Institutional Review Board

Manual

Institutional Review Board
Dutchess Community College
53 Pendell Road, Poughkeepsie, NY 12601
IRB@suny dutchess.edu

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**DISCLAIMER:**

THIS DOCUMENT IS INTENDED TO BE AN OVERVIEW OF THE IRB AND ITS PROCESSES

ADDITIONAL POLICIES AND PROCEDURES CAN BE FOUND IN THE CODE OF FEDERAL REGULATIONS
THE IRB COMMITTEE

The Institutional Review Board (IRB) for Dutchess Community College (DCC) is responsible for protecting the rights and welfare of human research subjects, in accordance with the 2009 Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects (45 CRF 46).

The committee’s charge and composition are as follows:

The purpose of the Institutional Review Board (IRB) is to ensure that the rights, safety and well-being of research participants are ethically protected.

The IRB shall be a President’s standing committee comprised of a minimum of seven (7) members who broadly represent the campus community, including faculty, staff, and administrators (exclusive of the Director of Institutional Research, Planning and Assessment).

The Director of Institutional Research, Planning and Assessment will serve in an advisory role to the IRB and will be responsible for training IRB members in appropriate research ethics and appropriate State and Federal regulations.

As noted above, the IRB serves at the behest of the President of the College. The Chair is appointed by the President. The Advisor, which is a non-voting position, is held by the Director of Institutional Research, Planning and Assessment. The remaining committee members are volunteers that include both faculty and staff.

Information about current IRB members can be found in the Member Directory.

Because the IRB is primarily comprised of volunteers, the committee only convenes as needed during the Fall and Spring semesters.
RESEARCH AT DUTCHESS

The IRB has oversight over all research activities at DCC involving human subjects, EXCEPT in cases of typical educational activities, pedagogical inquiries, and assessment efforts needed for internal purposes.

**research** = a systematic investigation… designed to develop or contribute to generalizable knowledge [45 CRF 46.102(d)]

**human subject** = a living individual about whom an investigator… obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information [45 CFR 46.102(f)]

Types of research activities that will not be considered or allowed include:
- Research involving persons under the age of 18 and other vulnerable populations
- Research in the local community, involving non-DCC populations and locations
- Research that is government-funded AND has not been reviewed and approved by another IRB with federal-wide assurance

In addition, research exceeding the level of minimal risk will likely be denied.

**minimal risk** = the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]

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IRB approval must be secured before beginning any research activities involving human subjects.

**General Requirements for IRB Approval** [45 CFR 46.111] =
- Risks are minimized… and… reasonable in relation to anticipated benefits
- Selection of subjects is equitable…
- Informed consent will be sought… and… appropriately documented
- When appropriate… adequate provision for monitoring the data collected to ensure the safety of subjects
- When appropriate… adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

There is one additional criterion for “external” researchers (those not affiliated with DCC) and “dual-status” researchers (those affiliated with DCC and another educational institution)—approval must be secured from the “home” or “other” institution, respectively. PIs may undergo IRB review at both DCC and the other institution at the same time. In such circumstances, DCC’s IRB may grant provisional approval. However, final approval will be withheld until equivalent documentation is received from the other institution.
INFORMED CONSENT

Informed consent is an integral part of the research process. Human subjects must voluntarily provide informed consent before engagement in any other research activities.

**General Requirements for Informed Consent** [45 CFR 46.116] =
- Provide... sufficient opportunity to consider whether or not to participate
- Minimize the possibility of coercion or undue influence
- The information... shall be in language understandable to the subject
- No informed consent... may include any exculpatory language... to waive or appear to waive any of the subject's legal rights...

The consent form must include:
- Statement that the project involves research and an explanation of the project’s purpose
- Description of the procedures to be followed, including identifying experimental procedures
- The expected duration of participation
- Descriptions of potential risks/discomforts and benefits/compensation
- Statement describing procedures used to protect subjects’ privacy or maintain confidentiality
- Who to contact about the research project and research subjects’ rights
- Statement that participation is voluntary
- Statement that refusal or discontinuance of participation will involve no penalties

When applicable, the consent form should also include these disclosures:
- Conflict of interest (either financial or commercial)
- Collection of physical and/or mental health information
- Collection of educational information
- Data storage for use in future, as yet unspecified, research

The IRB may waive the requirement to obtain informed consent when the project meets ALL of these conditions:
- The research involves no more than minimal risk
- The waiver/alteration will not adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver
- When needed, participants will receive additional pertinent information

The IRB may waive the requirement to document informed consent when the project meets EITHER set of conditions:
- The only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality
  - OR
- That the research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

While informed consent may be waived/altered, the occurrence of such is highly unlikely.
SUBMITTING AN APPLICATION

Persons interested in conducting human subjects research at DCC must submit an application to the IRB at IRB@sunydutchess.edu. Acknowledgment that the application has been received will be sent within one week of its submission. Principal investigators (PIs) are encouraged to contact the IRB Chair beforehand to discuss the proposed research.

