# Table of Contents

Scope ........................................................................................................................................................ 3  
What is the purpose of this manual? ......................................................................................................... 3  
What is Human Research? ........................................................................................................................ 3  
What is the Human Research Protection Program? .................................................................................. 3  
Who is qualified to be a Principal Investigator (PI)? .............................................................................. 4  
What training do my staff and I need to conduct Human Research? ....................................................... 4  
What financial interests do my staff and I need to disclose to conduct Human Research? ...................... 5  
How do I submit new Human Research to the IRB? .............................................................................. 6  
How do I write a Research Protocol? ........................................................................................................ 9  
How do I create a consent document? ....................................................................................................... 10  
How do I create an assent document? ..................................................................................................... 10  
What are the different regulatory classifications that research activities may fall under? ................. 10  
What are the decisions the IRB can make when reviewing proposed research? .................................... 11  
How does the IRB decide whether to approve Human Research? ......................................................... 11  
How does the IRB decide whether a study is considered to be a clinical trial? .................................... 12  
What will happen after IRB review? ...................................................................................................... 12  
What are my obligations after IRB approval? ...................................................................................... 12  
How do I document consent? ................................................................................................................. 14  
How do I document assent? .................................................................................................................... 14  
How do I submit a modification? ........................................................................................................... 14  
How do I submit continuing review? .................................................................................................... 15  
How do I submit a status update report? ............................................................................................... 17  
How do I close out a study? ..................................................................................................................... 18  
What if I want to do collaborative research? .......................................................................................... 19  
What are my record keeping responsibilities? ....................................................................................... 20  
How long do I keep records? .................................................................................................................. 20  
How do I get additional information and answers to questions? ........................................................... 21  
Appendix A-1 Additional Requirements for DHHS-Regulated Research.............................................. 22
**Scope**
Throughout this document “institution” refers to Villanova University.

**What is the purpose of this manual?**
This document “INVESTIGATOR MANUAL (HRP-103)” is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see page 4: “What training do my staff and I need to conduct Human Research?”

**What is Human Research?**
The “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” defines the activities that this institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in the “WORKSHEET: Human Research Determination (HRP-310),” located in the IRB Policies & Procedures section of Villanova University’s IRB website. Use this document for guidance as to whether an activity meets the Department of Health and Human Services (DHHS) definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and approval of exempt Human Research). If you have questions about whether an activity is Human Research, contact the Office of Research Protections who will provide you with a determination. If you wish to have a written determination, provide a written request to the Office of Research Protections.

**What is the Human Research Protection Program?**
The document “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” describes this institution’s overall plan to protect subjects in Human Research, including:

- The mission of the Human Research Protection Program.
- The ethical principles that the institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.
- When the institution becomes “engaged in Human Research” and when someone is acting as an agent of the institution conducting Human Research.
- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the institution with regard to Human Research
Who is qualified to be a Principal Investigator (PI)?

A Principal Investigator (PI) must demonstrate, to the satisfaction of the IRB, knowledge and understanding of the federal, state, and institutional policies, procedures, and regulations for the protection of human research subjects. A PI may only conduct research that is within the scope of the researcher’s expertise. Such demonstration may include:

- Completion of CITI Trainings and/or other institutional trainings
- Organizational approval from the Chair and Dean of the department on protocol submissions;
- Confirmation of faculty status or presence of a faculty advisor;
- Assertion of industry-standard professional credentials;
- A review of the research by a panel of qualified peers either internal or external to the organization.

Beyond qualifications, the Principal Investigator Status on Sponsored Projects Policy provides who is eligible for Principal Investigator or Co-Principal Investigator status at Villanova. In general, post-doctoral fellows, graduate or undergraduate students may only serve as Principal Investigators or Co-Principal Investigators when explicitly called for in the guidelines for a specific funding opportunity. Otherwise, they may not be named in these capacities. Please refer to the actual policy for additional information.

What trainings do my staff and I need to conduct Human Research?

This section describes the training requirements mandated by the Villanova University IRB. You may have additional training mandated by other federal, state, or institutional policies.

Please refer to Table 1. for an overview of the required trainings.

