Bioethical Statements: Commitment to High Ethical Standards

Protecting Patients and helping scientists work with confidence

3H Biomedical works with strong ethical principles for all of the services we supply to life science research and drug discovery. Our biological materials are enabling tools for basic research and the development of new treatments for human diseases and innovative diagnostic methods.

We understand that the use of biological materials may offer breakthroughs and new approaches in diagnostic and therapeutic of human disease. This practice may impact the rights of patients and donors as individuals. 3H Biomedical is committed to the highest ethical standards and principles to ensure the benefit of human health and privacy protection.

The ethical principles include:

- Respect for the human body
- Respect for the autonomy and wishes of the donor
- Respect for the privacy and medical confidentiality of the donor
- Respect for the right of all donors to make informed decisions about their own bodies
- These principles guide all of our works in collecting and distributing biological samples and information. However, many different guidelines and regulations contribute to our application of these principles.

Respecting Research Participants and Preserving Integrity

The most important issue in our ethical principles is protecting the privacy of individuals that donating their biological materials to us. We protect the confidentiality and integrity of individual donors and our collaborators.

3H Biomedical AB
Dag Hammarskjölds väg 34A
Uppsala Science Park
S-751 83 Uppsala, Sweden

Phone: +46 18 50 44 00
Fax: +46 18 51 38 44

E-mail: *Info@3hbiomedical.com*
Internet: www.3hbiomedical.com

Bioethical Statements: Commitment to High Ethical Standards

We are a company with wide privacy policy and integrity

- 3H Biomedical does not receive any personal information from the collaborating partners
- We will not provide information about our collaborating partners
- We will not provide information about the origins of biological material
- Any data supplied to researchers can not be trace back to the donor
- Confidentiality agreements are included in all business associate and collaboration agreements
- Our regulatory affairs and ethical officer ensure that all protected health information is handled according to company's policies.

Respecting Research Participants and Preserving Integrity

3H Biomedical accepts only biological samples that have been obtained after the prior written informed consent of the donor. We use only informed consent agreements that comply with requirements set forth by the ethical committee in Sweden and World Medical Association Declaration of Helsinki.

Our informed consent agreements set forth the following:

- Clear explanation of the range of intended uses of the biological material
- Explanation of possible commercial research
- Information about the duration of donor involvement
- Description of all privacy protection measures
- Inform about all risks and benefits associated with donation
- Due consideration for the previously expressed wishes of deceased donors
- Emphasis of the voluntary nature of donation and ability to withdraw

3H Biomedical AB
Dag Hammarskjölds väg 34A
Uppsala Science Park
S-751 83 Uppsala, Sweden

Phone: +46 18 50 44 00
Fax: +46 18 51 38 44

E-mail: *Info@3hbiomedical.com*
Internet: www.3hbiomedical.com

- Participation of legally authorized representatives to protect the interests of minors or other legally incapacitated individuals
- Donors are never compensated for the gift of their biological material

Confirming Our Commitment to High Ethical Standards

Informed consent agreements may be modified to adopt the culture, education, literacy and legal climate of foreign countries. However, all informed consent agreements are comply with the requirements and guidelines set forth above.

3H Biomedical will not work with collaborators without individual donor informed consent.

- We provide copies of our informed consent agreements for review by customers and collaborators
- We actively obtain information from independent well recognized ethicists and legal advisors/experts to verify that our procedures for assuring patient protection are complete and effective
- We safeguard and maintain internal documents related to all of our ethical concerns
- Respect for the feelings and beliefs of relatives of deceased donors

Ensuring Independent Review of Potential Risks and Benefits External and internal checks

3H Biomedical's research projects, protocols and informed consents have been rigorous evaluated, reviewed and approved by National ethical committee. These checks contribute to donor safety and privacy protection.

In addition, we have internal controls to ensure that our Ethics and Privacy Policies are followed.

3H Biomedical AB
Dag Hammarskjölds väg 34A
Uppsala Science Park
S-751 83 Uppsala, Sweden

Phone: +46 18 50 44 00
Fax: +46 18 51 38 44

E-mail: *Info@3hbiomedical.com*
Internet: www.3hbiomedical.com

- Review of all changes to Informed Consent Agreements to ensure that the essential features outlined above are maintained
- Ensure that all changes and comments made by ethical committee are implemented and are consistent with legal requirements.

Ethical Guidelines and Regulations Influence Our Actions

3H Biomedical adheres to guidelines set forth by numerous governmental agencies. Few statutes exist to dictate how tissue banks should conduct business. However, we consider and implement the advice and principles set forth by many of the worlds' pre-eminent organizations.

We adhere to regulations and principles set forth by the following:

- Guidelines of Swedish National Board of Health and Welfare
- Swedish Law on ethical review of research involving humans. (Etikprövningslagstiftningen) and Informed Consent
- Swedish Law on Biobank (Biobankslagen)
- Swedish Law on transplantation
- Swedish Medical Research Council's guidelines for ethical appraisal of medical research on humans. Guidelines for the ethical evaluation of medical research on humans (Riktlinjer för etisk värdering av medicinsk humanforskning). Guidelines for good medical research. (Riktlinjer för god medicinsk forskning).
- The Swedish Medical Products Agency (LVFS 2003:6), principles for good clinical practice (GCP)
- Swedish law of Personal Data Act (PUL) and the Personal Data Ordinance, Swedish Data Inspection Board's Authority Regulations (Personuppgiftlagen)

3H Biomedical AB
Dag Hammarskjölds väg 34A
Uppsala Science Park
S-751 83 Uppsala, Sweden

Phone: +46 18 50 44 00
Fax: +46 18 51 38 44

E-mail: *Info@3hbiomedical.com*
Internet: www.3hbiomedical.com

Bioethical Statements: Commitment to High Ethical Standards

- The World Medical Association Declaration of Helsinki
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 1993)
- Nuremberg code
- EG's Blood directive and tissue directive
- Good Clinical Practice. The EU Directive 2001/20/EC
- EU Commission Directive 2005/28/EC
- Council of Europe's Convention
- The European Group on Ethics in Science and New Technologies
- European Parliament and the Council of Europe's Directive 95/46/EC
- The American Medical Association
- The World Medical Association Declaration of Helsinki
- The American Society of Human Genetics
- The Food and Drug Administration, Department of Health, U.S.A

3H Biomedical is committed to ensuring that legal and ethical guidelines are followed during the procurement and retention of biological samples. As a result, the researchers we support can concentrate on creating novel diagnostic and therapeutic advances while remaining confident that the utmost ethical standards have been maintained.

3H Biomedical AB
Dag Hammarskjölds väg 34A
Uppsala Science Park
S-751 83 Uppsala, Sweden

Phone: +46 18 50 44 00
Fax: +46 18 51 38 44

E-mail: *Info@3hbiomedical.com*
Internet: www.3hbiomedical.com