



Human Biosamples and Health Data in Pharmaceutical Research

A responsible approach

Contents

P03	What is Bioethics?
P05	Our Approach to Working with Human Biosamples and Health Data
P06	An Introduction to Human Biosamples and Health Data
P10	Global Standards
P12	Our Principles on the Use of Human Biosamples and Data
P14	Protecting People's Rights
P18	Acquiring Human Biosamples and Data responsibly
P19	Using Human Biosamples Responsibly
P20	Managing Ethical Issues
P22	Working with you

Novo Nordisk's Bioethics Policy

In Novo Nordisk we will discover, develop and produce pharmaceutical products with respect for people, animals and the environment. This means that we will:

- continuously improve our performance
- promote bioethical awareness in Novo Nordisk
- operate by high ethical global standards in research involving people, animals, human biosamples and gene technology
- require adherence to high ethical standards by our external partners, contract research organisations and suppliers, and monitor their performance
- engage in stakeholder dialogue and partnerships helping us to deal with ethical dilemmas.



What is Bioethics?

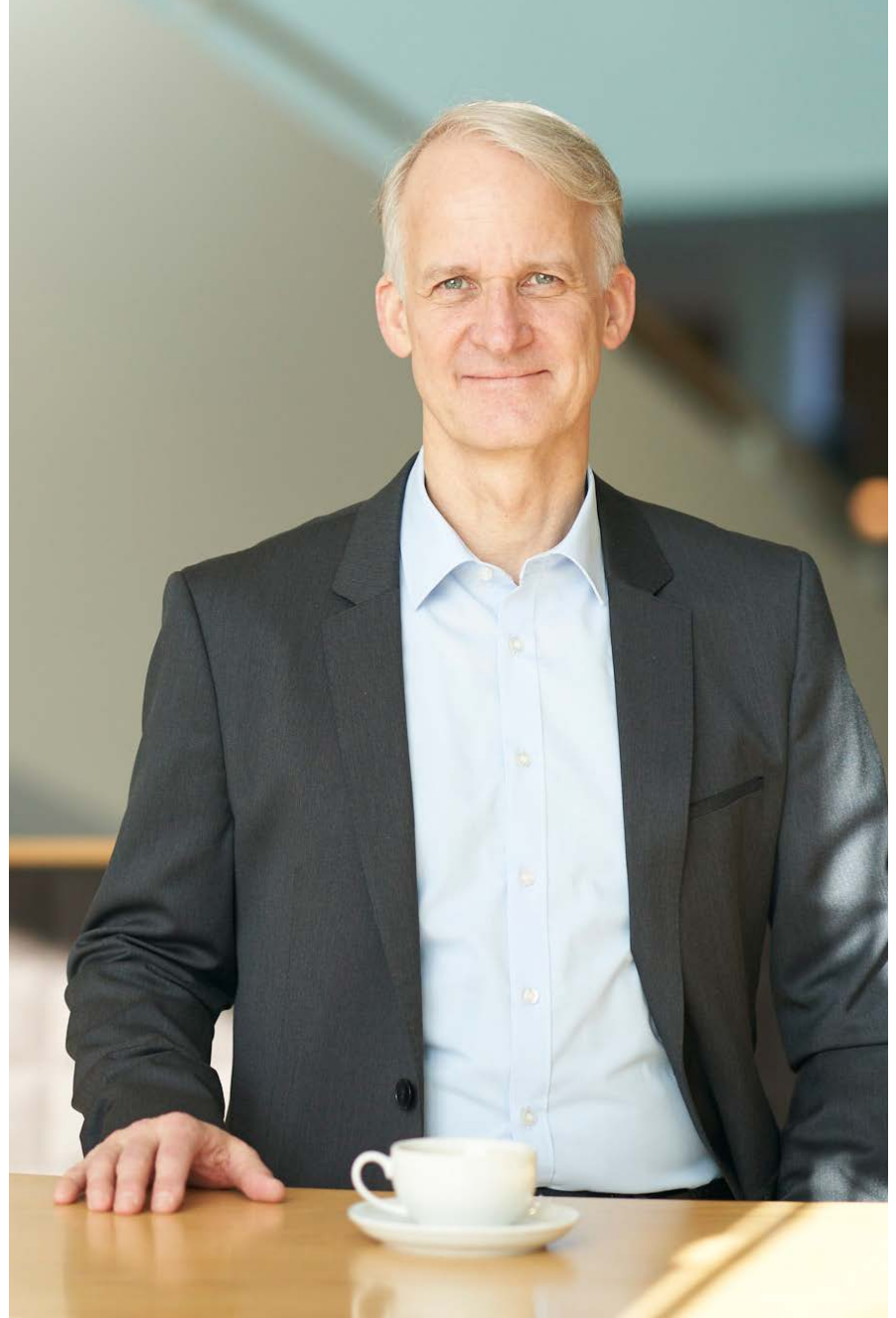
At Novo Nordisk, bioethics is the term we use for all ethical issues related to the use of life science technologies in the discovery, development and production of pharmaceutical products. It is very important to Novo Nordisk that, during all our work to make new medicines available for patients, we carefully consider the ethical implications of our research and development activities and listen to societal concerns. We focus on the ethical issues of clinical trials and research using human bio-samples and health data, animals, gene technology and stem cells. This brochure is focused on our use of human biosamples and health data in Research.

