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Conduct of Research in Medically Related and Behavioral Science Fields	REVISION	1
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DESIGNATED CONTACT (S)	FIRST ISSUED:	
Chief Operating Officer; General Counsel	OCTOBER 1976	

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## POLICY STATEMENTS

### General

Battelle engages in research, development, and education to advance medical science and technology knowledge, and in the medically related and the behavioral science, to benefit mankind through the application of our capabilities in science and technology to the needs of these fields, within the limits stated herein. Battelle does not engage in research that may be considered clinical medicine; law from engaging in the practice of medicine prohibits Battelle.

### Specific

These specific policy statements relate to four categories of medically related and behavioral science research in the following ways:

1. Research not involving human subjects. No restraint is placed on activity in this category, providing that ethical and regulatory standards established by the declaratory judgment and appropriate Government agencies and/or professional societies shall be adhered to in animal research.
2. Medical or behavioral research that involves passive observation or examination of human subjects, without involving physical or psychological impingement on, or manipulation of, the subject, not deliberately (directly or indirectly) inducing or altering body or mental functions in individuals or groups, and not involving the practice of medicine, is permissible.

Examples in this category include: whole body counting of radionuclides already present in the subject; examination of body tissues, fluids, or products taken by another party; observation of the effect of ambient environment on human subjects; factual or attitudinal surveys and interviews when a part of a project program; and administration of psychometric or psychological examinations.

3. Medical or behavioral research involving physical or psychological impingement on, or manipulation of, human subjects, and deliberately (directly or indirectly) inducing or altering body or mental functions, in Individuals or groups, involving the practice of medicine.

This type of study may be subcategorized as follows:

- a. Studies involving the practice of medicine. Battelle cannot engage in the practice of medicine as a matter of law.
- b. Clinical research—defined as investigation to determine the therapeutic benefit of a procedure to a patient selected for treatment. Battelle may not, as a matter of policy, engage directly in clinical research. In instances, however, where Battelle has developed materials, devices, or structures for use in the body, or to be applied externally to the body, or where Battelle has conducted background research to develop drugs, food additives, or procedures for treatment of human beings, Battelle may subcontract such studies to qualified subcontractors, where applicable law permits.
- c. Research involving procedures that may, in the informed judgment of the Committee (see below), induce a potentially harmful altered state or condition in the human subjects, is prohibited. This subcategory includes: surgical procedure, the removal of organs or tissues for biopsy, the administration or radiation, use of skin toxicity agents, the administration of prescription drugs, the use of in-dwelling electrodes, deliberately inducing mental aberrations, and the like. This subcategory of activity is prohibited.
- d. Medical or behavioral research involving procedures, which are not, in the informed judgment of the Committee, in any way expected to induce a potentially harmful altered state or condition. The procedures shall present no immediate or foreseeable physical or mental risk to the subject; it may impose not unreasonable degrees of discomfort, irritation, or harassment. The evaluation shall

include a determination that there is no pre-existing pathology on the subject, which could be worsened by such a procedure. Examples are: food tasting involving accepted foods and beverages: sampling from natural body orifices (such as mouth, nose, ears, etc.) not involving surgical procedure: effect of stress stimuli such as sound, light, vibration, acceleration, deceleration greater than 1 g: emotional stress; utilization of fog or smog chambers to produce minor eye irritation; sound tests; and exposure to other artificial environments. This subcategory of activity may be engaged in, subject to the Policy Background statements in this section.

4. Research to develop materials, devices, or structures for use in the body, or applied externally to the body, where the implantation and/or experiments with human subjects is to be done by others legally independent of Battelle; and research to develop drugs, food additives, or procedures for treatment of human beings, where the testing on human subjects will be done by others legally independent of Battelle, is permissible.
  - a. Battelle may accept contracts from medical research institutions (or individuals) to undertake supporting research and development, where the Sponsor undertakes and assumes full responsibility for the trials with human subjects.
  - b. Battelle may undertake prime contracts for such research and/or development of the materials, devices, etc., provided the testing with human subjects is subcontracted to a qualified Independent contractor, i.e., one who possesses the Independent right of final decision as to the testing procedure and all other aspects of the human subjects participation; also provided the applicable law permits Battelle to so contract. The subcontractor shall indemnify (hold harmless) Battelle, and provide adequate proof of financial responsibility to support the indemnity, e.g., by insurance or equivalent for the human subjects.