<table>
<thead>
<tr>
<th>TABLE 1. TRAINING REQUIREMENTS FOR HUMAN SUBJECTS RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ All four CITI Trainings listed below: Create an account at <a href="http://www.citiprogram.org">www.citiprogram.org</a>, selecting Villanova University from the pull-down. To choose correct CITI courses, you will be prompted to fill out a questionnaire when you log in.</td>
</tr>
<tr>
<td>1. CITI Conflicts of Interest (COI) (Do not confuse the COI COURSE with the COI MODULE in the other CITI courses.) Choose YES in the questionnaire when asked if you would like to take the COI course. Refresher required every 4 yrs.</td>
</tr>
<tr>
<td>2. CITI Responsible Conduct of Research (RCR) according to department. When you first log in to CITI, use the questionnaire to guide your choice. Refresher required every 3 yrs.</td>
</tr>
<tr>
<td>3. CITI Human Subjects Research according to department. There are two choices: Biomedical Research or Social &amp; Behavioral Research. Refresher required every 3 yrs.</td>
</tr>
<tr>
<td>4. CITI Revised Common Rule In practice of implementing the January 2019 regulatory changes governing human subjects research, all researchers submitting protocols for review will be required</td>
</tr>
</tbody>
</table>


Investigators and staff conducting human subjects research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. The CITI site can be accessed at http://www.citiprogram.org/.

CITI Refresher course trainings will be required either at the end of the three-year period, at the time of regulatory changes, or at the direction of the IRB.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

What financial interests do my staff and I need to disclose to conduct Human Research (FCOI)?

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institutional responsibility to promote objectivity in research.

Significant Financial Interests of an investigator, and those of the investigator’s spouse and dependent children, that are set forth in federal regulations and which reasonably appear to be related to the investigator’s institutional responsibilities to promote objectivity in research must be reported. This may include non-Villanova salary, equity interest, consulting fees, travel, and honoraria.

All individuals involved in the design, conduct, or reporting of research are required to disclose any financial interests they may have on a yearly basis.

Financial Conflicts of Interest disclosures (FCOI) are reported through COI RiskManager, located here.

If this is your first time completing an FCOI Disclosure, please email resadmin@villanova.edu with your Villanova username. You will then receive an acknowledgement email for your initial login.
Financial Disclosures must be submitted:

- On submission of an initial review.
- At least annually as part of continuing review or status update report
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Individuals subject to the Financial Conflict of Interest in Research Policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

- Joining the institution.
- Financial conflicts policies are revised in a manner that changes investigator requirements.
- Non-compliance with either the financial conflicts policies and procedures or a conflict management plan takes place.

IRB members are also required to disclose conflicts of interest that may arise in their review of research protocols. For more information on this, please review HRP-50 – SOP – Conflicting Interests of IRB Members.

**How do I submit new Human Research to the IRB?**

CAYUSE IRB is Villanova’s online protocol management system to support all activities relating to human subjects research at this institution.

To create a CAYUSE account, you must log on to CAYUSE IRB using your Villanova username and password. If you are not already logged on to your Villanova account in your current browser, you will be prompted to enter your VU username and password. If you are unable to access your account for any reason, email resadmin@villanova.edu and you will be asked to fill out and submit a CAYUSE request form, also found on Villanova’s IRB website under “Forms and Templates”. Please note that it takes at least 24 hours to be added as a new member.

To submit a new study, log in to CAYUSE IRB and click the “New Study” button in the upper right corner.
After entering the full title, create a new Initial submission by clicking the “New Submission” button in the upper right corner.

Click the “Edit” button to fill out the form and attach all requested supplements.

Review and confirm that you understand the roles and responsibilities of Investigators and Research Staff.
To add research staff and check staff trainings, fill out the form by clicking “FIND PEOPLE”
After completing all required fields (marked with a red asterisk), the Routing/Complete Submission button will appear in the left menu. Click to Submit. The protocol will then be routed to the PI, followed by co-investigators, for certification. Please note that your study cannot be processed by ORP until Organizational Approval is granted.

How do I write a Research Protocol?

When writing a Research Protocol, always keep a copy of your work outside of CAYUSE.

