



BioGrad Research Tissue Bank

Sample Donation Donor Information Sheet



Who is BioGrad?

BioGrad Limited is a commercial healthcare and life science organisation that includes brands such as BioGrad Diagnostics, BioGrad Prenatal, and BioGrad Biobank. Our mission is to provide innovative and affordable medical and diagnostic solutions while supporting the discovery of scientific knowledge through research. At BioGrad, we are particularly passionate about women's health, alternative therapies, and accessible healthcare.

BioGrad's Research Tissue Bank (RTB) is a privately funded human sample repository located in Liverpool, UK. We facilitate scientific research by offering chargeable access to a variety of high-quality samples. Our goal is to connect donors, clinics, and the scientific community to drive progress in various scientific and medical fields.

The purpose of this leaflet is to invite you to consider donating your tissue to BioGrad's RTB. Take your time to review this information, discuss it with others if you wish, and don't hesitate to reach out to our medical professionals with any questions. There is no rush to make a decision. If you need this information in a different format, please contact our team at 0345 565 1725.

Who will use my samples and for what purpose?

Human samples and derived products are essential for scientific and medical research. At BioGrad, we store biological samples and associated data collected with informed consent for various purposes. By donating your sample(s) to BioGrad's RTB, you support biomedical research, commercial and educational efforts. Your sample(s) may be used in research projects, training, quality control, or the development of test kits and devices. However, they will not be used for human treatment or prohibited purposes, such as reproductive cloning. BioGrad's RTB has NHS ethical approval (REC number 24/WA/0102), which allows us to share your sample(s) and associated data with UK research projects that align with our ethically approved research programs on cellular therapies, women's health and associated health conditions.

Cellular therapies are innovative treatments that use our own body's resources to manage or prevent diseases. By extending our ethical approval to UK researchers, we aim to strengthen research in this biomedical area and support studies on serious conditions like arthritis, neurodegenerative diseases, spinal injuries, and infectious diseases.

Women's health covers issues unique to women, as well as how gender differences affect general health conditions. Despite its importance, research in women's health often lacks support. By providing necessary biological samples and associated data to researchers working in this field we aim to advance scientific knowledge and improve health outcomes for women.

Your comfort and autonomy are our top priorities, and we will never use your sample in a way that makes you uncomfortable. All use of human samples, whether in the UK or abroad, will adhere to your consent, local regulations, and ethical standards. Scientists must obtain the necessary licenses and approvals to ensure that samples are handled properly and used for valuable purposes. If you have any questions or concerns about how your donated sample(s) will be used, please reach out to our team at 0345 565 1725.

Will my samples be used for commercial purposes such as consumer product testing?

Using human samples to test commercial products, such as medications and cosmetics, is a key step in reducing animal testing. By consenting to donate your sample(s), you permit the use of your sample and associated data for consumer product testing.

Will my samples be used in genetic testing?

Yes, our understanding of genes and their impact on health is growing. This knowledge helps identify disease causes and guide treatment options, like genetically engineering cells to target specific cancers. Additionally, genetic testing of samples is often used as a quality control method in labs to identify samples using a genetic fingerprint.

Will my samples be used in animal research?

While we work to reduce animal use in research, we acknowledge that many medical advances rely on carefully regulated studies involving animals. You will have the option to choose whether your samples should be used in this type of research.

Will I always know what projects my sample is used for?

No, we may not be able to tell you which projects used your sample(s) or what was achieved. Many different organisations request access for various biomedical research, commercial, and educational purposes. However, because we value your interest and contribution, we will try to keep donors informed about our scientific activities through various media channels.

