

# IRB APPLICATION PROCESS

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Prepare to be the best.

# Ethics in Research

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**“If there is any element of research in an activity, that activity should undergo review for the protection of human subjects”**

**– The Belmont Report, 2011, p.5.**



# What is the Institutional Review Board (IRB)?

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- The IRB is composed of at least five members of the Clarkson College community from a variety of disciplines with experience and preparation in research as well as community members.
  - IRBs use a group process to review research protocols and related materials to ensure ethical research practices.
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# Responsibilities of the IRB

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- **The IRB is responsible for the review of all research performed at Clarkson College in order to ensure that professional, ethical, and legal standards concerning the use of human participants are being followed (45 CFR Part 46).**
- The IRB shall determine that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
  - Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
  - Attention must be paid to subjects' vulnerability to coercion or undue influence in making an informed decision.
  - Additional safeguards must be provided for vulnerable populations including children, veterans of military service, prisoners, and individuals with impaired decision-making ability.

# Principal Investigator (PI)

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- The Principal Investigator is the person ultimately responsible person for the project.
  - Student researchers are required to be the Principal Investigator.
  - Faculty advisors should be listed as Co-Investigators.
- It is the PI's responsibility to submit all paperwork with the IRB.

# IRB Approval is Required


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- Human subject research and data collection **shall not** commence **until after** the IRB has approved the proposed study
  - Exception:
    - Relying solely on data that is publicly available
      - Data posted on public websites
    - Data collection for internal departmental, school, or other administrative purposes
      - That will not be disseminated outside of the College or involves sensitive information
  - If you are unsure if your study qualifies, consult with your faculty advisor (if applicable) or the Director of Research Compliance

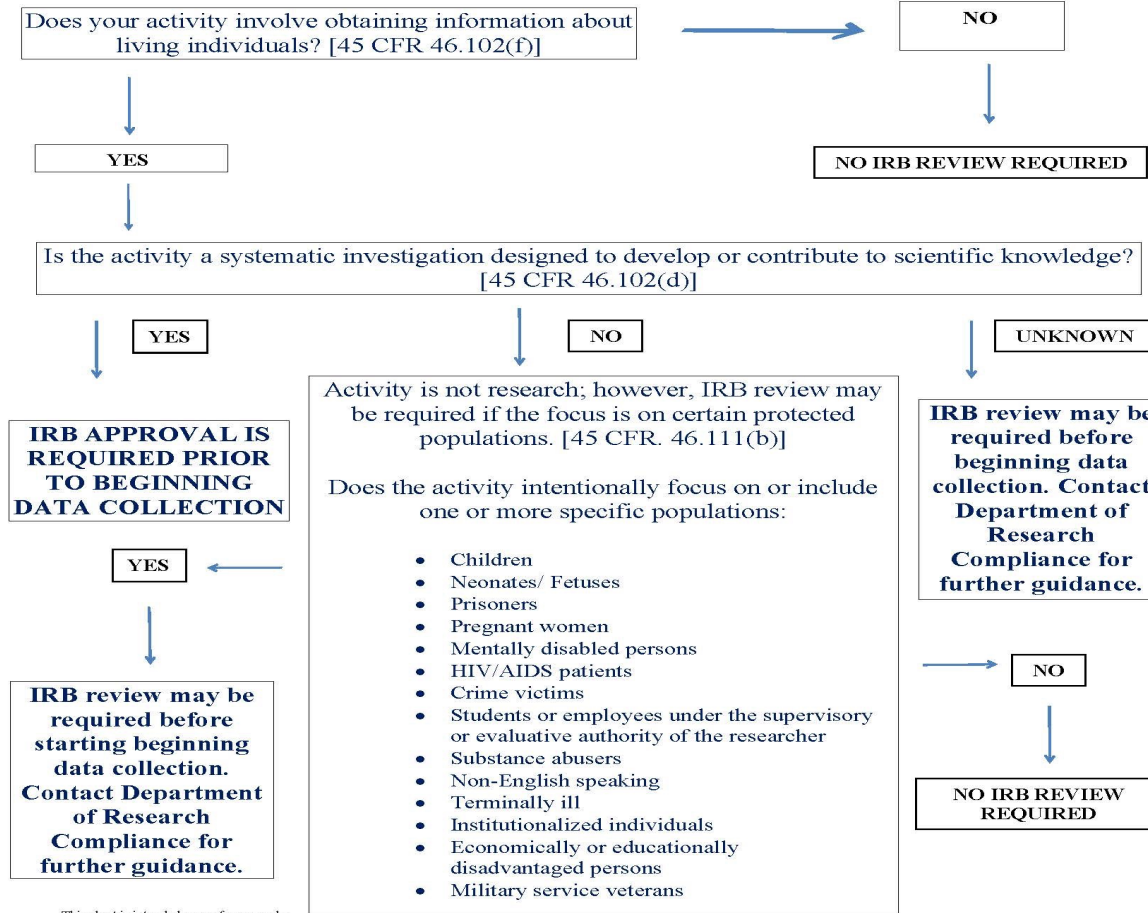
# Plan Ahead: Get Your Ducks in a Row

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Things to consider *before* you submit your application...