- If you believe your activity may not be Human Research, contact the Office of Research Protections prior to developing your Investigator Protocol.
- If you believe your protocol could qualify as a clinical trial, contact ORP for guidance
- Note that, depending on the nature of your research, certain questions will become available depending on the applicability of those questions to the answers you provided or selected in prior questions.
- You may not involve any individuals who are members of the following vulnerable populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.
  - Adults unable to provide legally effective consent
  - Individuals who are (infants, children, teenagers)
  - Prisoners
If you are conducting community-based participatory research, you may contact the Office of Research Protections for information about:

- Research studies using a community-based participatory research design
- Use of community advisory boards
- Use of participant advocates
- Partnerships with community-based institutions or organizations

**How do I create a consent document?**

Use the “INFORMED CONSENT TEMPLATE – REVISED COMMON RULE” to create a consent document.

Note that all consent documents must contain all the required and all additional appropriate elements of informed consent disclosure, which have been updated as per the regulatory requirements set forth in the Revised Common Rule as of January 21st, 2018.

IRB recommends that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

**How do I create an assent document?**

If your study involves the recruitment of minors as research subjects, use the age-appropriate assent template “ASSENT TEMPLATE (5-8 years old, 9-12 years old, 13-17 years old)” to create an assent document. If you plan to recruit children under the age of 5, you must develop an assent process that is approved by the IRB.

**What are the different regulatory classifications that research activities may fall under?**

Submitted activities may fall under one of the following four regulatory classifications:

- **Not “Human Research”:** Activities must meet the institutional definition of “Human Research” to fall under IRB oversight. Activities that do not meet this definition are not subject to IRB oversight or review. Review the Office of Research Protections’ “WORKSHEET: Human Research Determination (HRP-310)” for reference. Contact the Office of Research Protections in cases where it is unclear whether an activity is Human Research.

- **Exempt:** Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the Office of Research Protections’ “WORKSHEET: Exemption Determination (HRP-312)” for reference on the categories of research that may be exempt.
  - Limited IRB Review is a condition of exemption, and only applies to certain Exempt categories of research. Please contact ORP for more information.
Review Using the Expedited Procedure: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the Office of Research Protections’ Use “WORKSHEET: Expedited Review (HRP-313)” for reference on the categories of research that may be reviewed using the expedited procedure.

Review by the Convened IRB: Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB. This is referred to as a full-board study.

What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, or disapprove research:

- **Approval:** Made when all criteria for approval are met. See “How does the IRB decide whether to approve Human Research?” below.

- **Modifications Required to Secure Approval:** Made when IRB members require specific modifications to the research before approval can be finalized.

- **Tabled:** Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

- **Deferred:** Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.

- **Disapproval:** Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve Human Research?

The criteria for IRB approval can be found in the “WORKSHEET: Exemption Determination (HRP-312)” for exempt Human Research and the “WORKSHEET: Criteria for Approval (HRP-314)” for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the Villanova University IRB website.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.
You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval.

**How does the IRB decide whether a study is considered to be a clinical trial?**

A clinical trial is 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. The IRB will decide whether your research activity meets the definition of a clinical trial, and if so, will provide guidance on next steps to ensure that you are compliant with the federal requirements for clinical trials; which includes registering your study with clinicaltrials.org. For clinical trials, this institution commits to apply the “Clinical Trails Registration and Results Reporting Policy”.

**What will happen after IRB review?**

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- **If the IRB has approved the Human Research:** The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.

- **If the IRB requires modifications to secure approval and you accept the modifications:** Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.

- **If the IRB defers the Human Research:** The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable, and give you an opportunity to respond in writing. In most cases if the IRB’s reasons for the deferral are addressed in a modification, the Human Research can be approved.

- **If the IRB disapproves the Human Research:** The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

**What are my obligations after IRB approval?**

1) Do not start Human Research activities until you have the final IRB approval letter.
2) Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.

3) Ensure all external approvals required to conduct the study are in place.

4) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

5) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

6) Promptly update the IRB office with any changes to the list of study personnel.

7) Personally, conduct or supervise the Human Research. Recognize that the Principal Investigator is accountable for the failures of any study team member.
   a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
   b) When required by the IRB, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   c) Do not modify the Human Research without prior IRB approval.
   d) Protect the rights, safety, and welfare of subjects involved in the research.

8) Submit to the IRB:
   a) Proposed modifications as described in this manual. (See “How do I submit a modification?”)
   b) A continuing review application as requested in the approval letter. (See “How do I submit continuing review?”)
   c) A status update report as requested in the approval letter. (See “How do I submit a status update report?”)
   d) A closure application when the Human Research is closed. (See “How Do I Close Out a Study?”)

