



VILLANOVA UNIVERSITY

Human Research Protection Program (HRPP) Plan

Revised: January 25, 2019



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Scope

Throughout this document “institution” refers to Villanova University.

Purpose

This institution is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this institution’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research, funded or unfunded, and regardless of the source of any funding.

This institution’s Human Research Protection Program (HRPP) Plan is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP Plan is based on all individuals in this institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

Definitions

Agent

An individual who is an employee is considered an agent of this institution for purposes of engagement in Human Research when that individual is acting in any capacity as an employee of this institution.

An individual who is not an employee is considered an agent of this institution for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this institution.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this institution.

The Villanova University Approval, Signing Authority and Contract Review Procedure (available at [this link](#)), describes the authority of various offices and individuals to approve certain actions on behalf of the institution and review and sign contracts and other legal documents on behalf of the University. In the event of the absence of applicable policy or procedure, or in the event of a conflict between policies or procedures, the Office of the Provost and General Counsel will determine whether someone is acting as an agent of this institution.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, this institution is considered engaged in Human Research when this institution’s employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects



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for the research. This institution follows OHRP guidance on “Engagement of institutions in Research”¹ to apply this definition and exceptions to this definition.

Human Research:

Any activity that is “Research” as defined by DHHS and involves “Human Subjects” as defined by Department of Health and Human Services (“DHHS Human Research”).

Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research 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.

For the purpose of this definition:

- **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means 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 (for example, a medical record).
- **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Investigator

The investigator is the person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the Principal Investigator is the responsible leader of the team. The Principal Investigator (PI) or the Co-Investigator (Co-PI) will be the responsible party for the purposes of the institution’s HRPP Plan.

¹ <http://www.hhs.gov/ohrp/policy/engage08.html>



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Research as Defined by DHHS

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.²

Mission

The mission of this institution’s Human Research Protection Program Plan (HRPP Plan) is to protect the rights and welfare of subjects involved in Human Research that is overseen by this institution.

Ethical and Legal Requirements

In the oversight of all Human Research, this institution (including its investigators, research staff, students involved with the conduct of Human Research, the institution’s Institutional Review Board (IRB), IRB Chair and Vice Chair, Members, and Staff, the Institutional Official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

- Respect for Persons
- Beneficence
- Justice

This Institution commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by the Office of Research Protections and the Villanova University Institution Review Board (IRB). Activities that do not meet the definition of Human Research do not require review and approval by the institution’s IRB and do not need to be submitted to the institution’s IRB unless there is a question regarding whether the activity is Human Research, or the investigator would like assurance by requesting a formal determination that the activity is not considered to be human subjects research. Human research as defined by DHHS is an activity that is research and involves human subjects, as defined by DHHS. Human subjects, as defined by DHHS, is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, or (2) information that is both private information and identifiable information.

The Villanova University IRB reviews projects when:

1. the institution sponsors the research,
2. the research is conducted by or under the direction of any employee, student, or agent of Villanova in connection with his or her institutional responsibilities, including in

² For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.



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collaboration with other individuals who are not employees, students, or agents of the University,

3. the research is conducted by or under the direction of any employee, student, or agent of Villanova using any property or facility of this institution, including in collaboration with other individuals who are not employees, students, or agents of the University,
4. the research involves the use of Villanova University (VU's) non-public information to identify or contact human subjects, or
5. the research involves non-Villanova investigators using faculty, staff, or students as research subjects on Villanova property.

When this institution is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency that is a signatory of the Common Rule, the institution commits to apply the regulations of that agency relevant to the protection of Human Subjects. The Common Rule is a 1991 rule of ethics in the United States regarding biomedical and behavioral research involving human subjects. It is heavily influenced by the Belmont Report, which established ethical principles and guidelines for research involving human subjects. The core principles being respect for persons, beneficence, and justice.³

A Final Rule was issued in 2017 and adopted on January 21, 2019 by the U.S. Department of Health and Human Services (HHS) and other agencies to update the previous 1991 regulations (the Common Rule). These revisions were intended to reflect up-to-date practices of human subjects research, reduce the administrative and regulatory burden related to human subjects research, and better protect human subjects. Villanova University fully complies with this Revised Common Rule.

The Villanova University IRB is not a Food and Drug Administration (FDA)-covered review board. Therefore, the Villanova University IRB will engage an FDA-covered board in the case of research subject to the FDA requirements set forth at 21 CFR 50 (informed consent), 21 CFR 56 (IRB), 21 CFR 312 (investigational new drugs), 21 CFR 812 (investigational devices), and 21 CFR 814 (humanitarian use devices).

The institution's IRB or Institutional Official (IO) may elect to rely on a single IRB for research conducted at multiple locations or to engage other IRBs to review certain research.

If collaborative agreements are required to conduct human subjects research, the agreement must be signed by the ORP. If a data use or a data share agreement is required to conduct human subjects research, the ORP will make the final determination as to the necessity and will ultimately sign the agreement on behalf of the institution.