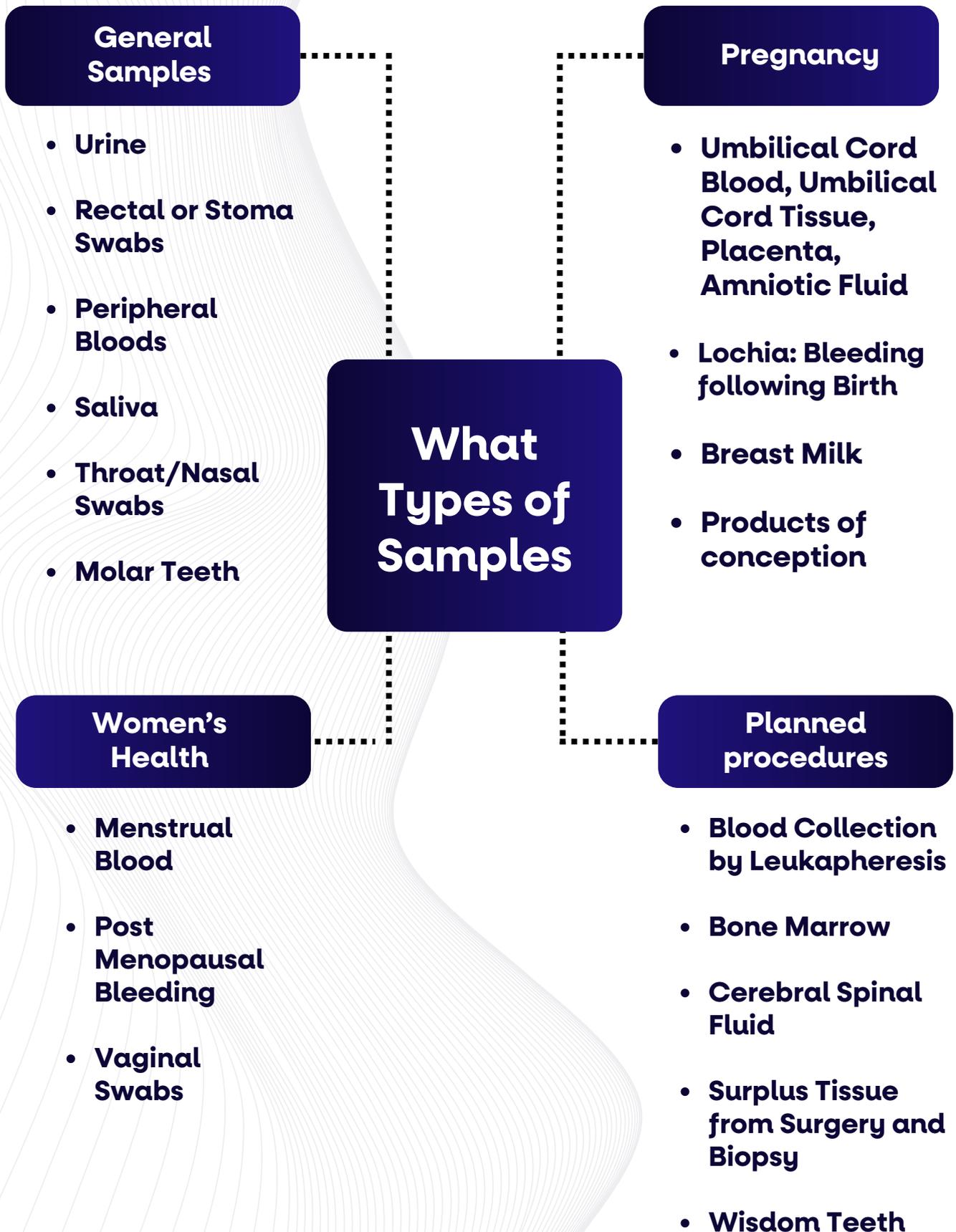
Will my donation remain confidential?

Yes, your donation will be kept confidential. Each sample will have a unique identification number to protect your identity during the biobanking process, including transport, processing, storage, and distribution. BioGrad will not share any identifying information with other organisations. However, we may share sample-related data, like demographics and health information, with those accessing your sample(s). In some cases, consent information may be shared with BioGrad's internal ethics committee.

Who can donate?

Eligibility criteria will differ for each sample type and will be evaluated by our clinical staff. In some cases, we may need to consult with your healthcare team or review medical records, but this will be done with your consent. You will be informed of your eligibility before the sample collection. For details on eligibility criteria for each sample type, please contact our clinical team on 0345 565 1725.

What types of samples can I donate and how are samples collected?



Collecting your sample(s) may require an additional finger-prick blood sample to check for infectious diseases. Our clinical team will inform you if this is needed.