Our Bioethics Policy sets out our general operational guidelines. This is consistent with our objective: to strive to be economically viable, socially responsible, and environmentally sound by considering each of these elements when making business decisions.

MARCUS SCHINDLER

*Chief Science Officer and Executive Vice President,
Research & Early Development, Novo Nordisk*

“Novo Nordisk highly appreciates that people donate biosamples and health data for our research activities and is grateful for their important and worthwhile personal contributions to the development of new medicines and treatments that improve people’s lives.”



Our Approach to Working with Human Biosamples and Health Data

Biosamples (e.g., tissues, blood and stem cells) from patients and healthy volunteers are important for research into finding new ways of preventing, detecting or treating diseases. Novo Nordisk uses human biosamples and health data during its research to discover new treatments for the diseases we focus on. We also use human biosamples to do vital tests during our clinical trials of new medicines, to study their effect, how patients respond and to check that they are safe to use.

People wishing to support research by donating biosamples and health data, need to trust that their biosamples and data will be collected, stored, and used ethically, and that their donations will be used for good purposes. Novo Nordisk hopes that people who donate

the biosamples and data used in our research, trust that they are making important and worthwhile personal contributions to the fights against diseases such as diabetes, obesity, cardiovascular disease, Alzheimer's disease, and rare diseases.

At Novo Nordisk, we regularly review and develop our policies related to human biosamples and data, as well as the governance and procedures we have in place to control the use of human biosamples and data in our research and development activities.

All Novo Nordisk employees involved in research using human biosamples and data are trained on ethical issues and internal procedures ensure that our employees comply with

our global ethical standards. Similarly, we have established global standards for our external collaborators and collaborate with hospitals, universities, and other suppliers where we believe that our standards can be met, and the key ethical issues are being addressed.

In this brochure, you can read more about the ethics of human biosamples and data in research and our efforts to always try to improve our performance.

Marcus Schindler

*Chief Science Officer and
Executive Vice President of Research
& Early Development, Novo Nordisk*

An Introduction to Human Biosamples and Health Data

Human biosamples are samples that come from the human body. They include tissues, fluids, cells, or molecules that have been produced by and occur naturally inside the body.

Many people agree (give their consent) that their biosamples can be used in research, in the hope that the research might find something new to help other patients in the future. The biosamples are almost always connected to some information about the donor of the biosample (e.g., gender and age), and sometimes information about their health, disease, treatments, and laboratory results. These types of information are often called personal health data, also just referred to as data.

Human biosamples and data have been very important for breakthroughs against diseases in the past and will continue to be vital to the search for new medicines in the future. Modern

science is at a very exciting moment where scientists now study diseases at the most detailed levels, by identifying genes and their function and understanding the role that special molecules play in the origin and progression of disease. These ways of studying diseases are thought to be key for finding new ways to prevent, diagnose, or treat diseases. Human biosamples and data provide a bridge between laboratory research and what doctors know about actual patients and diseases. Human biosamples allow researchers to study diseased or healthy samples in the laboratory and use their findings to develop new treatments for human health and disease.

Novo Nordisk relies on and is grateful to the many people who are willing to donate biosamples and data for use in research. Novo Nordisk uses human biosamples and data during our research to find new treatments for diseases, within our focus areas.

We also use human biosamples to do vital tests during our clinical trials of new medicines, to study their effect, how patients respond and to check that they are safe to use.

We use biosamples and data to discover ways of choosing which patients would benefit most from our medicines and which patients our medicines would not be suitable for.