For all programs within the previously defined categories designated above as (2), the final item under (3), and (4) above, it is vital that the program and protocol have the initial approval and continuing monitoring of a Committee. Such Committee is to be established by each Battelle Component desiring to engage in such programs. The Committee shall consist of persons so selected that the Committee will be competent to deal with the medical, legal, technical, safety, social, and ethical issues involved in the research, and to represent the community from which the subject population is to be drawn. The Committee must be composed of not less than five persons with various backgrounds to assure adequate review of a project or activity in which the member has a conflicting interest, except to provide information requested by the Committee. No quorum of a Committee shall consist entirely of Battelle staff members. Committee members who have a responsibility at Battelle for the program under consideration must disqualify themselves from the Committee for that program. The Committee shall maintain appropriate and Informative written records of all its deliberations. The fundamental concerns of the Committee shall be:

1. Protection of the rights and welfare of the individuals involved,
2. Determination of the risks to the subject and potential benefits to the subjects and mankind of the investigation, and
3. Determination that the informed written consent of the subjects will be obtained by methods that are adequate and appropriate.

With respect to such programs, the minimum requirements are:

Voluntary and informed written consent of the subjects must be obtained. A waiver of the requirement for written consent may be granted by the Committee of the Component for studies envisioned by item (2) of the above Policy Statement-Specific.

The subjects shall have the option to withdraw at any time, and must in all other respects be treated fairly.

The rights, welfare, and privacy of individuals shall be adequately protected, e.g., the subject shall be protected from the misuse of information. Identification of research or survey results by specific individuals may not be made without the express consent of the individual. The investigator shall provide a plan to protect the confidentiality of the information.

Openness and honesty are essential characteristics of the relationship between investigator and subject. When a methodology or requirement of a study necessitates withholding of information, the investigator shall insure the subject's understanding of the reasons for his action and shall restore the quality of the relationship at the end of the investigation. The investigator shall provide a plan for accomplishing these requirements.

**Compliance with all applicable Government regulations.**

The research objective must not be reasonably obtainable by any other means.

**Battelle Organization staff members shall not be utilized as subjects, to avoid any question of voluntariness, except that they may be used to sample accepted food and beverages, or in factual and attitudinal surveys, provided the subjects are not members of the Department conducting the research, and provided the subjects are protected against misuse of the information.**

**If a Component desires an exception to the policies of this section, for a specific low-risk program, it may request such exception in writing to the Chief Executive Officer, via the Component head, with recommended action and supporting information.**

The operating Components shall maintain uniform interpretations and procedures on substantive issues of this policy.

#### **Proposal Approvals**

The function of the Committee is additive to normal management and staff review and approval functions. For example, all investigations involving human subjects are to be conducted so that all practical steps are taken to avoid civil or criminal liability (such as for personal injury or malpractice), and the legal review of proposals for such investigations would normally include consideration of this principle. Each such proposed investigation will be reviewed from the standpoint of its effect on Battelle's reputation as a responsible, objective, scientific research organization.

### **POLICY BACKGROUND**

The general policy stated above recognizes the requirements of the purposes of Battelle, the restraints of applicable laws and regulations, the ethics of the activities contemplated, the need to protect the public image of Battelle, and the financial risks involved.

In all research performed by Battelle, but especially in the medical and behavioral fields, the health, safety, welfare, and privacy of participants must be paramount. Their rights must not be infringed. We must always protect and never knowingly harm a subject. The conduct of all programs must be highly ethical, informed, and thoughtful. This policy in no way diminishes the investigator's personal responsibility for the careful evaluation of the ethical, social, medical, and psychological consequences of the planned research. Investigators must be familiar with and conform to the ethical standards established by recognized professional societies. Also, all applicable laws and regulations must be followed, the requirements of the Sponsor must be followed if they are more restrictive, and the ethics of the activity and the impact on Battelle's image must be fully considered. Protection must be provided for the subjects against misuse of the findings.

In the Specific Policy Statement, a "human subject" is considered to be any human being exposed to any research or investigative procedure for determining the effect that such procedures have on such subjects. Included are: persons involved in psychological or behavioral science studies; normal volunteers, living donors of essential body fluids, organs, and tissues; and members of the general population who may be involved in environmental or epidemiological studies, and similar activities.

#### **Statutes Regarding the Practice of Medicine**

The determination of whether research, properly conducted by professional scientists, is embraced within the practice of medicine is difficult. Research, as such, has not been covered by any reported court decisions, which considered it squarely in terms of the right and liability of a trained professional, utilizing a normal subject, to discover new knowledge not necessarily of benefit to that particular subject. Case law generally characterizes such research as "experimentation" and holds it to be outside legitimate medical practice because it is not diagnosis, treatment, or therapy for the benefit of a patient. The reported cases simply have not established limits within which human research may be pursued. As noted above, Battelle's policy is that the applicable laws and regulations of all jurisdictions concerned with the activity, regarding the conduct of medical practice, are to be followed to avoid the practice of medicine.

