



Human Research Protections Program

I. Purpose

This policy describes the plan of the Weill Cornell Medical (WCM) to comply with ethical and legal requirements for the conduct and oversight of Human Research. The Human Research Protections Program (HRPP) applies to all human research that engages WCM and all human research submitted to the WCM Institutional Review Board (IRB) for review. All performance sites for WCM, US and non-US, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of this institution or as may be determined by the Department of Health and Human Services (DHHS) Secretary. WCM fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of WCM.

II. Revisions from Previous Version

None.

III. Definitions

Human Research Protections Program (HRPP): The responsibility for protecting the rights and welfare of research participants is not the sole responsibility of a single office or of the IRB, rather, this responsibility falls to multiple entities, including: WCM administrators, offices/departments, and committees whose roles/responsibilities directly or indirectly involve human research (e.g. Conflict of Interest Committee, Radiation Safety Committee, Institutional Biosafety Committee, etc.), Principal Investigators, faculty advisors, student researchers, and members of the research team. These entities collectively comprise the HRPP.

Human Research: Any activity that is either:

- “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS; and/or
- “Research” as defined by the Food and Drug Administration (FDA) and involves “Human Subjects” as defined by FDA

Research as Defined by DHHS: Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Research as Defined by FDA: FDA has defined "clinical investigation" to be synonymous with "research". "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Human Subject as defined by DHHS: Human subject (also referred to as participant) means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been

provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Engaged in Human Research: WCM is engaged in human research when its employees or agents are interacting or intervening with human subjects for the purpose of conducting research. This includes research conducted at, in agreement with or using any property or facility of WCM; conducted by or under the direction of any employee or agent of WCM (including students) in connection with their WCM position or responsibilities; involving the use of WCM's non-public information to identify, contact, or study human subjects.

Institutional Official (IO): The IO is the organizational official responsible for ensuring that the HRPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human research. The IO is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of its Federalwide Assurance (FWA).

Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

Principal Investigator (PI): The person responsible for the conduct of human research at one or more research sites. If the human research is conducted by a team of individuals at a research site, the PI is the responsible leader of the team

IV. Policy

No research involving human subjects may be conducted without IRB approval and no research may commence until all required Institutional approvals (including IRB) are obtained. Exempt research is subject to review for determination of exemption status, and limited IRB review and approval where required. At WCM, exemptions not requiring limited IRB review are reviewed and granted by Human Research Compliance (HRC) staff.

Ethical and Legal Standards

In the review and conduct of research, actions by WCM will be guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, often referred to as the Belmont Report (i.e., respect for persons, beneficence, and justice). The actions of WCM will also conform to all applicable federal, state, and local laws and regulations, (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe).

The basic legal principles governing research involving human participants are:

1. DHHS regulations for Protection of Human Subjects (Common Rule) in 45 CFR Part 46
2. FDA regulations for the Protection of Human Subjects in 21 CFR Parts 50 and 56
3. DOJ regulations for the Protection of Human Subjects in 28 CFR 512
4. DOD regulations for the Protection of Human Subjects in 32 CFR 219 and DoD Directive 3216.02
5. Privacy Rule regulations of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164
6. Department of Education (DoEd) regulations at 34 CFR 97, 34 CFR 99 (FERPA), and at 34 CFR 98 (PPRA)

7. Department of Energy (DoE) regulations at 10 CFR 745, DoE Order 443.1C (Approved: 11-26-2019); DoE Order 206.1 (Effective date 11-1-2018); and their accompanying Contractor Requirements Documents (CRDs)
8. EPA regulations at 40 CFR 26

HRPP Mission

The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- To provide timely and high quality education, review and monitoring of human research projects; and
- To facilitate excellence in human research.

Institutional Official Responsibilities

The Institutional Official has overall responsibility for WCM's HRPP. The duties of the Institutional Official are as follows:

- Fostering, supporting and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and compliance with applicable regulations and other requirements;
- Serving as the signatory authority and ensuring compliance with the terms of the organization's Federalwide Assurance filed with the Office of Human Research Protections;
- Ensuring that the HRPP and IRB have the resources and support necessary to fulfill their mission and responsibilities. Such resources include, but are not limited to:
 - a. Staffing commensurate with the size and complexity of the research program;
 - b. Appropriate office space, meeting space, equipment, materials, and technology;
 - c. Resources for the production, maintenance, and secure storage of HRPP and IRB records;
 - d. Resources for overseeing the conduct of research, including audits and investigations;
 - e. Access to legal counsel;
 - f. Access to consultants during the review process as needed to ensure that the IRB has the appropriate expertise to review the research before it; and
 - g. Training in human research protections and other relevant subject matter for researchers, IRB members, and staff to support the review and conduct of human research in accordance with applicable ethical standards, regulations, laws, and requirements.
- Ensuring that the IRBs function independently by, among other mechanisms, being directly accessible to the IRB Chairs and members if they experience undue influence or if they have concerns about the function of the IRBs;
- Oversight of the Institutional Review Boards (IRBs);
- Verifying that reliance upon an external IRB is acceptable and appropriate;
- Oversight of research conducted under the auspices of WCM; and
- Taking action as necessary to ensure the protection of human subjects, the integrity of research and the HRPP, the autonomy and authority of the IRB, the proper conduct of research, and to ensure compliance with regulatory and other requirements. This includes the authority to suspend, terminate, or disapprove research, and to sanction or restrict research privileges. Such actions will be reported to the HRPP and IRB when appropriate (e.g., so that the HRPP and IRB may take any necessary actions to ensure the protection of human subjects).