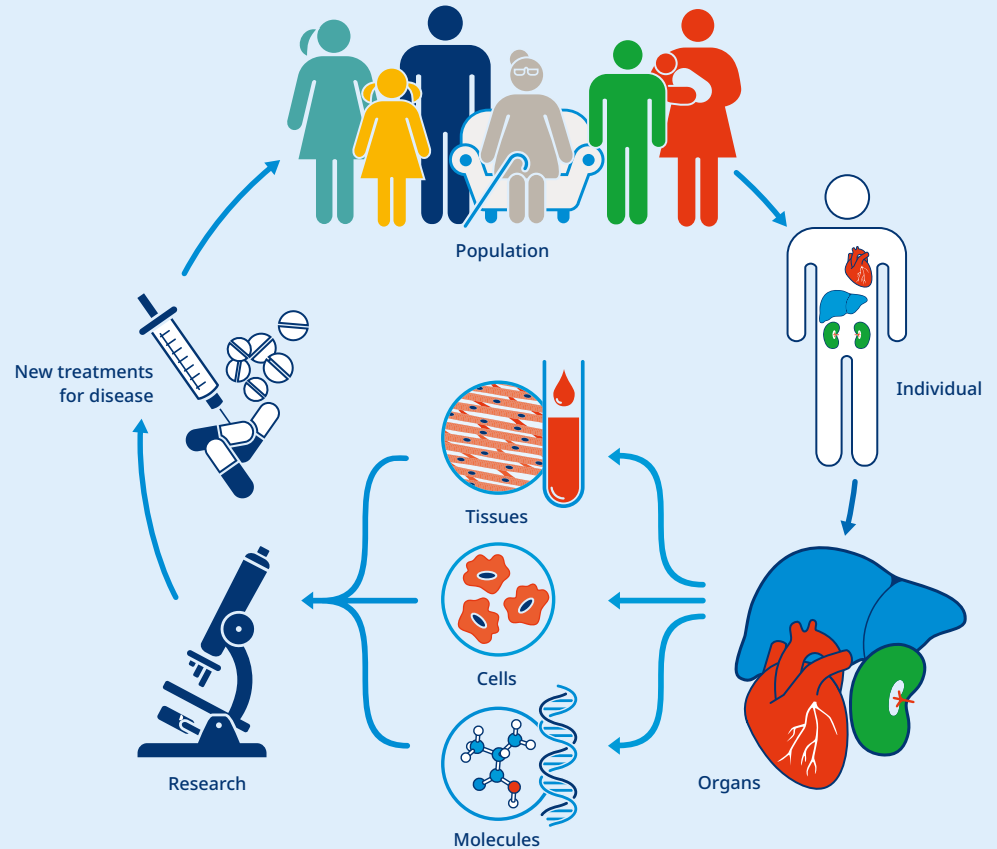
Human biosamples and data can become available for use in research (donated) in several different ways, for example:

1. When patients undergo procedures during which biosamples are removed from the body for tests or as part of treatment (e.g., blood sampling, biopsy, or surgery) small leftover amounts of the biosamples are often available for research.

Human Biosamples

Individuals contributing to research to discover new treatments

2. Patients or healthy volunteers can be asked to give extra biosamples at a doctor's appointment or at a special appointment to donate biosamples.
3. Blood donors can be asked if some of their blood, that they are donating to save the lives of others, might be used for research if it cannot all be given to a sick person.
4. Biosamples can come from the body of a person after death.
5. Patients and healthy volunteers can donate data to biobanks and other institutions about their health, lifestyle, demographics, and other relevant personal information, accessible to approved researchers undertaking vital research into the most common and life-threatening diseases.



Novo Nordisk obtains human biosamples and data from people taking part in research projects and clinical trials through universities, hospitals and other research organisations that work with us, or from organisations set up as professional blood banks, tissue banks or biobanks.

The human biosamples we use are obtained from donors in several countries and the research we do using human biosamples is done at Novo Nordisk's own facilities and in collaboration with other businesses or universities.

Biosample in Research

Novo Nordisk's research aims to find new treatments that will be effective and safe for many people. To do this, we need to study biosamples from many individuals from the population. Each biosample is unique and represents a specific human being. We use biosamples at a number of different 'levels', including tissues, cells and molecules from each of the parts of the body that are affected by the diseases we focus on.





KARIN CONDE-KNAPE

Senior Vice President

Global Drug Discovery, Novo Nordisk

"We continuously research to discover new and better drugs to improve the treatment and lives of people living with serious chronic diseases. We use human biosamples and health data in our search for new medicines, and it is important for us to always use high quality human biosamples and data that have been donated ethically and meet international standards."

Global Standards

Novo Nordisk takes a responsible approach when addressing the ethical issues related to the acquisition, storage, and use of human biosamples and data. Acting responsibly when using biosamples and data in our research starts by recognising that using human biosamples is, in fact, studying real people, each of whom has rights that should be respected.

As ethical issues have no borders, Novo Nordisk has established global standards and requirements for our employees, our business partners and suppliers involved in the use of human biosamples and data. These standards and requirements cover topics such as consent, donor recruitment, obtaining approvals for research and acquiring of biosamples and data in socially responsible ways.