The IRB application must include:

- A completed Application Form, along with a signed copy of the last page of the form
  - PIs will be asked to explain the purpose of the research, outline the informed consent process, describe procedures to protect subjects’ privacy/records, etc.
- A research proposal describing the sample, procedures, and measures
- A written consent form, preferably using the Consent Template
  - The readability of the final document MUST be lower than the 10th grade level and SHOULD be lower than an 8th grade level of comprehension.
- Recruitment materials (be it a flyer, email invitation, in-class announcement, etc.)
- The PI’s certificate of training in the protection of human research subjects

When applicable, the IRB application should also include:

- A copy of all survey questions/instruments, in the case of survey research
- A form for documenting monetary compensation, preferably using the Payment Form
- A debriefing statement, in the case of research involving deception
- IRB approval from other institution (required for external and dual-status researchers)

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PIs and their teams must be trained in the protection of human research subjects. Common certification options include:

- Protecting Human Research Participants, a free course offered by the National Institutes of Health (NIH)’s Office of Extramural Research
- Human Subjects Research (social-behavioral-educational track), a subscription-required course module offered by the Collaborative Institutional Training Initiative (CITI)

Certification must have been obtained or renewed within the past three years, and must be maintained for the duration of the research. As noted above, PIs are required to submit documentation of their own training, and are encouraged to obtain certificates from all team members.
INITIAL REVIEW OF RESEARCH

The IRB Chair will determine whether the proposed research is exempt from IRB oversight or requires committee review. Exemptions will only be granted in those circumstances specified in federal regulations [45 CFR 46.101(b)].

- IRB oversight is not applicable to:
  - DCC faculty conducting research for pedagogical or assessment purposes
  - DCC staff conducting research for compliance or internal assessment purposes
  - DCC students conducting laboratory research (that does not involve human subjects) during normal educational activities

Applications requiring expedited or full review will be forwarded to the IRB committee.

- All required paperwork and materials related to the research proposal must be submitted before an IRB committee meeting is scheduled.
- Initial review of an application may take up to 60 days. The process could last longer when more information is needed or modifications are required.

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Potential outcomes of IRB voting include approval, deferment, and rejection.

- **APPROVAL** will be granted when a majority of the convened IRB committee agrees that the proposed research adheres to federal regulations concerning the protection of human subjects. (Provisional approval may be granted, on a case-by-case basis, to external and dual-status researchers pending IRB approval from the other institution.)
- **DEFERMENT** will be used in cases when specific modifications to the proposed research are required or the committee needs more information. PIs may be asked to meet with the IRB to answer questions.
- **REJECTION** will typically occur when a majority of the convened IRB committee agrees that the proposed research
  - Does not adequately protect human subjects,
  - Is determined to exceed minimal risk, or
  - Is beyond the scope of IRB practices or expertise.

A written response to the IRB application will be sent within one week of the initial committee meeting held to discuss it. If the proposed research is deferred or rejected, an explanation of the IRB’s decision will be provided. PIs will have the opportunity to respond to that decision.
KEEPING THE IRB INFORMED

The research project must be conducted in the manner in which it was approved by the IRB, in accordance with IRB policies, DCC policies, and federal regulations governing human subjects research. The IRB may choose to observe any aspect of the research process at any time to confirm compliance. Failure to comply will result in immediate suspension or termination, and written notification of such will be provided to the PI. If needed, appropriate officials will also be informed.

After a research project is approved by the IRB, the consent form will be IRB-stamped with a project identification number (to be used in all correspondence), approval date, and expiration date. The IRB-stamped form must be used when obtaining written informed consent. All subjects must receive a copy of the IRB-stamped consent form for their records.

When subjects receive monetary compensation for their participation, the researcher must document such payment. All subjects should receive a copy of the payment form for their records.

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IRB approval for any revisions to the research must be sought prior to implementation, using the Amendment Form. Exception: procedural changes are acceptable in situations where there are apparent, immediate hazards to subjects that need to be eliminated. If any unanticipated problems involving risks to subjects or others, or if any serious adverse events occur, then the PI must inform the IRB Chair within 24-48 hours AND submit an Incident Form within one week of the event.

If the project is expected to continue more than one year, then the PI must submit a Renewal Form for continuing review of research (which must be conducted no less than once a year). Researchers are encouraged to submit for renewal at least one month in advance of the project’s expiration date to avoid disrupting the research process. If IRB approval is not secured in advance, then all research activities must cease immediately after the expiration date.

When the project is complete, the PI must submit a Completion Form. Completion means:

- The research is permanently closed to the enrollment of new subjects.
- All subjects have completed research interventions and follow-ups (if applicable).
- No further analysis of coded/identifiable data will be conducted—either analysis is complete or the data have been permanently de-identified (all identifiers and keys to codes destroyed).

PIs must retain all documents for at least five years after the research is completed or terminated.
**FORMS AND TEMPLATES**

**Application Form**  
Submit at the beginning of the research process, before conducting any research activities involving human subjects

**Consent Template**  
Submit with the application form

**Payment Form**  
Submit with the application form, when subjects will receive monetary compensation

**Amendment Form**  
Submit anytime during the approval period, when changes in research activities are desired

**Incident Form**  
Submit within one week of an unanticipated problem or serious adverse event  
*Reminder: the IRB Chair must be informed, by phone or email, within 24-48 hours*

**Renewal Form**  
Submit when continued approval is desired, preferably one month before the project’s expiration

**Completion Form**  
Submit when the research project is complete, no later than one month after the project’s expiration

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**Need more information?**  
**Have suggestions?**

Email IRB@sunydutchess.edu