- What are you really trying to discover?
  - Is your research design sound?
    - Methodology
    - Recruitment
    - Data Collection and Analysis
  - What type of participant consent is required?
    - This is based on the population to be studied and your method for doing so.
  - Site approval for the study?
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HUMAN SUBJECTS REGULATION DECISION CHART  
(45 CFR part 46)




This chart is intended as a reference only. All researchers must review the IRB manual and are encouraged to contact the Department of Research Compliance for further guidance.



# Submitting Your Application

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- Work with your advisor (if applicable) to ensure that your study is ready for IRB submission and approval.
  - Complete the IRB Determination Form located on the IRB webpage to determine the type of application to be submitted.
  - IRB Applications can be found on the IRB Forms web page, as well as on Canvas or the Student Success Guide.
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# Supporting Documentation

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- Be sure to include all supporting documentation with your application
  - **IRB approval may be delayed or denied due to missing documents**
    - ✓ Citi Training Certification for both bio-medical *and* social/behavioral research
    - ✓ Data collection instruments (e.g., interview or survey questions, pre/post-test tools, or evaluation documents)
    - ✓ Letters of permission from the study site(s) with the application and state the role of the investigator at the site (e.g., staff or manager).
    - ✓ Recruitment language (e.g., letter, email, phone call script)
    - ✓ Consent forms
    - ✓ Educational materials that will be disseminated to participants (e.g., Powerpoint slides or handouts)

# Levels of Review

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- **Exempt -**
  - Anonymous surveys (that do not include protected populations)
  - Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves
  - Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects
- **Expedited -**
  - Collection of data from voice, video, digital, or image recordings made for research purposes
  - Research on individual or group characteristics or behavior
  - Review of minor changes in previously approved research or research protocol
- **Full-Board -**
  - Involves protected populations
  - Considered more than minimal risk

\* Examples only. Complete category items and descriptions located in Applied Research Manual and IRB Applications



# Types of Applications

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- There are two different IRB applications
    - Exempt
    - Non-Exempt (Expedited or Full-Board)
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# Exempt Applications and Approval

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- **Research that qualifies as exempt *must still be submitted and approved by the IRB.***
  - Applications may be submitted at anytime
  - Reviewed on a rolling basis

# Non-Exempt Applications (Expedited and Full-Board)

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- There is one application for either expedited or full-board review.
    - Be sure to check the appropriate level of review box
  - **Expedited:**
    - Applications may be submitted at anytime
    - Reviewed on a rolling basis
  - **Full-board:**
    - Applications must be submitted by the posted submission deadlines
    - Reviewed 5 times per academic year
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**IRB APPLICATION SUBMISSION DEADLINES AND  
MEETING SCHEDULES  
(FULL-BOARD ONLY)**

**ACADEMIC YEAR 2021-2022**

Exempt and Expedited Applications can be submitted at any time and will be reviewed on a rolling basis. Full board applications will be reviewed per the full board review schedule below.

<b>MONTH</b>	<b>IRB SUBMISSION DEADLINE (FULL-BOARD APPLICATIONS ONLY)</b>	<b>IRB MEETING SCHEDULE (FULL-BOARD ONLY)</b>
<b>September</b>	<b>September 12, 2021</b>	<b>September 23, 2021</b>
<b>November</b>	<b>November 7, 2021</b>	<b>November 18, 2021</b>
<b>February</b>	<b>February 13, 2022</b>	<b>February 24, 2022</b>
<b>April</b>	<b>April 17, 2022</b>	<b>April 28, 2022</b>
<b>June</b>	<b>June 12, 2022</b>	<b>June 23, 2022</b>

The Clarkson College IRB meets 5 times per academic year. All full-board applications must be received by the IRB submission deadline for the next IRB Review.