Responsible use of human biosamples and data in research must meet legal requirements and comply with ethical standards at all times. The donation of human biosamples, their storage

and the way they are used are controlled by laws in many countries. Furthermore, important international conventions, declarations, standards, and guidelines need to be observed.

Novo Nordisk supports and works in accordance with relevant international conventions, declarations, standards, and guidelines. Among these are the World Medical Association's Declarations of Helsinki and of Taipei, the Convention on Human Rights and Biomedicine of the Council of Europe (the Bioethics Convention), the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, the Council of Europe Recommendation on research on biological materials of human origin, the UN Guiding Principles on Business and Human Rights and the General Data Protection Regulation (GDPR). Although there are country-to-country differences in regulation, these international conventions, declarations, standards, and guidelines have common themes.

Global Standards

Novo Nordisk takes the quality of the human biosamples it uses in research very seriously. Failure to preserve the quality and integrity of donated human biosamples will not only compromise the research done using biosamples, but it also fails to respect the wishes of donors to support high quality research capable of producing advances in science and medicine for the good of future patients and the population.





Research laboratory in
Beijing, china

Novo Nordisk has used these to set our own principles and global standards for responsible use of human biosamples and data. However, where a local law sets an even higher standard, our employees must also comply with that law.

Our employees are trained in our global requirements, and must comply with our company policies, standard procedures, instructions, and internal guidelines wherever they work. This

is the basis of our responsible use of human biosamples and data. Our principles and standards do not just apply to our own staff. When we work with another organisation that provides access to human biosamples and/or data or that works with us on some of our research, we also expect them to meet our high global standards, even if the laws in their own country do not require such high standards. This is the basis of our responsible acquisition and use of human biosamples and data.

Our Principles on the Use of Human Biosamples and Data

To ensure global standards across Novo Nordisk, we have a set of principles that must be adhered to by Novo Nordisk staff and our business partners, such as collaborators, suppliers, or contract laboratories working on our behalf. The following summarises these principles.

Novo Nordisk takes a responsible approach by addressing the bio-ethics issues relating to the acquisition, storage, and use of human biosamples and data. Biosamples and data used by Novo Nordisk are obtained from individual countries and these are governed by national laws and international conventions.

Although variations exist in local laws, cultures, customs and practices, internationally common principles provide the foundation for Novo Nordisk's position. All Novo Nordisk's research work using human biosamples and data must align with this position.

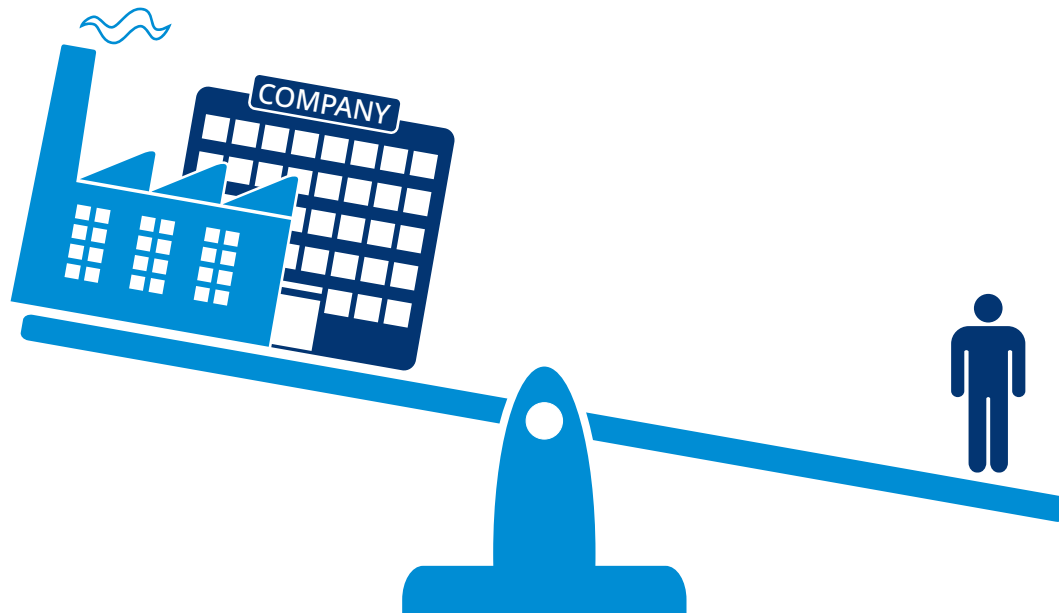
- Novo Nordisk recognises its responsibility to respect the legal and ethical rights of the people who donate human biosamples and data.
- Novo Nordisk's research using human biosamples and data complies with all relevant national and international laws and regulations and takes note of external guidelines on bio-ethics and best practice, insofar as they apply. Novo Nordisk's internal governance processes assure the legality and ethics of its uses of biosamples and data.
- Biosamples and data must be donated with appropriate consent, or with legally and societally acceptable alternatives to individual donor consent where necessary. Consent to donate human biosamples and data should not be influenced by coercion, financial inducements or give rise to financial gain for the donor or next of kin. All uses of biosamples and data must always be within the scope of consent.
- The right of donors to withdraw consent for future uses of their biosamples and data must be respected, where practicable, without question and without detriment to their clinical care.
- Novo Nordisk has strict standards for financial transactions relating to the acquisition of human biosamples and data for research uses. These are aligned with Article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which states that the human body and its parts must not directly give rise to financial gain.
- Public trust and confidence are protected by ensuring that research activities using human biosamples and data are approved by an ethics committee (EC) / Institutional Review Board (IRB) or equivalent, where applicable.

