or online questionnaires and forms, free text generated in the course of an interview, or audio recordings or transcripts.
- **When taking part in a study or trial, you will be allocated a study number,** which will be used as a code to identify you on all your study forms, questionnaires and interview data (study data). The reason for collecting your study data will depend upon the study/trial design and will be explained in your patient information leaflet.
- **Your personal details will not be passed to anyone outside the study research team.** The study research team may include persons working on the study at other locations, such as the unit working on quality of life, and the trial statistician.
- **Your study data will be held electronically on a database using your study number and study identifier only.** We may periodically transfer these data to other members of the research team for the preparation of trial progress reports and analyses. It will not be possible to identify you on the data files sent from SITU.
- **At the end of a study,** we will carry out the statistical analysis and publication of the study results but it will not be possible to identify you in these reports and publications.
- **Authorised persons from the UK Regulatory Authority (the Medicines and Healthcare Products Regulatory Authority) or the study Sponsor** (the organisation responsible for the overall conduct of the study) may require access to your study data as part of a clinical trials regulatory inspection. These inspections are conducted to ensure that studies are carried out to the highest possible scientific standards. **All will have a duty of confidentiality to you as a research participant.**

Storage of your data

- **Any personal identifiable data obtained by SITU whilst you are in a study will remain strictly confidential.** The information will be held securely on paper and/or electronically at SITU. Your study data will also be stored securely at SITU on paper and/or electronically and will only be accessible by authorised personnel. Your personal and study data will be held in separate physical and electronic locations and access will be strictly controlled.

Your right to withdraw from a study

- **Your participation in our studies is voluntary** and at any time during a study, you have the right to withdraw consent. We will only use any study data collected up until the time you withdraw.

Study closure and archive

- **Any study data held at SITU following study closure, will be archived for up to twenty years after completion of the study, depending on the trial/study,** according to applicable regulatory requirements (Good Clinical Practice, EU Clinical Trials Regulations). At the end of the archiving period, arrangements for confidential destruction will be made.

General Data Protection Regulation 2018

- **A ‘task in the public interest’ is relied on as a legal basis for processing data** from participants of research. The legal bases for processing are regularly reviewed and balanced against individual rights and freedoms. In addition, consent from participants is obtained to avoid a breach of the common law duty of confidentiality.

Contact

- **If you have any questions about your data,** please contact the researcher named on your patient information leaflet, or contact SITU using **situ.trials@ucl.ac.uk**.
- If you still require assistance you can contact the Data Protection Team **data-protection@ucl.ac.uk** for assistance.