



Position Statement
Bioethics
Global Business Practice Standards Manual

Baxter believes that biotechnology can provide significant benefits to life and that these technologies carry with them responsibilities. Any Baxter decision to commercialize a biotechnology-derived product or therapy will receive careful consideration of the risks and the benefits of the technology in light of the information available. The ability to perform an activity will not automatically justify the activity. As a company, these principles and processes govern our efforts to research, develop, and provide products for critical therapies for patients worldwide.

Bioethics Guiding Principles

Baxter places the highest priority on the safety and efficacy of our products, and we support government agencies in safeguarding health and well being throughout the world.

Baxter listens to and considers feedback from the public and responds to concerns about the social, ethical, and technical application of biotechnology in the research, development, manufacture, and sale of our therapies and products. Baxter's response to these concerns will be based on ethical considerations and scientifically sound hypotheses, theories, and data.

Baxter actively participates in public discussions and professional forums encouraging science-based policies and regulations that serve the public interest as an ethical priority.

Baxter will determine the potential benefit of our applied biotechnology.

Baxter will ensure that any research undertaken by Baxter or at its direction is designed to produce valued health enhancements or advancement of scientific knowledge while seeking to identify and minimize relevant risks.

Baxter complies with applicable legislation and regulatory requirements, and supports accepted ethical and professional standards in the research, development, manufacture, and sale of its products. Specifically, Baxter is sensitive and responsive to concerns related to the conduct of all research on humans: Baxter is committed to protecting the life, health, privacy and dignity of those participating in clinical trials, as well as to protecting the integrity of the data obtained from these studies. These standards are found in, but are not limited to, the following documents:

- Guidelines for Good Clinical Practice (GCP), edited by the International Conference on Harmonization (ICH), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP)
- Declaration of Helsinki
- International Ethical Guidelines for Biomedical Research Involving Human Subjects
- Applicable privacy and data protection standards

Baxter supports the conscientious use of animals in research when no other valid scientific alternative exists. To the extent possible, Baxter will minimize the use of animals in our research and, where utilized, will treat them humanely and with the highest standards of care.

Baxter recognizes that protecting the environment and maintaining the biological diversity of our planet is of vital importance to human life. Baxter believes in the importance of maintaining global biodiversity and sustainable use of global resources.

This bioethics standard applies to work performed at the direction of Baxter by external contract research organizations, consultants, and third-party vendors. Where Baxter performs as a third party vendor, Baxter will take into account the bioethical conduct of the contracting organization in determining whether or not to take on the work.

Framework for Application of Bioethics Guiding Principles

Baxter's planning processes, policies, and procedures consider these "Bioethics Guiding Principles" as we carry out research and develop, manufacture, and sell our products.

Baxter will assess the potential risks and benefits of proposed research and development. Research and development is justifiable where:

1. The potential risks to individual subjects are minimized.
2. The potential benefits to individual subjects are enhanced.
3. The potential benefits to individual subjects and society are proportionate to or outweigh such risks.

Baxter's Operations Committee, through the application of the "Bioethics Guiding Principles" and with the advice of appropriate scientific and ethical advisors, will make the final decision on whether to proceed in areas that require a consideration of bioethical issues.

Review

This bioethics policy, and the decisions that have been made under its guidelines, will be reviewed and revised as appropriate based on technological advancements, legal and regulatory changes, and current social and ethical considerations.

Bioethics Position Statements

In response to debates regarding social, ethical, and technical application of specific biotechnology, Baxter may issue position statements under the guidance of this bioethics standard. Baxter has developed position statements that can be accessed from Baxter's Internet.

Baxter Position Statements

[Bioethics](#)