- Novo Nordisk protects the privacy of people who donate human biosamples and data by safeguarding the use of biosamples and sensitive personal data with appropriate security measures.

Novo Nordisk continuously reviews its bioethics standards and conduct relating to the acquisition and use of human biosamples and data and interacts with regulatory bodies and other key stakeholders to maintain and further develop the appropriate ethics standards at an international level.

Donor Rights Weigh Heaviest

Novo Nordisk recognises its responsibility to respect the legal and ethical rights of the people who donate human biosamples and data.



Protecting People's Rights

Specific ethical issues

Consent

Novo Nordisk is committed to respecting the dignity and fundamental rights of people who take part in research. They have the right to decide whether to take part in research or not and must be provided with enough understandable information to help them decide. This is the process of 'informed consent' (often shortened to 'consent'). This applies to all research involving people, including the use of biosamples and data in research. It is important that donors are given the chance to agree to the use of their biosamples and data before they are used. People must be free to decide for themselves, without any pressure, promises or fear that could influence their decision. Special arrangements must be in place when a person is unable to consent for themselves – someone else who is legally authorised to make that choice on their behalf must be involved.

Novo Nordisk has global standards and a procedure for consent to the donation and use of biosamples and data in research that our employees and our business partners must comply with. This

procedure describes the types of information that must be given to the person who is being asked to donate biosamples and data and what they should be asked to agree to. We do not use any biosamples or data if the consent does not meet our global standards.

Sometimes it is possible to be very detailed and specific when we inform donors about the research, we would like to perform using their biosamples and data. This gives the donor a very clear picture of what they are agreeing to. This is known as 'specific consent' and Novo Nordisk uses this type of consent where appropriate.

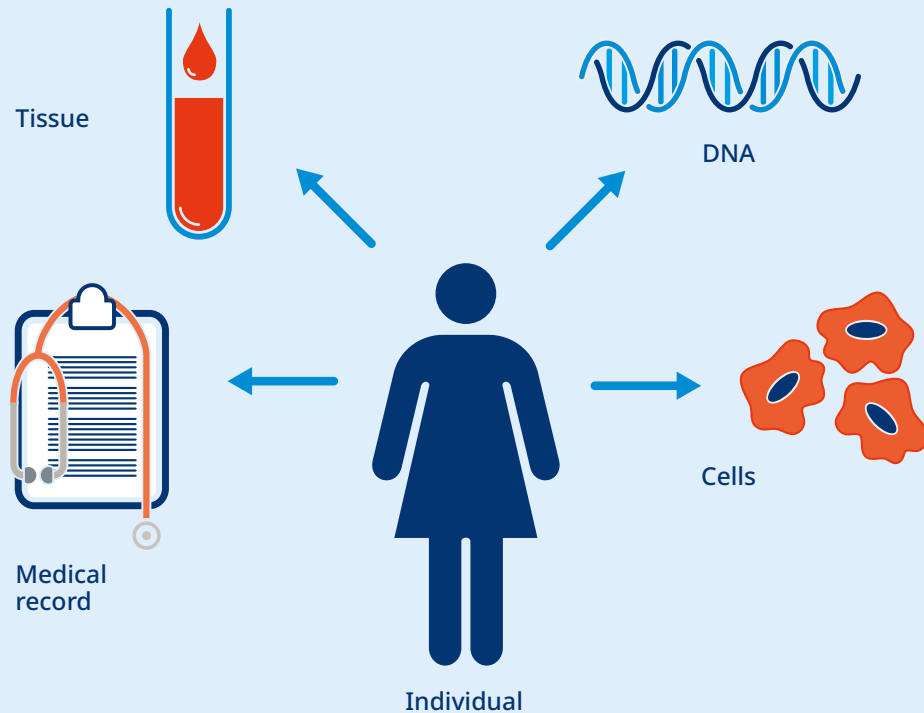
However, it is not always possible to give the exact details of how biosamples and data will be used at the time donors are asked for their consent. In these cases, the donors are asked to give consent to their biosamples, and data being used in a broad range of ways for research that cannot be described in detail. This 'broad consent' is becoming increasingly recognised as a valid way of giving consent for the use of biosamples and

data in future research and Novo Nordisk accepts this consent as long as it is allowed by law in the country where the donation takes place.

