| HRPP Policy Number: 101<br>Version: 5.0<br>Effective Date: 8/11/25 | Introduction | Supersedes Document<br>Dated: 12/01/16, 01/23/18, 7/16/19, 8/1/20 |
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## HRPP Policy 101: Introduction



### 1.1 Purpose and Scope of the Manual

This manual contains a current compilation of federal, state, University of Denver rules, regulations, policies and procedures applicable to the protection of human research subjects, sets forth appropriate mechanisms for their implementation and is regularly updated to reflect new standards, regulations and the University policy.

### 1.2 Applicability

The policies and procedures set forth in this manual are applicable to all faculty, staff, employees, and students at the University who propose to use human subjects in research, development, and related activities.

The IRB has jurisdiction and oversight responsibilities over human subjects research in which the University is engaged. Specific examples would include but not be limited to research:

1. For which the University receives funding.
2. Conducted by or under the direction of faculty, students, or staff of the University in connection with their institutional responsibilities.
3. Conducted by or under the direction of any faculty, students or staff of the University using any property or facility of the University.
4. The University requires research investigators who are not its employees or agents:
    a. To obtain the collaboration of a University faculty member.
    b. To ensure all PIs (internal and external to the institution) comply with all relevant IRB determinations, federal and state regulatory requirements, DU IRB requirements and human subjects protection standards.

Compliance with this policy or the procedures set forth herein will in no way render inapplicable pertinent laws of the State of Colorado, any local law which may bear upon the proposed activity or the Rules and Regulations of the Board of Trustees of the DU System.

### 1.3 Background Information

Review of the history of human subjects research provides us with many examples of unethical and inhumane treatment of human research subjects. Perhaps the most infamous examples were perpetrated by Nazi physicians during World War II, but there are several other examples of unethical research activities that took place in the United States.

As a result, several international codes arose that addressed the issues of ethical treatment of research subjects. In 1947, the Nuremberg Code established ten major ethical principles for

human subjects research and later the World Medical Association established its own code of research ethics at a meeting in Helsinki, Finland and revised it several times over the years to keep pace with the changing technologies and types of human subjects research.

In the United States, concern over the rights and welfare of humans involved in research prompted changes in grant policy. In 1974 Congress enacted the National Research Act (P.L. 93-348) establishing a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, the National Commission published the now well-known Belmont Report that identified three basic ethical principles as relates to human subjects research. The principles are; respect for persons, beneficence, and justice. In January 1981, human subject regulations were amended to provide a common framework within which Institutional Review Boards (IRBs) could review human subjects research. The regulations were codified in 1991 under Title 45, Part 46 of the Code of Federal Regulations. Subpart A of the codification was accepted by seventeen Federal Agencies as "the Common Rule." In additional to Subpart A, other subparts were incorporated into the Common Rule to provide safeguards for vulnerable populations that require additional legal, regulatory and institutional protections.

## 1.4 Mission

The mission of The University of Denver (University) is to achieve excellence in the interrelated areas of undergraduate education, graduate education, research and public service. The University provides superior and comprehensive educational opportunities at the baccalaureate through doctoral and special professional educational levels.

The University contributes to the advancement of society through research, creative activity, scholarly inquiry and the development of new knowledge. The University preserves and promotes the arts, benefits the state's economy, serves the citizens through public programs and provides other public service.

## The University's Human Research Protection Program (HRPP)

Coupled with the research programs, the University strives to protect the rights and welfare of human subjects who choose to participate in biomedical or socio-behavioral science research and has an organized and systematic program in place for the protection of research subjects that includes a commitment to the principles and guidelines for protecting research subjects contained in the Belmont Report. Central to this program, the University maintains a Federal Wide Assurance (FWA) of Compliance (hereafter referred to as "Assurance") with the Department of Health and Human Services' Office for Human Research Protections (OHRP) (FWA # 00004520). This Assurance is renewed every five years and commits the University to abiding by all federal regulations and guidelines with respect to its research activities involving human subjects.

