**St James’s Hospital Histopathology Biobank**

**Privacy Notice**

1. **Introduction**

The purpose of this Privacy Notice is to explain to you, our participants how we in the Histopathology Biobank (biobank/’we’/’us’) collect, store, use and share, specimens (blood, tissue and other bodily fluids) and healthcare data about you that you have agreed to share with us.

Participants are data subjects of the biobank for the purposes of GDPR and as such, the biobank fully respects your right to privacy and actively seeks to preserve your rights under EU and Irish laws.

1. **Who are we?**

The Histopathology Biobank is managed by St. James’s Hospital (‘the Hospital’ / ‘SJH’) of

James’s Street, Dublin 8, Ireland D08 NHY1.

St. James’s Hospital is the data controller of the biobank and is responsible for keeping your biomaterial and personal data secure.

The Histopathology Biobank is governed by a biobank steering committee which is made up of clinical, administrative and scientific staff; Clinical Lead: Dr Richard Flavin, Laboratory Manager: Fiona Kearney, Biobank Clinical Scientist, Medical Laboratory Assistant and Medical Laboratory Administrator.

You can contact us by email at biobank@stjames.ie

1. **What is the Histopathology Biobank?**

The Histopathology Biobank or biorepository is a specialized pathology laboratory that allows for future clinical or research studies by collecting, processing, and storing biospecimens. Biospecimens, often obtained from surgeries and relevant healthcare data donated by you, maybe used as part of a clinical work-up or in prospective or retrospective studies.

Your biological specimens and related healthcare data information will only be shared for research projects which we hope will improve the prevention, diagnosis and treatment of breast and colon related diseases.

Research projects may include early detection, diagnosis, new treatments, cancer genomic research, medical devices, how cancer changes over time, cancer prevention and the causes of cancer in families.

Your donated specimens and related healthcare data may be included in many international research studies to speed up developments to improve outcomes for all those with breast and colon disease and cancer.

Any specimens and information that you share with the Histopathology Biobank will be treated with the highest standards of security and confidentiality, in accordance with data protection law.

We will only use, your biological specimens and healthcare data for the purposes explained in this privacy notice.

This Privacy Notice explains the following:

* What personal data do we need?
* How do we collect your personal data?
* What is our legal basis for processing your personal data?
* How do we securely store your personal data?
* Who do we share the personal data and/or samples with?
* Will genetic/genomic research be carried out?
* How long do we store your personal data and samples?
* How can you withdraw from the biobank?
* What are your rights under data protection law?

1. **What personal data do we need?**

## Personal Data

We collect information such as your name, gender, date of birth, medical record number (MRN), and contact details, such as your postal address, email address and phone number.

## Special Category Data

We collect information about your health from your medical records, such as your medical history, histology laboratory results, type of cancer, details of treatment, previous illnesses and procedures, family medical history and health related lifestyle data.

We also need information about any tests you have undergone such as X-ray, ultrasound, CT, MRI, genetic and molecular diagnostic tests.

## Biological Samples

In addition to the specimens you donate, we will ask your permission to access and store historical specimens and information relating to that specimen (for example if you had an operation or biopsy in the past).

1. **How do we collect your personal data?**

We collect your personal data from the following sources: 1) directly from you, 2) from St. James’s Hospital, 3) through linkage with other databases/bioresources as appropriate.

## Directly from you

We will collect your name, date of birth, contact details, medical history and related healthcare data directly from you.

We may provide you with a questionnaire which will ask information such as your weight, height, where you were born, and your past medical history. These questionnaires can be compared with other studies internationally.

* 1. **From St. James’s Hospital**

We will collect healthcare data from your hospital chart, hospital electronic patient records and other hospital databases such as diagnostic scans and laboratory results.

With your permission, we will access your biological specimens provided by you.

## Linkage with other databases/bioresources

Other national databases exist such as the National Cancer Registry, which may hold important and relevant cancer related information about you and with your permission, we will request that this cancer related information is shared with us.

1. **What is our legal basis for processing your personal data?**

Any specimens and/or associated personal data will only be used to advance research, which can improve healthcare outcomes for all. The legal basis under the General Data Protection Regulation (GDPR) for processing your personal data is in the public interest Article 6(1) (e) and for scientific research under Article 9(2) (j).

We will ask for your explicit consent at the time of data collection as an extra safeguard in the legal process.

1. **How do we securely store your personal data and samples?**

Any data we collect from you will be stored confidentially and securely. We are committed to ensuring all access to, use of, information and /or samples is performed in a secure manner.

We are committed to ensuring that any use of your personal data is safeguarded by appropriate technical and organisational security measures in accordance with Article 32 GDPR requirements.

All information in the biobank is stored using a unique code instead of your name to reduce the risk of you being identified if there were any accidental or unlawful disclosure. This is termed anonymization.

It is this unique biobank code that will be used when analysing and sharing information with researchers.

We keep your contact information (your name, address, phone number) separate to the information about your health that the biobank stores. The key to the code to link back to you is stored with this on a secure computer and is restricted to a limited number of approved biobank staff.

All information required by the biobank is entered onto a secure database by authorised personnel. The database is stored on a secure, password protected hospital computer located in the Biobank Office on the St. James’s Hospital campus. Access to this location is restricted (swipe card access only). All hard copy personal data is stored securely in premises which has access restricted to approved personnel.