9) Report any unanticipated or adverse events promptly to IRB on CAYUSE using the “Incident” tab located in the drop-down menu under “+ New Submission”

10) Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

11) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”).

12) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

13) Maintain active protocol if analysis of identifiable data is involved.

14) See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do no override the baseline requirements of this section.

15) If the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the Office of Research Protections or study sponsor with any questions.
16) In some cases (e.g. clinical trials) additional review may be required by other compliance committees. This may include review by the Data Safety Monitoring Board (DSMB), in which case the Investigator will be responsible for cooperating and facilitating that oversight and review. The DSMB policy is currently under development. The IRB Office will notify you if this additional review applies to your research.

**How do I document consent?**

Do not alter the stamped consent form. Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.

**How do I document assent?**

Assent, as defined in the regulations, means a child’s affirmative agreement to participate in research. Mere failure to object should not be interpreted as assent. (45 CFR 46.402(b)).

The Villanova IRB will approve the assent process appropriate for your study, which may include a procedure for how to best document assent. The IRB will provide further guidance on case by case basis.

**How do I submit a modification?**

Login to Cayuse IRB and click on the protocol you wish to modify.

Click on the “New Submission” button in the upper right corner, then select “Modification.”
Click Edit to fill out the form and describe all changes on the Modification Cover Page. Be sure to include all changes described on the Cover Page throughout your protocol document and the Cayuse Application and update all supplements. Before submitting the modification for review, you must:

- Ensure all study staff have completed their annual online Financial Conflict of Interest (FCOI) form
- Ensure all study staff are up to date on all required CITI training

After completing all required fields (marked with red asterisk), the Routing/Complete Submission button will appear in the left menu. Click to Submit. The protocol will then be routed to the PI, followed by co-investigators, for Certification.

Please note that the research activities cannot include the modification until IRB approval is received. Modifications that are solely limited to updates to the list of study personnel will be acknowledged via expedited review.

**How do I submit continuing review?**

Full-board studies and studies determined by the IRB to be clinical trials must submit an annual continuing review.

Note that all clinical trials, including those approved as exempt or expedited, are required to submit annual continuing reviews.

Login to Cayuse IRB and click on the protocol you wish to renew.
Click on the “New Submission” button in the upper right corner, then select “Renewal.”

Click Edit to fill out the form. Before submitting the research for continuing review, you must:

- Ensure all study staff have completed their annual online Financial Conflict of Interest (FCOI) form
- Ensure all study staff are up to date on all required CITI training

After completing all required fields (marked with red asterisk), the Routing/Complete Submission button will appear in the left menu. Click to Submit. The protocol with then be routed to the PI, followed by co-investigators, for Certification.

If the continuing review involves modifications to previously approved research, submit those modifications as a separate request for modification by creating a new Modification submission in Cayuse along with the Renewal submission.

If the continuing review application is not received by the date requested in the approval letter, you will be restricted from beginning any new Human Research until the completed application has been received.
If the approval of Human Research expires, all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures beyond expiration of approval is a violation of institutional both federal regulations and organizational policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

**How do I submit a status update report?**

Expedited studies that are determined by the IRB to involve no more than minimal risk must submit a status update report.

Note that some expedited studies previously requiring continuing review will now require a status update report instead. Contact ORP for more information.

If you have an expedited or exempt study that is also a clinical trial, please see “How do I submit a continuing review?”

Login to Cayuse IRB and click on the protocol you wish to renew.

Click on the “New Submission” button in the upper right corner, then select “Status Update Report.”

Click Edit to fill out the form. Before submitting the research for its annual status report, you must:

- Ensure all study staff have completed their annual online Financial Conflict of Interest (FCOI) form
- Ensure all study staff are up to date on all required CITI training

After completing all required fields (marked with red asterisk), the Routing/Complete Submission button will appear in the left menu. Click to Submit. The protocol will then be routed to the PI, followed by co-investigators, for Certification.

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**How do I close out a study?**

Login to Cayuse IRB and click on the protocol you wish to close.

Click on the “New Submission” button in the upper right corner, then select “Closure.” Click Edit to complete the form and then submit.