In other circumstances, unique biosamples have been collected in the past without the consent of individual donors. One example is when patients have received medical treatment in the past and small amounts of biosamples that are left over after diagnostic tests have been stored as part of their hospital records, but the patients were not asked for consent to their biosamples being used in research. After some time, it might be impossible to recontact these patients to ask for their consent. To collect the same types of biosamples from new patients with consent could take many years or may even be impossible. In these circumstances, it can be allowable to use such biosamples in research without individual donors' consent, but only if allowed by law and permission from an authority, such as a state or government body, can be obtained. Novo Nordisk accepts this type of permission only where the consent of donors is not possible.

Privacy and Security

Protecting sensitive personal information



Human biosamples contain information about the donors. This cannot be seen and understood in normal circumstances, but the use of technology allows this information to be read.

Privacy and Security

Human biosamples contain information about the donors' biology which, in normal circumstances, ordinary people cannot see or understand. However, by using the right technologies in the laboratory, scientists can learn a lot about the donors' health and diseases. In fact, when studying genes, it is sometimes possible to discover hereditary information which could provide knowledge about other members of donors' families. Often, when biosamples are removed from the body, donors agree that personal information or information from their medical records can be shared with researchers to help the research be more powerful. Therefore, biosamples can be thought of as types of sensitive personal information that can only be read and understood by researchers using the right equipment.

Because of the sensitive nature of the personal information, Novo Nordisk has global standards to control how biosamples and other sensitive personal information are handled,

stored, and used. These standards apply to all our employees who have access to biosamples and related information about donors. Novo Nordisk is never provided with donors' names or other direct personal identifiers. However, Novo Nordisk keeps the personal information that has been shared with us, and the information that has been revealed from our research using the biosamples, private, secure, and safe. We meet the requirements of all relevant laws that protect personal information and privacy. You can read more about Novo Nordisk's way of handling personal data on [Novo Nordisk.com](https://www.novonordisk.com), under our Data Privacy Policy.

In order to accelerate drug discovery and development, Novo Nordisk may use big data and Artificial Intelligence (AI) systems. Such systems are designed to respect the rights and dignity of all people and will consider both the societal benefit and any impact to individuals. You can read more about our AI principles on [Novo Nordisk.com](https://www.novonordisk.com) under Data and AI ethics.



Donation is a Gift

Taking part in research is something a person does because they want to help the search for new knowledge and the fight against diseases. Many agree that people should not be encouraged or tempted to take part in research by paying them or by giving them something valuable, as this might make people vulnerable and willing to take risks with their health and their bodies.

The same is true for the donation of human biosamples – donors should give their biosamples as gifts to research, to help science discover new information or develop new medicines that

Donation is a Gift

People should not be paid to donate biosamples or in other ways tempted to sell parts of their bodies. A donation is a gift to help research.

will help others in the future. People should not be paid to donate biosamples or in other ways be tempted to sell parts of their bodies for use in research and in many countries, this is prohibited by law. Novo Nordisk does not accept any biosamples if the donors have been paid, even if it is legal in the country where the donation took place.

It can be acceptable to cover any costs that donors have had to allow them to take part in research, such as travel costs or other reasonable out-of-pocket expenses. Novo Nordisk will accept biosamples where there is no risk that these payments unduly influenced people to donate biosamples.

Novo Nordisk fully supports international conventions and guidelines that state that it is not acceptable for any person or organisation to buy or sell a part of a human body (biosamples), whether from a living or dead person. However, when an organisation is involved in providing the service to process and supply human bio-

samples for use in research, the organisation will have costs that come from running the service, such as staff salaries, containers, packaging and specialist equipment. Novo Nordisk accepts and pays its share of these costs to organisations that supply us with human biosamples, for example a hospital or a company. Many organisations also provide extra specialist services, such as purification of certain molecules from biosamples. This requires special skills and knowledge, without which the biosamples they supply would be less useful for research. It is also acceptable for Novo Nordisk to pay for these special skills and services, as long as it is clear that the payments are for the services.

