

BRISTOL-MYERS SQUIBB COMPANY

BIOETHICS POLICY STATEMENT (Policy Excerpts)

THIS POLICY SETS FORTH OUR COMMITMENT TO CONDUCT ACTIVITIES RELATED TO NON-CLINICAL AND CLINICAL RESEARCH & DEVELOPMENT OF OUR PHARMACEUTICAL PRODUCTS IN ACCORDANCE WITH THE HIGHEST LEGAL, ETHICAL AND SCIENTIFIC STANDARDS, INCLUDING:

- International Conference on Harmonization (ICH) GCP and the ethical principles that have their origin in the World Medical Association Declaration of Helsinki
 - Good Laboratory / Manufacturing / Clinical / Distribution Practice
 - International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS)
 - International Committee of Medical Journal Editors (ICMJE)
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KEY PRINCIPLES

- All BMS employees understand that they are responsible for compliance with this Policy
 - BMS is committed to ensuring patient rights and safety are safeguarded at all times
 - Research activities will be performed in compliance with all local regulatory requirements and quality and safety standards in those countries in which we conduct research
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POLICY STATEMENTS

- A qualified Independent Ethics Committee/Institutional Review Board (IEC/IRB) must review and approve all BMS sponsored/supported interventional clinical studies prior to initiation. Subjects must not be enrolled until such approval is received as well as all local regulatory or governmental authorizations required in the country in which the study will be conducted.
- The assessment of risk/benefit is a complex task; risk of injury or discomfort to an individual research subject can be physical or psychological. Potential benefits may be to the individual research subject or the population to which the research subject belongs. BMS carefully assesses the type and degree of both risk and benefit for a given research population and seeks to minimize risk to each subject in order to answer a scientifically/medically important research question which may benefit the research population. Study design must be adequate to achieve the stated aim of the research and the nature and likelihood of all benefits and risks should be clearly stated.
- Research subjects may only be enrolled in a study after providing their voluntary informed consent; the informed consent process must reflect the underlying principles and spirit of truly informed consent. Potential research subjects must be clearly and fully informed about the purpose, processes, risks/benefits and other critical factors regarding the study in which they may participate, and have the opportunity to request further information regarding their participation in the study. The special needs of vulnerable populations must be considered and addressed and such subjects must be afforded the opportunity to provide or withhold their consent whenever possible.

Research subjects are free to withdraw at any time without detriment to their ongoing medical care.

- For clinical studies that include a control group, the standard of care provided to the control group(s) should be, at a minimum, equivalent to established and commonly employed treatments that are medically and ethically appropriate to treat the disease.
- Placebo controlled studies should only be utilized only where there is a genuine uncertainty about the therapeutic merits of the proposed treatments being studied (clinical equipoise) and where doing so does not present an undue risk to the subject.
- BMS will register and disclose results from all R&D qualifying clinical studies; in addition contractual registration and disclosure requirements for clinical studies conducted with development partners will be defined.
- BMS is committed to the principles of good publishing practices and will adhere to the requirements of the ICMJE on authorship when determining both internal and external authorship for publication of research study data. [Click here to read a summary of Bristol-Myers Squibb Company Policy on Scientific Publications.](#)
- Reimbursement or compensation to research subjects must be consistent with the principle of voluntary participation in the study i.e., no real/perceived coercion. Any such reimbursement or compensation should be appropriate to the local economy and must be reviewed by the IEC/IRB.
- Compensation to researchers must not in any way reward, or appear to reward, past prescribing of BMS products or induce future prescribing of BMS products. Payments must reflect fair market value for services rendered and be reasonable in light of the time and effort involved.
- BMS is committed to further enhance pediatric health through appropriate research activities in the pediatric population, as such, products in development will be considered for their use in pediatric populations. If a product is considered appropriate, clinical studies will be conducted in accordance with all national and international requirements regarding inclusion of children in research.
- BMS will strive to evaluate the safety and efficacy of its medicines in pertinent sub-populations for whom the response may differ from the population studied in the core dossier with the appreciation that statistically significant sampling may not be feasible.
- BMS will ensure that women are adequately represented in development programs to allow for valid analyses of differences in intervention effect.
- Use of biological materials and technologies must be reasonable and ethical to ensure the safety and welfare of BMS employees, the environment, and the communities in which we operate.
- The development of safe and effective medicines at times requires the care and use of animals for research and testing. All procedures involving the care and use of animals must comply with applicable laws and regulations, and BMS Animal Care and Use Directives. BMS employees are expected to treat all animals used in BMS facilities in a caring and humane manner.
- BMS is committed to maintaining the privacy of subjects by ensuring that all data is anonymised to conceal the subject's identity.