Corporate Policy 1.1.1.7	
<b>Battelle Policies Manual</b>	Tab/Section Legal/Legal Matters
DESIGNATED CONTACT (S) Secretary, Human Subjects Committee/General Counsel-BCD	Subject Human Subjects in Research

## POLICY

All Battelle research involving the use of human subjects shall be reviewed and approved by a Battelle human Subjects Committee unless such research is specifically exempted from such review by applicable Federal regulation.

### SUPPLEMENTARY INFORMATION

In all research performed by Battelle involving human subjects, the right, health, safety, and privacy of the human subjects is paramount. Battelle will protect and not knowingly harm any human subject. The conduct of research projects involving human subjects shall be highly ethical, informed, and thoughtful. This policy in no way diminishes the Researcher's personal responsibility for the careful evaluation of the ethical, social, medical, and psychological consequences of the research. Researchers shall be familiar with and conform to the ethical standards established by recognized professional societies, as well as applicable laws and regulations. Client imposed requirements, which are more restrictive than the foregoing, shall also be followed.

For purposes of this policy, a "human subject" is defined as any living individual about whom a Researcher conducting research obtains: (1) data thought intervention or interaction with the individual; or (2) identifiable private information. This definition includes, but is not limited to: individuals involved in psychological or behavioral studies; living donors of essential body fluids, organs, and tissues, and individuals participating in environmental or epidemiological studies.

### HUMAN SUBJECTS COMMITTEE (HSC) PROCEDURES

Battelle will establish a Human Subjects Committee(s) (hereinafter HSC) in conformance with the requirements of 45 CFR Part 46 and its Assurance with the U.S. Department of Health and Human Service (DHHS), both of which are hereby incorporated into this policy by reference. The number and configuration of each HSC so established will reflect the purposes of this policy and the business needs of Battelle.

The responsibilities of the HSC will be as set forth in 45 CFR 46, Battelle's Assurance with (DHHS), both of which are hereby incorporated into this policy by reference. The number and configuration of each HSC so established will reflect the purposes of this policy and the business needs of Battelle.

The responsibilities of the HSC will be as set forth in 45 CFR Part 46 and Battelle's Assurance with DHHS, and other applicable rules and regulations. The function of the HSC is additive to normal management and staff review and approval functions. For example, all projects involving human subjects are to be conducted so that all practical steps have been taken to avoid civil or criminal liability (such as for personal injury or malpractice), which is also a matter for contract and/or legal reviews. Each proposed project would also be reviewed from the standpoint of its effect on Battelle's reputation as a responsible, objective scientific research organization.

## **Office of Research Administration (ORA)**

Battelle will establish one or more Offices of Research Administration (ORA) to provide administrative support to the HSC(s). The responsibilities of the ORA are described in Battelle's Assurance with DHHS.

### **Responsibilities of Researchers, Research Managers and Contracting Officers and Administrators**

#### **Determination of Human Subject Involvement**

1. Those involved in the decision to prepare a proposal (Researchers and their managers) shall make the initial determination as to whether the research involves human subjects.
2. When it is not clear whether the research involves human subjects, the ORA shall be notified through its Secretary so that the determination can be made.
3. The involvement of human subjects in research activities must be indicated on the Battelle PIF C Form.

#### **Preparation of Protocol**

1. Research staff shall prepare a protocol giving a complete description of the proposed research. In the protocol, research staff shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and assure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt from HSC review.
2. Samples of proposed informed consent forms will be included with each protocol.

#### **Scientific Merit and Ethical Consideration Review**

Research managers, through appropriate procedure established within their respective departments, are responsible for reviewing research protocols for ethical considerations and scientific merit.

#### **Submission of Protocol to the HSC**

Researchers shall assure that all research involving human subjects is submitted to the HSC and, on request of the HSC, for appearing before the HSC to review the research.

#### **Submission of Supplement to Original Protocol to HSC**

1. Researchers shall submit to the HSC a supplement to the original protocol when:
  - a) It is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects; or
  - b) It is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects; or
  - c) It is proposed to change the involvement of human subjects and that involvement is significantly different from that initially approved by the HSC.

## **Complying with HSC Decisions**

Research staff shall comply with all HSC decisions, conditions, and requirements.