³ https://en.wikipedia.org/wiki/Belmont_Report



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Investigators, who are currently not affiliated with Villanova University, must sign an agreement to conduct research on campus, with the Villanova student population, and/or use of Villanova’s resources and facilities; and must comply with established Villanova University policies, training, and financial disclosure requirements concerning the conduct of human subjects research.

If the human subjects research requires data extraction from Villanova University, the study must first be approved by the University.

Approval of human subjects research by Villanova University IRB does not equate to an institutional approval.

The Principal Investigator cannot sign compliance documents or agreements on behalf of Villanova University.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the ORP, which will provide a determination.

When reviewing research that involves community-based research, the IRB obtains consultation or training. Community-based participatory research (CBPR) is explained as a partnership approach to research that equitably involves, for example, community members, institutional representatives, and researchers in all aspects of the research process and in which all partners contribute expertise and share decision making and ownership⁴.

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, status update reporting, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

⁴ References for community-based participatory research: Israel, B.A., Schulz, A.J., Parker, E.A., & Becker, A.B. (1998). Review of community-based research: Assessing partnership approaches to improve public health. *Annual Review of Public Health*, 19, 173-202. And Israel, B.A., Schulz, A.J., Parker, E.A., Becker, A.B., Allen, A., & Guzman, J.R. (2008). Critical issues in developing and following CBPR Principles. In M. Minkler & N. Wallerstein (Eds.), *Community-based participatory research for health: From process to outcomes* (2nd ed., pp. 47-66). San Francisco: Jossey-Bass.



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For clinical trials, this institution commits to apply the “Clinical Trials Registration and Results Reporting Policy”. For instances requiring a Data Safety Monitoring Board (DSMB), please contact the Office of Research Protections for guidance. The VU DSMB policy is currently being developed.

This institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”).

Sponsored Human Research

For both sponsored and non-sponsored Human Research this institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Human Research Protection Program Policies and Procedures’

Policies and procedures for the HRPP Plan are available on the following Web site: <https://www1.villanova.edu/villanova/provost/research-administration/research-protections/irb/policies-procedures.html>.

The HRPP Plan will be presented to the President of the institution for approval but the authority to implement the Plan, develop policies, guidelines, and other resources to assist the research community, is delegated to the Associate Vice Provost of Research and ORP.

Human Research Protection Program Components

Institutional Official (IO)

The Associate Vice Provost for Research is designated as the Institutional Official (IO).

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Create the HRPP Plan budget.
- Allocate resources within the HRPP Plan budget.
- Appoint and remove IRB members and IRB chairs.
- Hire and fire ORP staff.
- Determine what IRBs the institution will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research.
- Create policies and procedures related to the HRPP Plan that are binding on the institution.
- Appoint an investigations committee of IRB Members, when warranted, to investigate new information received by the Office of Research Protections.
- Suspend or terminate research approved by the institution’s IRB.
- Disapprove research approved by the institution’s IRB.



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The Institutional Official has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the HRPP Plan.
- Periodically review this Plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements.
- Institute regular, effective, educational forums and/or training programs for all individuals involved with the HRPP Plan.
- Ensure that the research review process is independent and free of coercion or undue influence and ensure that officials of the institution cannot approve research that has not been approved by one of the IRBs designated by the institution.
- Ensure that the IRB Chair(s) and members have direct access to the IO for consultation and assistance if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the HRPP Plan.
- Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Enforce policies of the IRB and ensure that appropriate processes are in place to review and correct any systemic or individual instance of actual or potential non-compliance.
- Investigate and remediate identified systemic problem areas, and where necessary remove individuals from involvement in the HRPP Plan.
- Ensure that the Human Research Protection Program has sufficient resources, including an IRB appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal-wide assurances (FWA) and addenda.
- Fulfill educational requirements mandated by the Office of Human Research Protections (OHRP).

All members of the Institution

All individuals within the institution have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the Villanova University ORP when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by Villanova University's IRB or the IRB designated by the Institutional Official.



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- Report allegations of undue influence regarding the oversight of the HRPP Plan or concerns about the HRPP Plan to the Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the HRPP Plan to the IRB.

IRBs

New research submissions must be submitted to the ORP. A determination will be made as to which IRB or IRB of record is appropriate for each research protocol.

The list of IRBs designated by the Institutional Official to be the IRBs relied upon by the HRPP Plan and the scope of review of these IRBs is listed in the IRB rosters available from the Office of Research Protections.

This institution may rely upon IRBs of another institution provided one of the following is true:

- The IRBs are part of an Association for the Accreditation of Human Research Protection Program (AAHRPP) accredited institution.
- This institution’s investigator is a collaborator on Human Research that is primarily conducted at another institution and the investigator’s role does not include interaction or intervention with subjects.
- The institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather, or possess private identifiable information about subjects, nor obtain the consent of subjects.)
- This institution’s investigator is a collaborator on Human Research that is primarily conducted at another institution whose IRB is not accredited by AAHRPP, the investigator’s role includes interaction or intervention with subjects, and we have established a reliance agreement with the outside IRB after a careful vetting process.
- A federal funding agency directs us to rely on an external IRB.