*NOTE: Review of applications (Exempt, Expedited or Full-Board) will not take place during the following blackout dates (when faculty are off-campus):*

- **December 15, 2021 – January 3, 2022**
- **March 7, 2022 – March 13, 2022**
- **May 4, 2022 – May 10, 2022**
- **August 10, 2022 – August 21, 2022**

# How to Submit Your Application

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- **All IRB applications (and required attachments) must be submitted through the submission form located on the Clarkson College IRB webpage ([IRB APPLICATION SUBMISSION PORTAL](#)) or mailed to Clarkson College Institutional Review Board, 101 S. 42nd Street, Omaha, NE 68131.**
  - Applications must be submitted by the Principal Investigator listed on the application.
  - Incomplete applications will be returned to the Principal Investigator without review.
  - Attachments shall be included in the form of appendices.
    - Applications missing required attachments will be returned to the Principal Investigator without review.
  - Refer to the Submission and Review Schedule located on the IRB webpage/Canvas/Student Success Guide for full-board submission deadlines and meeting dates. Exempt and Expedited applications can be submitted at any time and will be reviewed on a rolling basis.



# SUBMIT APPLICATION VIA IRB WEBPAGE



I am

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[Institutional Review Board](#)

[IRB Application Submission Portal](#)

[IRB Determination Form](#)

[IRB Forms](#)

[Human Subjects Determination Form](#)

[Exempt Application](#)

[Non-Exempt Application](#)

[Survey Monkey Formatting Request Form](#)

[Change of Protocol](#)

[Waiver of Written \(Signed\) Consent Form](#)

[Template for Invitation and Implied Informed Consent Form](#)

[Template for Adult Consent Form](#)

[Template for Parent-Guardian and Child Permission Form](#)

[Template for Adolescent Assent Form for Participants Aged 12-18](#)

[Request for Renewal](#)

[Study Closeout Form](#)

[Unanticipated Problem/Adverse Event Reporting Form](#)

# IRB APPLICATION SUBMISSION FORM



## IRB APPLICATION SUBMISSION PORTAL

Andrea Walker, Ph.D.  
Director, Research Compliance  
PH 402-552-2277  
walkerandrea@clarksoncollege.edu

Lucas Sieburg, M.A.  
Chair  
PH 402-552-6133  
IRB@clarksoncollege.edu

### CONTACT INFORMATION

**Submission Date \***

**Principal Investigator (PI) Name \***

The PI is the person ultimately responsible for the project.

**PI Email \***

PI Email

**PI Phone Number \***

PI 10-Digit Number


**PI Status \***

**Co-Investigator (CI) Name (Students this will be your Faculty Advisor) \***

Please enter the CI Full Name if applicable here.


# IRB Review and Decision Timeline

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- **Exempt and expedited applications are reviewed on a rolling basis.**
    - Within 14 days of the submission of an exempt or expedited application, the IRB chair will notify the PI of the IRB decision.
    - For approved applications, the chair will send the IRB# and approval and expiration dates in a letter.
    - For applications that are not approved, the chair will notify the PI that approval is pending further information or revisions.
    - Depending on the Level of Determination, revised applications are reviewed before or at the next scheduled meeting.
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# IRB Review and Decision Timeline

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- **Full-board applications are scheduled for review at the next IRB meeting.**
    - Within 14 days of the conclusion of the IRB meeting, the IRB chair will notify the PI of the IRB decision.
    - For approved applications, the chair will send the IRB# and approval and expiration dates in a letter.
    - For applications that are not approved, the chair will notify the PI that approval is pending further information or revisions.
    - Depending on the Level of Determination, revised applications are reviewed before or at the next scheduled meeting.
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# After IRB Approval

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- Changes in study protocol may not be made without prior IRB approval
    - If modifications are required, you must submit a **Change in Protocol Form**
    - You may not implement new protocols until *after* the IRB has approved the changes
  - IRB approval expires one year after the approval date
    - If you need more time, you must submit a **Request for Renewal Form**
  - Upon completion of the study, you should submit a **Study Closeout Form**
    - *Required* for Expedited or Full-Board
    - *Encouraged* for Exempt
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## Other IRB POLICIES (*see Applied Research Manual*)

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- Unanticipated Problems or Adverse Events
  - Data Collection without IRB Approval
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# Questions Along the Way?

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- Utilize available campus resources
    - Department/Program Directors
    - The Writing Lab
    - The Applied Research Forum
  - Consult with your faculty advisor (if applicable)
  - Contact the IRB Chair

Lucas Sieburg, M.A.  
Chair  
PH 402-552-6133  
IRB@clarksoncollege.edu
  - Contact the Director of Research Compliance

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