HUMAN BIOSAMPLES IN PHARMACEUTICAL RESEARCH

A responsible approach
In Novo Nordisk we will discover, develop and produce biological medicines 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
- act in accordance with international conventions.
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 biosamples, animals, gene technology and stem cells.

The 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 (The Triple Bottom Line) by considering each of these elements when making business decisions.
Novo Nordisk highly appreciates that people donate biosamples for our research activities and is grateful for their important and worthwhile personal contributions to the development of new medicines that improve people’s lives.”
OUR APPROACH TO WORKING WITH HUMAN BIOSAMPLES

Biosamples (e.g. tissue and blood samples) from patients and healthy volunteers are important for research into finding new ways of preventing, detecting or treating diseases. Novo Nordisk uses human biosamples 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 need to trust that their biosamples 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 used in our research trust that they are making important and worthwhile personal contributions to the fights against diseases such as diabetes, obesity and haemophilia.

At Novo Nordisk, we regularly review and develop our policies related to human biosamples and the governance and procedures we have in place to control the use of human biosamples in our research and development activities in line with our Triple Bottom Line commitments.

All Novo Nordisk employees involved in research using human biosamples 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 our efforts to always try to improve our performance.

Mads Krogsgaard Thomsen
Executive Vice President and Chief Science Officer, Novo Nordisk
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 and treatments.

Human biosamples 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 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 what they find to update what is known about human health and disease.

Novo Nordisk relies on and is grateful to the many people who are willing to donate biosamples for use in research. Novo Nordisk uses human biosamples during our research to find new treatments for diseases such as diabetes, obesity and haemophilia. 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 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 can become available for use in research (donated) in several different ways, for example:

1. When patients undergo procedures (e.g. blood sampling, biopsy or surgery) during which biosamples are removed from the body for tests or as part of treatment, it is often possible for small left-over amounts of the biosamples to be available for research.
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.

Novo Nordisk obtains human biosamples from people taking part in research projects and clinical trials through universities, hospitals and
HUMAN BIOSAMPLES

Individuals contributing to research to discover new treatments

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.
RASMUS JØRGENSEN
Vice President, Diabetes & Cardiovascular Disease, Global Research, Novo Nordisk

“Our research aims to discover new ways to improve the treatment of diabetes and the lives of people with diabetes. This research needs us to be able to study human biology in our laboratories and we use human biosamples to do that. It is important for us to always use high quality human biosamples that have been donated ethically and according to high international standards.”
Novo Nordisk takes a responsible approach when addressing the ethical issues related to the acquisition, storage and use of human biosamples. Acting responsibly when using biosamples 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. These standards and requirements cover topics such as consent, donor recruitment, obtaining approvals for research and acquiring of biosamples in socially responsible ways.

Responsible use of human biosamples 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 in research 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 and the UN Guiding Principles on Business and Human Rights. Although there are country-to-country differences in regulation, these international conventions, declarations, standards and guidelines have common themes. Novo Nordisk has used these to set our own principles and global

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.
standards for responsible use of human biosamples, which comply with the latest most important international conventions, declarations, standards and guidelines. 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. Our principles and standards do not just apply to our own staff. When we work with another organisation that provides access to human biosamples 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 of human biosamples.
OUR PRINCIPLES ON THE USE OF HUMAN BIOSAMPLES

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 bioethics issues relating to the acquisition, storage and use of human biosamples. Biosamples 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 must align with this position.

- Novo Nordisk recognises its responsibility to respect the legal and ethical rights of the people who donate human biosamples.
- Novo Nordisk’s research using human biosamples complies with all relevant national and international laws and regulations and takes note of external guidelines on bioethics and best practice, insofar as they apply. Novo Nordisk’s internal governance processes assure the legality and ethics of its uses of biosamples.
- Biosamples must be donated with appropriate consent, or with legally and societally acceptable alternatives to individual donor consent where necessary. Consent to donate human biosamples 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 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 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 recognises its responsibility to respect the legal and ethical rights of the people who donate human biosamples.

- Novo Nordisk protects the privacy of people who donate human biosamples 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 interacts with regulatory bodies and other key stakeholders to maintain and further develop the appropriate ethics standards at an international level.
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 in research. It is important that donors of biosamples are given the chance to agree to the use of their biosamples 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 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 what they should be asked to agree to. We do not use any biosamples 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. 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 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 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 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**

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
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 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.

**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 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 biosamples 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’.

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.
ACQUIRING HUMAN BIOSAMPLES RESPONSIBLY

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

Organisations supplying us with biosamples or doing research for us using biosamples will undergo a human biosample supplier evaluation. They will only be accepted as suppliers of human biosamples 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 to improve how they work to meet high international standards. Novo Nordisk always checks new suppliers of human biosamples 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 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 we use responsibly, we also believe it improves the quality of the research we do to help us find new effective and safe medicines.

TINA BOSSOW
Advisor, 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, it could wrongly signal that Novo Nordisk doesn’t care about the rights of donors.”
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.
Novo Nordisk has a system in place to make sure that we control the use of human biosamples across all our research activities and facilities around the world in line with our commitment to our Triple Bottom Line. 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, 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 in the most responsible and effective way.
A key way 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, in-house 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. 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 in our research.
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. 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 in research is not just a matter of supply, demand and controlling what we do. Users of human biosamples 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 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 responsibly. We do this directly as a company, but we also take part in the work of pharmaceutical industry associations, biobanking societies and networks, government-led taskforces and other groups where we see an opportunity to make a useful contribution and learn to improve how we work,” explains Brian Clark, Director of 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 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 webpages: novonordisk.com

Contact
Novo Nordisk welcomes feedback, comments and suggestions on this brochure. Please send your comments to: bioethics@novonordisk.com