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

Institutional Review Board Authority

To conduct its responsibility effectively, WCM maintains IRBs to review research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects participating in research activities conducted under the auspices of WCM. Unless

WCM has agreed to rely upon an external IRB for the review of a human research protocol, the WCM IRBs have the following authority to:

- Determine a project does not constitute human research;
- Grant exemptions from IRB review;
- Review non-exempt projects by either Full Committee or Expedited Review and approve, disapprove, or require revisions to secure approval;
- Assess risk of non-exempt research as minimal or greater than minimal;
- Require, review, and approve recruitment materials, consent documents, and HIPAA authorization forms as appropriate for a research project and may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
- Approve waivers of informed consent, documentation of consent, and HIPAA authorization (according to regulatory requirements);
- Conduct continuing review of research requiring such review (e.g., research reviewed by the convened IRB, FDA-regulated research, etc.) at intervals appropriate to the degree of risk of the research, but not less than once per year;
- Evaluate and request changes to project procedures or conflict of interest management plans when an interest related to a research project may affect participants;
- Monitor or observe the consent process and the conduct of human research to ensure that the rights and welfare of research participants are adequately protected;
- Work with WCM administrators (e.g., department heads, deans, chairs, and program directors) in ensuring that non-exempt human research activities are conducted as approved by the IRB;
- Suspend or terminate IRB approval for research that is not being conducted in accordance with the IRB's requirements or is associated with unexpected serious harm to research participants;
- Make determinations in instances of noncompliance (e.g. serious or continuing noncompliance) or unanticipated problems involving participants or others, and implement corrective actions; and
- Investigate reports of human research activities conducted without prior IRB approval and report findings as appropriate; and
- Review any human research protocol conducted at WCM, even if reviewed by an external IRB, and has the right to disapprove or terminate approval of a research protocol that has been approved by the IRB of record. However, no one at WCM shall approve the implementation of human research that has been disapproved or not yet approved by the IRB, nor may anyone override a decision of the IRB.

Human Research Compliance

Human Research Compliance is the institutional component charged with overseeing human research conducted at WCM and is responsible for determining the appropriate review type and/or the determination of engagement in human research and managing the WCM IRB. Human Research Compliance staff should have open communication with researchers and research staff and be responsive to questions, concerns and suggestions. Researchers or staff members may request a meeting with Research Integrity staff to discuss planned research, submission questions, and current regulations and policies. Anonymous concerns or questions may be sent to staff who will address concerns accordingly. Human Research Compliance has the authority and responsibility to:

- Provide guidance and direction to researchers conducting or planning to conduct human research;
- Require investigators and IRB members to complete training according to institutional and federal requirements;
- Determine the appropriate review type for each project and submission;
- Determine when projects are exempt from IRB review requirements (i.e., make exempt determinations);
- Manage review and approval processes for the University's IRBs for non-exempt research including new projects, continuing reviews, and amendments to approved research;
- Coordinate reviews by external IRBs, including development of IRB Authorization and Investigator Agreements when warranted;
- Conduct post approval monitoring and auditing of human research;
- Assess complaints and reported problems for "internal" resolution or for referral to the IRB;
- Assess the quality of the WCM HRPP and make recommendations for improvement;

- Establish and update written procedures and guidance documents;
- Ensure IRB policy and procedures are publicly available;
- Communicate changes in policies, submission forms, review worksheets, and other IRB documents to IRB members and researchers via trainings, listserv messages, emails, and/or notices on the IRB website; and
- Communicate with representatives of other institutional components when human research protection requirements intersect with the component's institutional authority or responsibility.

Undue Influence

Attempts to unduly influence HRPP or IRB members or staff to obtain a particular result, decision, or action by the HRPP or IRB are not tolerated at WCM. Reports of potential undue influence will be thoroughly investigated and, if determined valid, corrective actions will be taken by WCM to manage the situation and prevent additional occurrences.

Operating Procedures

The Institutional Official and the IRB shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of WCM.

V. Procedure

None.

VI. References

Belmont Report
45 CFR 46
21 CFR Parts 50 and 56
28 CFR 512
32 CFR 219 and DoD Directive 3216.02
45 CFR Parts 160 and 164
34 CFR 97, 34 CFR 99 (FERPA), and at 34 CFR 98 (PPRA)
10 CFR 745, DoE Order 443.1C, DoE Order 206.1
40 CFR 26