After completing all required fields (marked with red asterisk), the Routing/Complete Submission button will appear in the left menu. Click to Submit. The protocol will then be routed to the PI, followed by co-investigators, for Certification.
If the application for closing out a Human Research study is not received by the date requested in the approval letter, you will be restricted from beginning any new Human Research until the completed application is received.

**What if I want to do collaborative research?**

When collaborating with a researcher at another institution, both the Villanova IRB and the external IRB may engage in one or more methods to ensure that the cooperative research has proper initial review and oversight. Please see below for common methods of collaboration.

Data Sharing/Use Agreement: A formal, written document shared between two or more collaborators and their institutions to outline the parameters for sharing/using data collected during and following the course of their researcher’s study.

- Used when: A Villanova PI is either receiving, giving, or sharing data with a researcher at another institution.

Reliance Agreement: A reliance agreement, which is also referred to as an IRB Authorization Agreement (IAA), is a formal, written document that provides a mechanism for two or more institutions collaborating on research to delegate institutional review board (IRB) review to a single IRB or “IRB of record.”

- Used when: A Villanova PI is conducting human subjects research in conjunction with a researcher at another institution, and the research falls under the expedited or full-board categories of review. The institutions involved make a joint, formal agreement to cede review to one of the institution’s IRB. For exempt studies, a reliance agreement may not be an option.

Please contact the [Office of Research Protections](#) to get started or ask questions about whether this is appropriate in your situation.
What are my record keeping responsibilities?

The PI is responsible for maintaining appropriate research-related records. All research records must be available for immediate inspection by authorized representatives of federal regulatory agencies, the sponsor, Villanova University, and the IRB. The PI must maintain, as appropriate:

- A list of qualified persons to whom the PI has delegated significant research-related duties;
- Signed and dated informed consent forms, or consent in the format approved by the IRB;
- If applicable, consult with the Office of Research Protections regarding record keeping of broad consent;
- Research privacy forms, (e.g. Health Insurance Portability and Accountability Act (HIPAA) authorizations and consent documents)
- All records submitted to the IRB with evidence of IRB-certified approval notifications;
- All data collection forms;
- Participant enrollment log;
- Other records as directed by the Villanova University IRB
- For studies involving additional review by the Data Safety Monitoring Board (DSMB), record keeping and reporting responsibilities can be found in the DSMB policy, which is currently under development. Contact ORP if you believe this may apply to your research.

As best practice, the PI should maintain, as applicable:

- Signed and dated Curriculum Vitae (“CVs”) for all investigators;
- Records of completed trainings for all members of the research staff
- Signature sheet documenting signatures and initials of all persons authorized to make entries or corrections on data collection forms, as described in the data management plan submitted to and approved by the IRB;
- Monitoring reports to document findings of monitoring the study;
- Any other documentation of research activities that would enable authorized representatives of federal regulatory agencies, the sponsor, Villanova University, and the IRB to ensure compliance with the Human Research Protection Program (HRPP) plan.

How long do I keep records?

Maintain your Human Research records, including signed and dated consent documents for at least three years after completion of the research. Federally funded projects require records to be retained for 5-years after the completion of the study. Maintain signed and dated Health Insurance Portability and Accountability Act (HIPAA) authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.
How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the Villanova University IRB website at https://www1.villanova.edu/villanova/provost/research-administration/research-protections/irb/policies-procedures.html.

If you have any questions or concerns, about the Human Research Protection Program, contact the Office of Research Protections at:

Office of Research Protections
800 Lancaster Ave
Villanova, PA 19085
ORP General Phone: 610-519-4228
IRB@villanova.edu
ORP@villanova.edu

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by the Office of Research Protections, follow the directions in the “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” under “Reporting and Management of Concerns.”

Members of the University community are strongly encouraged to raise compliance-related questions or concerns. These 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.

Reports can be made via EthicsPoint, available 24/7, online at https://secure.ethicspoint.com/domain/media/en/gui/35905/index.html or by calling toll-free 855-236-1443. You can obtain more information regarding the hotline at: http://www1.villanova.edu/villanova/president/uco/hotline.html.

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.
Appendix A-1  Additional Requirements for DHHS-Regulated Research

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.

2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.

3. Investigators, in consultation with the funding agency, can choose to honor a research subject’s request that the investigator destroy the subject’s data or that the investigator exclude the subject’s data from any analysis.

4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.

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