### **Obtaining Informed Consent**

1. Researchers shall obtain informed consent in accordance with the HSC approved protocol and for assuring that no human subject will be involved in the research prior to obtaining any required informed consent.
2. Unless otherwise authorized by the HSC, research staff shall assure that informed consent shall:
  - a) Be obtained from the subject or the subject's legally authorized representative; and
  - b) Be in language understandable to the subject or the representative; and
  - c) Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate, and that minimize the possibility of coercion or undue influence; and
  - d) Not include exculpatory language through which the subject or the representative is made to waive any of the subject's legal right or releases, or appears to release the sponsor, the institution, or its agents or employees from liability for negligence.

### **Providing Basic Elements of Informed Consent**

1. Unless otherwise authorized by the HSC, informed consent shall include the following information:
  - a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; and
  - b) A description of any reasonably foreseeable risks or discomforts to the subject; and
  - c) A description of any benefits to the subject or to others which may reasonably be expected from the research; and
  - d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; and
  - e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and
  - f) For research involving more than minimal risk, an explanation as to whether any compensation will be provided, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; and
  - g) Identification, including telephone numbers, of institution research and HSC staff to contact for answers to questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury to the subject; and

- h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

### **Providing Additional Elements of Informed Consent**

1. When required by the HSC, the Research Manager shall provide one or more of the following additional elements of information to each subject:
  - a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus), if the subject is or may become pregnant which are currently unforeseeable.
  - b) Anticipated circumstances under which the subject's participation may be terminated by the Research Manager without regard to the subject's consent.
  - c) Any additional cost to the subject that may result from participation in the research.
  - d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
  - e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
  - f) The approximate number of subjects involved in the study.

### **Documentation of Informed Consent**

1. Researchers shall be responsible for assuring that informed consent is documented by the use of a written consent form approved by the HSC and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the HSC.
2. Researchers shall assure that each person signing a written consent form is given a copy of that form.
3. Researchers may use a written consent form which is either:
  - a) A document that embodies the elements of informed consent required by the HSC. This document may be read to the subject or the subject's legally authorized representative, but in any event, the Research Manager shall give either the subject or the representative adequate opportunity to read the document before signing it, or
  - b) A "short form" document stating that the elements of informed consent required by the HSC have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, Research Manager shall assure that:
    - (i) A witness is present at the oral presentation.
    - (ii) The HSC shall approve a written summary of what is to be said to the subject or legally authorized representative.
    - (iii) The short form only is signed by the subject or the representative.

- (iv) The witness signs both the short form and a copy of the written summary of the oral presentation.
- (v) The person actually obtaining consent signs a copy of the summary.
- (vi) A copy of both the short form and summary is given to the subject or the representative.

### **Retention of Signed Consent Documents**

Researcher shall retain the consent documents signed by human research subjects and maintain any other documentation that may pertain to the selection, participation, and protection of the subjects as required or requested by the GSC for a minimum of three (3) years from the date of project completion.

### **Submission of Progress Reports on the Research**

In addition to the normal project reports, Research Manager shall report the progress of the research to the HSC as often as and in the manner prescribed by the HSC but no less than annually.

### **Reports of Injury or Unanticipated Problems Involving Risk**

1. Researchers shall report promptly, through normal management and administrative channels, to the HSC Chairperson any injuries to human subjects.
2. Changes in research during the period for which HSC approval has already been given shall not be initiated by Researcher without HSC review and approval, except where necessary to eliminate apparent immediate hazards to research subjects.

### **Reporting Changes in the Research**

1. Researchers shall report promptly to their research managers proposed changes in a research activity.
2. Changes in research during the period for which HSC approval has already been given shall not be initiated by Researcher without HSC review and approval, except where necessary to eliminate apparent immediate hazards to research subjects.

### **Reporting Noncompliance**

Researchers and research managers shall report promptly to the HSC Chairperson any serious or continuing noncompliance with the requirements of this assurance or the determinations of the HSC.

### **Notifying FDA Concerning Investigational New Drug**

Researchers shall provide required notification to the Food and Drug Administration (FDA) and their management whenever it is anticipated that an investigational new drug or device exemption will be required.

### **AUDIT**

The activities and records of the HSC will be audited on an annual basis to determine compliance with applicable laws and regulations, Battelle's Assurance, and this policy. Responsibility for this audit function will reside with the Battelle Vice President of Environment, Safety, and Health with assistance from the Battelle Law Department.

## REFERENCES

1. 45 CFR 46, including Subparts B, C, and D.
2. The Federal policy for the Protection of Human Subjects (56FR280003).
3. Battelle Memorial Institute Multi-Project Assurance No. M-1221.
4. Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").
5. The World Medical Association Declaration "of Helsinki, June, 1964, as amended.
6. The Nuremberg Code, Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 1811-182. Washington, D.C., U.S. Government Printing Office, 1949.