Therefore, Novo Nordisk never pays organisations that supply us with biosamples for the biosamples themselves, but we pay for fair costs and the specialist services related to supplying high quality biosamples for research. The price only relates to the costs and the value of the specialist services and should not, in any way, turn the biosamples into goods that have a 'market value'.

Acquiring Human Biosamples and Data Responsibly

At Novo Nordisk, we believe that to use human biosamples and data responsibly, our duties start with the selection of the organisations that supply us with human biosamples and/or data, or that we partner with to do research. These organisations must meet our standards for us to be confident that we use human biosamples and data responsibly.

Organisations supplying us with biosamples and data or doing research for us using biosamples and/or data, will undergo a human biosample supplier evaluation. They will only be accepted as suppliers of human biosamples and data if they meet all our standards. If they do not meet our standards, we enter into a dialogue and inform the suppliers about what they need to change. In this way, we do not only select suppliers that meet our standards, but we also help organisations working with human biosamples and data to improve how they work to meet high international standards.

Novo Nordisk always checks new suppliers before we agree to do business with them and we also recheck those organisations that we are already working with every few years, to make sure that they still meet our standards. Novo Nordisk gets human biosamples and data from many organisations in many countries, so checking and approving suppliers requires a lot of effort, but we believe that this makes a big impact on respecting people's rights and dealing with the most significant ethical issues. By acquiring the human biosamples and data we use responsibly, we also believe it improves the quality of the research we do to help us find new effective and safe medicines.



Using Human Biosamples Responsibly

Novo Nordisk ensures that the way we use human biosamples is responsible. Research that uses human biosamples, whether carried out at Novo Nordisk by our own employees or by external business partners and collaborators, is reviewed and approved internally before it is initiated.

The review makes sure that:

- The research complies with laws and regulations.
- The research complies with our global principles on the use of human biosamples.
- The biosamples come from an approved supplier.
- Consent, privacy and security and any payments to donors or suppliers are ethical and in accordance with our standards.
- The research will use the biosamples in the best way to produce high quality results.

This internal review is not required by law, but we believe it ensures that the company uses human biosamples responsibly as well as provides higher quality research results. When required by law, our research studies are also sent for review and approval to external ethics committees (sometimes called institutional review boards, ethics boards or similar), who make extra checks and give us legal permission to do our research.

TINA BOSSOW

*Global Key Expert,
Human Biosample Governance*

"It is very important for us to evaluate all human biosample suppliers against our global standards. If we don't apply our standards to the organisations that supply us with biosamples and data, it could wrongly signal that Novo Nordisk doesn't care about the rights of donors."



Managing Ethical Issues

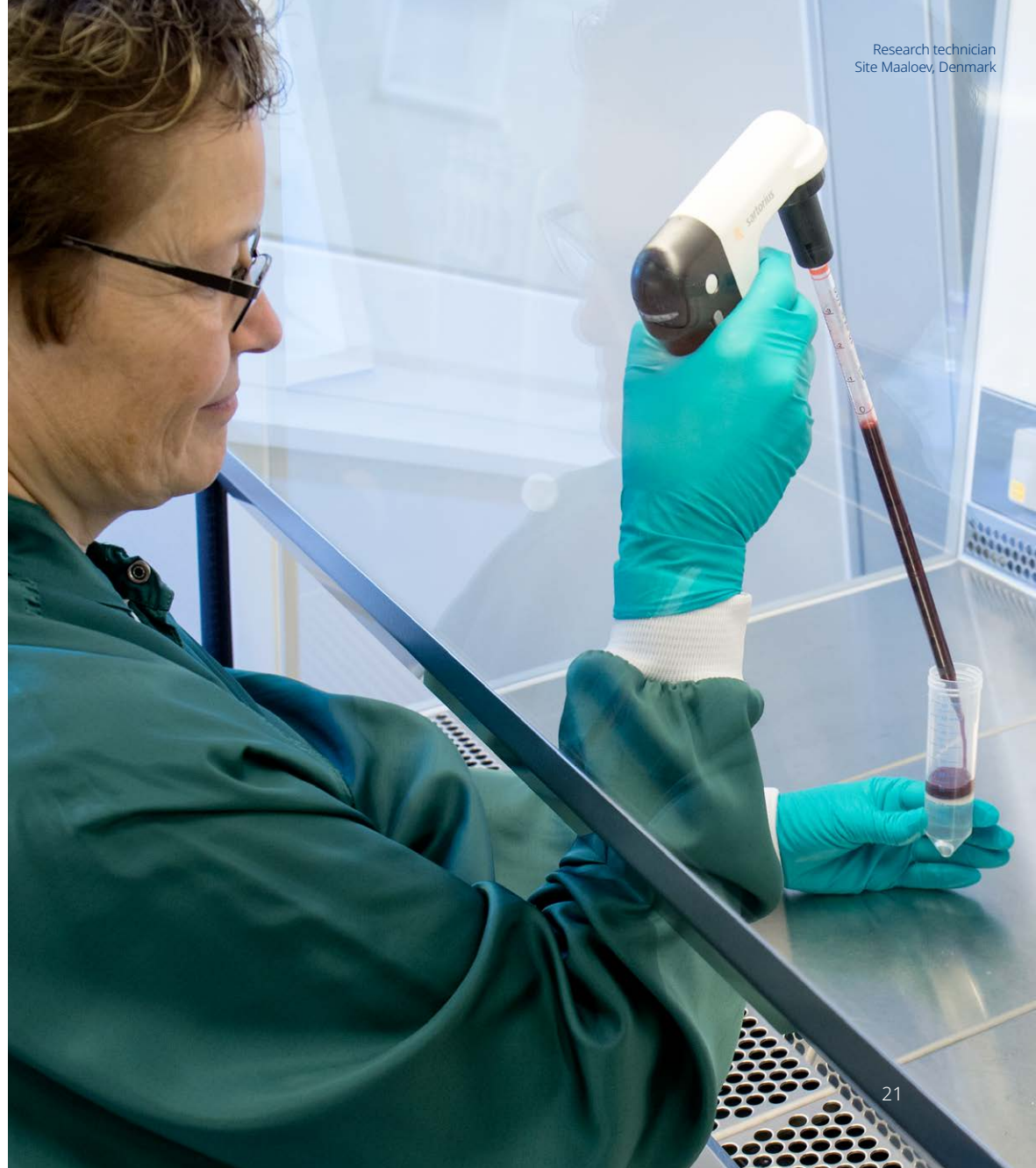
Governance system ensures high standards