Based on the principles of the Belmont Report - respect for persons, beneficence, and justice - the over-arching goal of the Human Research Protections Program (HRPP) is to protect the rights and welfare of human research subjects at the University.

## 1.5 Institutional Commitment

### Institutional Official (IO)

The University leadership is committed to upholding the University's Assurance, improve the research infrastructure to ensure a strong HRPP and, through evaluation and assessment, initiate required improvements in the HRPP. At the University, the individual designated by the Provost as ultimately responsible for the Assurance and implementation of the University HRPP is the Senior Vice Provost for Research & Graduate Education, also referred to in the Assurance as the

Institutional Official (IO). The IO is the University official responsible for ensuring that the HRPP has the resources and support necessary to comply with federal regulations and guidelines that govern human subjects research.

As an agent of the institution, the IO is legally authorized to represent the institution in matters regarding human subjects research, is the signatory official for all Assurances and assumes the obligations of the University's Assurance. The IO is also responsible for review and evaluation of reports on HRPP performance and Quality Improvement (QI) activities. The IO is responsible for further institutional review and approval or disapproval of research approved by the University Institutional Review Board (IRB) (neither the IO nor any other University official can approve research that was disapproved by the IRB). To facilitate this oversight function, the Office of Research Integrity & Education forwards to the IO copies of all IRB meeting minutes, containing reports of IRB deliberations on human subjects protocols, the results of QI audits and noncompliance findings, if needed or requested. All correspondence and reports sent to federal regulatory agencies regarding investigator or institutional noncompliance are signed by the IO.

**Research Integrity Director**
The Research Integrity (RI) Director implements needed improvements and follow-up actions relating to the principal investigator (PI) and institutional compliance of University's HRPP. The RI Director is responsible for monitoring changes in federal, state or local regulations, policies and guidelines relating to the human subjects research, ensuring that the IRB and IO are informed of the changes and assuring compliance with all requirements.

In general, however, it is the responsibility of all faculty, staff and students, IRB members, IRB staff, University staff negotiating with research sponsors, and anyone else involved in human subjects research to uphold the ethical standards delineated in the Belmont Report and assure that the highest level of human subjects protections are in place and implemented at all times.

## 1.6 Human Subjects Research Oversight

### Federal and State Regulations in regards to Human Subjects Research

The OHRP provides leadership on human research subject protections and implements a program of compliance oversight for U.S. Department of Health & Human Services (HHS) regulations for the protection of human subjects. Visit the OHRP website at **http://www.hhs.gov/ohrp/**. OHRP works to support and strengthen the nation's system for protecting those who volunteer to participate in research that is conducted or supported by agencies of HHS. OHRP also provides guidance to IRB members and IRB staff as well as to scientists and research administrators on the complex ethical and regulatory issues relating to human subjects protections in medical and behavioral research.

Within HHS, the Food and Drug Administration (FDA) has oversight over FDA-regulated research (drugs, biologics, medical devices, and foods) as described in the FDA oversight policies Title 21, Parts 50 and 56. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. For more information on Code of Federal Regulations visit the FDA website at:

**21 CFR Part 50**
**21 CFR Part 56**

The University will comply with all applicable state laws regarding human subjects research. If research takes place outside the state of Colorado, the IRB will consult with legal counsel, as

appropriate, who provides interpretation and guidance to the IRB. In situations where there are conflicts between federal and state, or other applicable laws, legal counsel will be consulted to advise on the resolution of the conflicts.

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The Office of the Senior Vice Provost for Research & Graduate Education is responsible for the administration and oversight of research ethics at the University. The IO oversees the functioning of the IRB. The ORIE Director is responsible for provision of IRB administrative support. Administrative professional staff are periodically evaluated regarding their knowledge and interpretation of relevant policies and procedures regarding human subject protections.

### 1.7 Revision and Maintenance of the Manual

The Office of Research Integrity & Education is responsible for maintaining and updating this manual. All new or revised manual materials will be posted on the Research Policies website at: https://www.du.edu/orsp/research-policies.