The way samples are collected depends on the type you are donating. Some samples can be collected at home, while others will be taken by a healthcare professional in a clinical setting. Our clinical team will discuss the arrangements with you beforehand. Samples will only be collected with your explicit consent, and you will receive information about the collection process and any associated risks before you give consent. For more details, please reach out to our clinical team at 0345 565 1725 or visit our website at <https://www.biogradbiobanking.co.uk/>

For how long and where will my samples be stored?

Samples can be used by scientists right after they are collected, but they can also be stored for many years at ultra-low temperatures before use. We may test your sample(s), separate them into components, or isolate specific cells before storage.

If your samples are retained, they will be securely stored at BioGrad which is licenced by the Human Tissue Authority (licence number 22707) or another licensed biobanking institution. If we use distributors outside the UK, your sample(s) may be temporarily stored at their facilities before being sent to the requesting research organisation. Any associated data and clinical information will be stored securely in electronic systems.

Will I be given feedback of any clinically significant findings?

Testing for Infectious Diseases and Health Markers



Your sample may be tested for infectious diseases (e.g., Hepatitis or HIV) or other clinically recognised signs of ill health. If a result indicates an immediate and significant risk to your health or that of others, we will inform you provided the test was conducted within two weeks of sample collection in an accredited environment. These tests are for screening purposes only; your healthcare provider may need to conduct follow-up testing.

Testing for Health Insights



We may also test your sample for health-related biomarkers, such as genetic variations or indicators of disease risk. These results may suggest a predisposition to certain conditions that may or may not develop or be relevant to you. Because of this uncertainty, we will not share such results with you.

Will I directly benefit from my donation?

Your donation is important for advancing scientific and medical knowledge and the health of others. While it won't directly help you medically, it may lead to discoveries that benefit others. Future patients could gain from the research insights or affordable diagnostic tests made possible by your donation. Organisations and researchers that receive your sample(s) may profit from royalties, licenses, or product sales. However, you will not receive any financial benefits from the discoveries or products created from your donated sample(s).

Will I be paid for my donation?

Yes. Your donation is crucial to our goals, and we want to show our appreciation by acknowledging your involvement. We believe in offering fair remuneration - or, if you prefer, the opportunity to direct your remuneration as a charitable donation - as a thank you for your support in advancing biomedical research and development.

In particular, you may choose to support our Women's Health Research Programme, with contributions going into a dedicated fund used to conduct vital research in this area. If you're interested in this option, please speak to a member of our team. Participation in this initiative is entirely voluntary and will not affect your involvement in the study.

Will I be contacted again after my initial donation?

At BioGrad, we want to reconnect with you for future sample donations or to gather more information about your recent donation. We regularly assess the need to reach out to donors, always considering the potential benefits and your autonomy.

Can I donate again?

You can donate samples as often as you wish, provided there are no clinical concerns or limitations. Once you have consented to donate a specific type of sample, your consent will be considered enduring—meaning it remains valid for future donations of that same sample type. If you choose to donate again, you won't need to complete a new consent form each time. Instead, our team will ask you to review your previously completed consent and confirm you are happy to proceed.

If you wish to make changes to your consent, or if we have updated our consent form, we will provide you with a new form to review and complete before your next donation.

Can I change my mind?

Yes, you can change your mind at any time. Whether you wish for us to remove your details from our database or you have changed your mind about a previous donation and want to withdraw your consent, you can do so by contacting rtb.consent@biograd.co.uk. When you withdraw consent, BioGrad will destroy your sample(s) and associated data. If your samples were shared with another organisation within the last 2 weeks, we will do our best to recall them and request their ethical destruction, as long as they haven't been used yet. Please note that samples or data already used cannot be recalled.

I wish to donate my sample to BioGrad's RTB What happens next?



Registration: Register your interest in donating your samples to BioGrad by completing a short registration form



Receive Information: BioGrad will send you an email with important documents, including a consent form and this donor information sheet. You may also receive a health and lifestyle questionnaire depending on your donation.



Completion of Forms: You must fill out the consent form prior to donating your sample. There's no rush to complete the forms. Assistance is available from our friendly team if you have any remaining questions.



Consent Review: The clinical team reviews the forms and may contact your doctor to check eligibility. You may be excluded based on the review, but could still donate later or offer other samples.



Sample Collection: Once eligibility is confirmed, the sample collection will proceed.



Receive Payment: Remuneration will be provided after we successfully receive the sample(s) at BioGrad and confirm that they are usable for further processing.