All staff accessing information are required to sign a confidentiality agreement as part of their employment contractual agreements.

Biological specimens are stored securely. Access is restricted to approved personnel only.

1. **Who do we share personal data and/or samples with?**

The histopathology biobank is an important resource as it allows researchers to access biological specimens and related healthcare data for research projects to improve outcomes for breast and colon cancer patients. By sharing widely, we can speed up developments in the area of breast and colon cancer and disease to improve outcomes for all.

We collaborate with both academic researchers who may work in universities, hospitals, or research institutes around the world and also researchers working in industry, such as pharmaceutical companies, on approved research projects for breast and colon cancer and disease only.

Currently, all research studies are collaborations with the biobank. Results are shared back to us, so that we can use these to improve outcomes for all.

In order to be approved for access to coded samples and data - the researchers must:

* Apply to the Biobank Steering Committee (as per LF-BNKHIST-005/Doc 469) who will decide if the research will advance developments in the area of breast and colon cancer and disease and
* Apply and be approved by the Tallaght University Hospital and St. James’s Hospital Joint Research Ethics Committee and each of the following approvers: o The Office of Research & Innovation (Trinity College Dublin and St James’s) o The Department of Legal & Insurance (St James’s)

o The Data Protection Officers (Trinity College Dublin and St James’s) and

* Researchers must sign legal agreements which restrict the use of the samples and related information to a specific approved research project and must agree that no re-identification of individuals is permitted.

Any healthcare data or biological specimens shared with researchers will not include your name or other direct identifiers. All information and specimens are identified by a unique identifier code, and only limited information is given to researchers (i.e. the information they need for their research project). They must justify why they need this information in their biobank application ethics submission.

# TRANSFERS OUTSIDE THE EEA

We may need to transfer anonymised Personal Data outside the European Economic Area (EEA) if the project is approved for access. We will ensure that any transfer of information or samples outside the EEA is only permitted if a comparable level of protection to the GDPR is guaranteed.

1. **Will genetic/genomic research be carried out?**

Genetic/genomic research (research which examines peoples’ genetic information (genes) to help us understand how disease behaves) on breast and colon disease and cancer may be carried out on specimens donated to the biobank.

Approved researchers may extract DNA from samples to carry out research on breast and colon related diseases.

Only researchers who have been approved following the process outlined above will be able to access samples and related healthcare data for genetic or genomic research.

1. **How long do we store your personal data and samples?**

Research takes many years, and advances in medical science are only possible through research studies which take long periods of time. For this reason, healthcare data is stored indefinitely as a valuable resource supporting breast and colon cancer research.

The data about your health will always be useful to researchers even after your samples have been used up.

Your samples will be stored for as long as they are viable, or until the sample has been used up. After this, the sample is recorded as exhausted.

You are free to withdraw your consent to our use of your samples and data at any stage.

1. **How can you withdraw from the Biobank?**

You can withdraw from taking part in the biobank at any time. If you would like to withdraw, please contact us on (01) 4103336 or at biobank@stjames.ie

From this point on, your specimens and healthcare data will not be used for research. However, it will not be possible to destroy samples and healthcare data already shared for research, before this date.

Any research which is currently underway will continue to completion (as to remove the information from an ongoing study, would impact on the integrity of that research study, and prevent publication).

We will keep a record that you changed your mind and record the destruction of your specimens and healthcare data from the biobank.

Specimens referred to the pathology laboratory in St James hospital for diagnostic testing will not be possible to destroy as these form part of the diagnostic archive

1. **What are your rights as a data subject under data protection law?**

You have the following rights in relation to any use of your personal data (health data, contact information etc.) by the biobank. See [www.stjames.ie](http://www.stjames.ie) for full details.

**Right of access**

You have the right to request a copy of the information that we hold about you.

**Right of rectification**

You have the right to correct data that we hold about you that is inaccurate or incomplete.

# Right of erasure

In certain circumstances, you can ask for the data we hold about you to be erased from our records (unless it would seriously impair research which is already underway).

# Right to restriction of processing

You have the right to restrict the use of your data where certain conditions apply, to have the right to restrict the processing e.g. transferring data to third parties.

**Right to object**

You have the right to object to any use of your information (for example if it is inaccurate).

# Data Protection Training

All biobank staff complete GDPR and information security training delivered by St James’s Hospital. The SJH contract of employment, signed by the employee, provide information about the required procedures relating to data protection and confidentiality.

# Contact Details and More information

If you have any queries relating to the processing of your personal data for the purposes outlined above or you wish to make a request in relation to your rights, you can contact:

* Histopathology Biobank:

Email biobank@stjames.ie

* Data Protection Officer, St James’s Hospital, Dublin 8

Email dataprotection@stjames.ie

If you are not satisfied with the information we have provided to you in relation to the processing of your data or you wish to raise a concern with the Data Protection Commission. The contact details are:

**Data Protection Commission 21 Fitzwilliam Square South, Dublin 2, D02 RD28, Ireland.**

## Tel: (01) 765 0100 or 1800 437737

**Email: info@dataprotection.ie**

**Contact form:**<https://forms.dataprotection.ie/contact>

# Changes to the privacy notice

We regularly review and, where necessary, update this privacy notice.