Reliance on an external IRB requires an Institutional Agreement for IRB Review and a local review for compliance with local policies of the institution. When Human Research carried out at this institution or by its agents is reviewed by an IRB at another institution, this HRPP will follow established policies and procedures that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.

The IRBs relied upon by this institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the institution. All Human Research must be approved by the Villanova University IRB designated by the Institutional Official. Officials of this institution may not approve Human Research that has not been approved by Villanova University’s IRB.



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- Suspend or terminate approval of Human Research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management Plan, if any, allow the Human Research to be approved. The IRB shall confer with the Conflict Review

Committee established pursuant to Villanova University's Financial Conflict of Interest in Research Policy.

This institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.

When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, status update reporting, and review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and institution) of its decisions, make relevant IRB policies and records available to the relying institution or institution and specify an IRB contact for communication.

IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.



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Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Institutional Official.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice or recommend or engage outside experts upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the institution.
- Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans

Deans have the responsibility to:

- Oversee the review and conduct of Human Research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Office of Grants and Contracts

The Office of Grants and Contracts has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Education and Training

All new employees who will be involved in the review or conduct of research with human subjects are to review this Plan as part of initial orientation. The Office of Research Protections will provide a refresher training for current employees as needed to maintain awareness of this policy.

IRB members, IRB staff, and others involved in the review of Human Research, including the Institutional Official, must complete initial and continuing training.



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Prior to serving on a Villanova IRB, all appointed members must:

- Complete the required Collaborative Institutional Training Initiative (CITI) Human Subject Research Courses, and any other required training, before serving on the IRB;
- Disclose Significant Financial Interests, according to the Villanova University Financial Conflict of Interest in Research Policy; and other Conflicting Interests as defined per HRP-50 – SOP – Conflicting Interests of IRB Members
- Meet with the IRB Chair and/or ORP for orientation.
- Ongoing education of IRB members may include educational presentations provided during IRB meetings, review and discussion of relevant publications, journal articles, and materials from relevant federal agencies during IRB meetings, attendance at appropriate IRB training conferences, courses and professional association meetings and ongoing involvement on the IRB.

Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

Questions and Additional Information for the IRB

The Office of Research Protections welcomes your questions, information, and feedback.

Contact and location information for the Office of Research Protections is:

Office of Research Protections
Villanova University
ORP General Phone: 610-519-4228
ORP@villanova.edu
IRB@villanova.edu

Reporting and Management of Concerns

Members of the Villanova University community are strongly encouraged to ask questions and raise any concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP Plan either orally or in writing. Concerns may be reported to the IRB Chair, Office of Research Protections, Institutional Official, Legal Counsel, University Compliance Officer, Deans, or Department Chairs. Reports can also be submitted via the EthicsPoint hotline as further described below.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

To make such reports, contact the Institutional Official:

Amanda M. Grannas, Ph.D.



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Associate Vice Provost for Research; Professor of Chemistry
Email: amanda.grannas@villanova.edu
Phone: (610) 519-4881

Concerns can be raised via the EthicsPoint hotline, a confidential online and phone-based service that gives faculty, staff, and students an anonymous and confidential way to report misconduct in the workplace, classroom, or laboratory, instances of non-compliance, or other violations of law or University policy.

EthicsPoint is available 24/7, online at the following link ([here](#)) or by calling toll-free **855-236-1443**. You can obtain more information regarding the hotline at the following link ([here](#)).

The University prohibits retaliation against any individual who, in good faith, makes a report, files a complaint, or participates in the investigation or resolution of an allegation. Concerns about possible retaliation should be reported immediately to the Institutional Official or the University Compliance Officer.

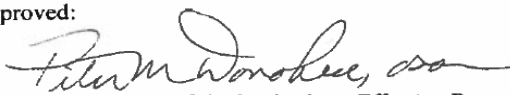
Monitoring and Auditing

In order to monitor and ensure compliance, the University Chief Internal Auditor, University Compliance Officer, Office of the General Counsel, and other internal or external subject matter experts and/or auditors who have expertise in federal and state statutes, regulations and institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted. This monitoring and auditing is in addition to, and not in lieu of, the institution's IRB's authority to monitor and audit research, which includes the right to monitor, review and audit any Human Research conducted in connection with the research described in the "**Legal Requirements**" section above.

Approval and Revisions to the Plan

This HRPP Plan will be presented to the President of the institution for approval. The Plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this Plan to assess whether it is providing the desired results. At the request of the Institutional Official, the University President, or designee has the authority to amend this Plan as deemed necessary.

Approved:

 2/18/19
<Name> President of the institution <Effective Date>

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