DUTCHESS
COMMUNITY COLLEGE

Institutional Review Board

Manual

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

Application Form: ***https://survey.alchemer.com/s3/5424962/dccirbapp***

MAY 2021

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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 COMMITTEE

The Institutional Review Board (IRB) at Dutchess Community College (DCC) is guided by the 2018 Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects [45 CFR 46]. For more information about the federal regulations, please visit: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html.

The IRB serves at the behest of the President of the College. Its charge is "to ensure that the rights, safety and well-being of research participants are ethically protected" (DCC's Professional Staff Handbook, August 2015, Page 4.2.2). The committee, overseen by the Office of Institutional Research, Planning and Assessment, includes volunteer faculty and staff. As such, the committee only convenes during the Fall and Spring semesters as needed.

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IRB Members

NAME & EMAIL	POSITION @ DCC	HIGHEST DEGREE
Cavanaugh, Kevin cavanaug@sunydutchess.edu	Professor of English	PhD, Curriculum & Instruction, SUNY Albany
Hall, Michael michael.hall@sunydutchess.edu	Professor of Behavioral Sciences	MA, General Experimental Psychology, University of Nebraska
Mead, Rachel rmead@sunydutchess.edu	Interim Director of ACT Center	MFA, Creative Writing, CUNY City College
Murray, Matthew matthew.murray@sunydutchess.edu	Assistant Professor of Government	PhD, Political Science, CUNY Graduate Center
Newkirk, Marta newkirk@sunydutchess.edu	Assistant Dean of Student Services	MA, Educational Psychology, Marist College
Riela, Suzanne ***Chair*** suzanne.riela@sunydutchess.edu	Associate Director of Institutional Research	PhD, Social/Health Psychology, SUNY Stony Brook
Schnackenberg, Scott scott.schnackenberg@sunydutchess.edu	Director of Institutional Research	BS, Computer Science and Sociology, Clarkson University
Schneider, Martin martin.schneider@sunydutchess.edu	Director of Grants	Juris Doctorate, National Law Center, George Washington University

KEY DEFINITIONS

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)]

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. [45 CFR 46.102(e)(2)]

Interaction includes communication or interpersonal contact between investigator and subject. [45 CFR 46.102(e)(3)]

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). [45 CFR 46.102(e)(4)]

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(e)(5)]

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. [45 CFR 46.102(h)]

Minimal risk means that 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(j)]

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(l)]

GENERAL POLICIES

The IRB has oversight over all research activities at DCC involving human subjects, except in cases of typical educational activities, pedagogical inquiries, and internal assessment efforts. While there are additional categories of research that are exempt from IRB oversight, the determination of exemption must be made by the IRB rather than prospective researchers.

IRB review and approval (or exemption) must be obtained before beginning any human subjects research activities. This applies to all DCC faculty, staff, and students conducting research, either within the college or in the larger community. Non-DCC researchers who wish to include DCC students or employees in their research must also undergo IRB review.

The following research activities will NOT be considered or allowed:

- Research involving persons younger than 18
- Research exceeding the level of minimal risk
- Research involving animals or biological specimens or biomedical procedures
- Research that is government-funded, and has not been reviewed and approved by another IRB with federal-wide assurance

All research personnel must have been trained in the protection of human research subjects. Certification must have been obtained within the past five years. Certificates from CITI (https://www.citiprogram.org/) and PHRP (https://phrptraining.com/) are acceptable. Principal investigators (PIs) are required to submit documentation of their training.

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General requirements for IRB approval [45 CFR 46.111]:

- Risks to subjects are minimized and reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be sought and appropriately documented
- There are adequate provisions for ensuring the safety of subjects, protecting the privacy of subjects, and maintaining confidentiality of data
- There are additional safeguards to protect the rights and welfare of subjects vulnerable to coercion or undue influence (including economically or educationally disadvantaged persons)

General requirements for informed consent [45 CFR 46.116(a)]:

- Subjects voluntarily provide informed consent before engagement in research activities
- Subjects have sufficient opportunity to discuss and consider whether or not to participate
- The possibility of coercion or undue influence is minimized
- Subjects are provided information in language that is understandable
- The information provided is organized and sufficiently detailed to facilitate comprehension
- There is no exculpatory language that waives or appears to waive any subject's legal rights, or that releases or appears to release the investigator or institution from liability for negligence

APPLICATION PROCEDURE

Persons interested in conducting human subjects research at DCC must complete the online application form at **https://survey.alchemer.com/s3/5424962/dccirbapp** and send supporting materials to **IRB@sunydutchess.edu**. Principal investigators (PIs) are welcome to contact the IRB Chair beforehand to discuss their proposed research.

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The following documents must be submitted:

- A completed **Application Form**, to explain the purpose and conditions of the research
- A written consent form that is clear and understandable
- A concise research proposal (1-2 pages) describing the sample, procedures, and measures
- Recruitment and other dialogue materials for corresponding with potential subjects (be it an email invitation, flyer, in-class announcement, etc.)
- Copies of all survey instruments and/or interview questions
- PI's certificate of training in the protection of human research subjects

When applicable, the following documents must also be submitted:

- A form for documenting monetary compensation
- A debriefing statement when the research involves deception
- IRB documentation from one's "home" institution

The **Informed Consent Form** must include the following [45 CFR 46.116(b)]:

- 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
- Description of procedures used to protect subjects' privacy and maintain confidentiality
- Statement that the collection of identifiable private information will (or will not) be de-identified and will (or will not) be used for additional research studies
- Who to contact about the research project and research subjects' rights
- Statement that participation is voluntary, and that refusal or discontinuance of participation will involve no penalties

REVIEW OF RESEARCH

The IRB Chair and/or designated IRB representative(s) 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 the federal regulations [45 CFR 46.104].

- Note that 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

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Applications requiring expedited or full review will be forwarded to the IRB committee. All required paperwork must be submitted before an IRB committee meeting is scheduled. 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 and institutional policies.
- **Deferment** will occur when specific modifications to the proposed research are required or the committee needs more information. PIs may be asked to meet with the IRB.
- **Rejection** will occur when a majority of the convened IRB committee agrees that the proposed research does not adequately protect human subjects, exceeds minimal risk, or is beyond the scope of IRB practices or expertise.

Initial review of an application may take up to 60 days. A written response to the IRB application will be provided. If the proposed research is deferred or rejected, the response will include an explanation of the IRB's decision, and PIs will have the opportunity to respond to that decision.

RESEARCH CONDUCT

Research projects must be conducted in the manner in which they were 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 of the project, and written notification of such will be provided to the PI. Appropriate officials will also be informed.

Informed consent is integral to the research process. Human subjects must voluntarily provide informed consent before engagement in any other research activity. Signatures can be written or electronic. A copy of the consent form must be provided to each subject. [45 CFR 46.117(a)]

IRB approval for any revisions to the research must be sought prior to implementation. EXCEPTION: Procedural changes are acceptable in situations where there are apparent, immediate hazards to subjects that need to be eliminated. Any unanticipated problems or serious adverse events should be reported to the IRB Chair within 48 hours of the event.

If a project is expected to continue more than one year, then the PI must contact the IRB Chair to initiate continuing review of research. Researchers are encouraged to submit for renewal one month before the project's expiration date to avoid disrupting the research process. If continuing IRB approval is not secured, then all research activities must cease immediately after the expiration date.

When a project is complete, the PI must contact the IRB Chair indicating:

- The number of subjects that participated in the project
- That the research is permanently closed to the enrollment of new subjects
- That 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 destroyed)

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