Novo Nordisk has a system in place to make sure that we control the use of human biosamples and data across all our research activities and facilities around the world in line with our principles and bioethics policy. The system is run on a day-to-day basis by a special team, which is anchored in research part of the company. It works closely with those responsible for ensuring that all of Novo Nordisk's research activities, not only those using human biosamples and data, are ethically sound and that we work to continuously improve our bioethical standards.

This work is done with the support of senior management and takes advice from a group of employees selected from different parts of Novo Nordisk's research organisation who bring their experience and knowledge to help us continuously update and develop the company's use of human biosamples and data in the most responsible and effective way.

A keyway to manage ethical issues is to prevent them from happening. Our management controls are part of the prevention effort. Knowledge and understanding of underlying ethical values and principles are equally important and Novo Nordisk provides all employees using human biosamples with information, inhouse training and education.

Bioethics does not stand still. Science moves forward and societies change, as do attitudes, values, and expectations about research. It is important that Novo Nordisk keeps up to date with national and international standards, best practices, guidelines, conventions, and declarations related to human biosamples and data. The Human Biosample Governance team is involved in monitoring developments in this area to make sure that these are reflected in how we use human biosamples and data in our research.



Working with you

Novo Nordisk is committed to sharing and learning from best practices and hearing the voices of the various people who have an interest in the responsible use of human biosamples and data. We continue to learn a lot from others working in this field and from patients, the public and groups with special expertise.

The use of human biosamples and data in research is not just a matter of supply, demand and controlling what we do. Users of human biosamples and data are part of a diverse group of stakeholders. These range from patients, the public and society as a whole, to technical and scientific experts, medical doctors, nurses and other medical professionals and policy makers, government officials and politicians.

Each has something to say and to add to how we should best use human biosamples and data in research.

“Novo Nordisk watches, listens, learns, and contributes to various discussions and debates related to the bioethical, regulatory, and quality best practice aspects of using human biosamples and data responsibly. We do this directly as a company, but we also take part in the work of pharmaceutical industry associations, biobanking societies and networks and other groups where we see an opportunity to make a useful contribution and learn to improve how we work,” explains Tina Bossow, Global Key Expert, Human Biosample Governance

TINA BOSSOW

Global Key Expert, Human Biosample Governance

“Novo Nordisk watches, listens, learns and contributes to various discussions and debates related to the bioethical, regulatory and quality best practice aspects of using human biosamples and data responsibly.”



TAKE A CLOSER LOOK

Ethical considerations are part of everyday life in research and development at Novo Nordisk. This brochure is part of a series of brochures on bioethical issues. You can download these brochures and find further information on Novo Nordisk's approach to the use of human biosamples in research on Novo Nordisk's bioethics web pages:

novonordisk.com

Contact

Novo Nordisk welcomes feedback, comments and suggestions on this brochure.

Please send your comments to: **bioethics@novonordisk.com**

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