SAINT ANSELM COLLEGE
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INSTITUTIONAL REVIEW BOARD
100 Saint Anselm Drive, Manchester, New Hampshire 03102-1310 • 603-641-7000 • www.anselm.edu

The Institutional Review Board (IRB) at Saint Anselm College has been established to protect the rights, privacy, and welfare of human research subjects recruited to participate in research conducted under the auspices of the College. A human research subject is defined as a living individual about whom an investigator obtains data through intervention or interaction, or identifiable private information.

The role of the IRB committee is to review all human subject research to ensure that it is in compliance with the Department of Health and Human Services regulations for the protection of Human Research Subjects (45 C.F.R. Part 46) and to ensure that it is consistent with the policy and procedures of Saint Anselm College. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both federal regulations and College policy. The IRB meets once a month from August to May. Please note that *no research may begin until final IRB approval has been granted*.

Mandatory Research Integrity Training. Saint Anselm College expects all researchers to conduct their work with the highest degree of integrity. To that end, the College has set forth minimum standards for mandatory research integrity training, including a requirement that ALL individuals conducting research with human subjects complete the *IRB Protection of Human Subjects online training course*. This course is offered by the Collaborative Institutional Training Initiative (CITI) and is available to Saint Anselm faculty and staff. More information on how to complete the online training is available on the IRB website (https://www.anselm.edu/faculty-staff/institutional-review-board).

For externally funded research with human subjects, please note that College policy requires that all researchers with external funding sources complete the *Responsible Conduct of Research online training course*. This course is taken in addition to the IRB Protection of Human Subjects course described above, and is also available to Saint Anselm faculty and staff through CITI.

IRB Application Instructions: Submit a digital copy of the complete IRB application form **with signatures** and all supplemental materials as an e-mail attachment to irb@anselm.edu.

Application deadline: applications must be received at least 14 days prior to the next scheduled IRB meeting to be included in the agenda.

Students: please note that your application must be reviewed and signed by a supervising faculty member prior to submission (see Section 2 under Responsible Investigators and Section 12 for signature page).

Questions? Contact the current committee Chair (see the website) https://www.anselm.edu/faculty-staff/institutional-review-board

Please include all the following required items with your application:

- [ ] A cover page or memo that lists all materials submitted
- [ ] IRB Application Form
- [ ] IRB Protection of Human Subjects online training certificate(s) for each member of the research team
- [ ] All advertisements, announcements, letters, or other recruiting materials
- [ ] All scales, survey instruments, questionnaires, interview scripts, etc.
- [ ] Statement of Assurance from all investigators

Please include the following items as applicable and check those attached:

- [ ] Complete federal or non-federal grant application (e.g. NIH or voluntary agency grant applications) except attachments
- [ ] Responsible Conduct of Research online training certificate (externally funded research only)
- [ ] Attachment for Informed Consent Waiver
- [ ] Informed consent document(s)
- [ ] Parental permission document(s)
- [ ] Child assent document(s)
- [ ] Translated & authenticated versions of the above consent, permission, and/or assent document(s) for likely non-English speakers
- [ ] Support letters
- [ ] Others, please list

SAINT ANSELM COLLEGE

IRB Application Form - Initial Review

Section 1. General Information

1. Project Title: _____

2. Submission Date:_____

3. Anticipated Project Start Date:_____

4. Anticipated Project End Date:_____

5. Sponsor or other Support *(list industry sponsor, government support, etc.)*:

_____

6. Will unique identifiers be available to the research team? ☐ No ☐ Yes

(Unique identifiers include research subject's name, SSN, address, phone number, student/faculty ID, email address and/or any research ID links to a unique personal identifier)

7. Using non-technical language, please provide a 3-4 sentence summary of the project objectives.

Section 2. Key Personnel

Principal Investigator (PI): A Principal Investigator is an individual who conducts an investigation, i.e., under whose immediate direction research is conducted or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. A Principal Investigator (PI) directs some or all aspects of the research project, including the design of the study, conduct of the study, analysis and interpretation of the collected data, and writing of resulting manuscripts.

Responsible Investigators (RI): All RIs must have a paid appointment at Saint Anselm College. An RI is required if the PI is a student, or is not credentialed to perform/supervise the study procedures. An RI is also required if the PI is not qualified to be responsible for all study-related decisions.

Note: If the PI is a SAC student, this application must be signed by the supervising faculty member. By signing the Responsible Investigator Certification page listed in Section 12, the Faculty Advisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the Advisee listed as *Principal Investigator*.

	Principle Investigator (PI)	**Responsible Investigator** *(If different from PI)*
Name		
Degree		
Department		
Email		
Phone		
Address or Campus Box		

☐ Attach Curriculum vitae for outside researchers

OTHER PERSONS ASSOCIATED WITH THIS PROJECT				
Co-Investigators				
Name	**Degree**	**Department**	**Phone number**	**Access to identifiable subject information/data?**

Other Personnel *(List other study personnel involved in the conduct of the study, including additional personnel who will obtain subjects' informed consent, interact with subjects in person and/or on the telephone, have access to and/or collect and analyze protected health information (PHI), have access to individually identifiable data, e.g., lab data or samples).* Please inform the IRB with any changes to personnel.

Name	**Phone number**	**Role in Study**	**Access to identifiable subject information/data?**

	Section 3. Funding				
1.	**Funding Source** (Check all that apply)	☐	Unfunded/ Investigator Out-of Pocket	☐	Departmental
		☐	Undergraduate Research Award	☐	Non- profit foundation
		☐	Faculty Summer Research Grant		
		☐	Agency– specify:		
		☐	Commercial– specify:		
		☐	Other funding source – specify:		
2.	**Funding Mechanism**	☐	Grant	☐	Gift
		☐	Contract	☐	Internal
		☐	Other funding source – specify:		

3.	**Administered by**	☐	Saint Anselm College	☐	Other (specify):
4.	**Funding Status**	☐	Awarded	☐	Pending
	Sponsor Name				
5.	**Other Project Identifiers**	Grant/ Contract Number (if applicable)			
		Other identifiers:			
6.	**For Externally Funded Studies:** If the research is supported either in whole or in part by external funds (federal, state or private), *one COMPLETE copy of each grant application or contract must be included* with this application.				

Section 4. Conflict of Interest Disclosure

Definition: Significant Financial Interests are defined as interests valued at greater than $10,000 including employment or an equity ownership of more than 5% held by any of the study team personnel and their spouse and/or dependent children.

Yes	No	
☐	☐	Does **PI** have the Significant Financial Interests involved by conducting this research study?
☐	☐	Does **RI** have the Significant Financial Interests involved by conducting this research study?

(Conflict of Interest Statements are required to be completed by all study team personnel listed on this application.)

Section 5. Research Sites

1.	Yes	No	
	☐	☐	SAC Facilities
	☐	☐	Non-SAC Facilities – Please list collaborating sites:

2. Other Collaborating Institutions/Facilities

If you are collaborating with other sites, provide:

a. the name of each institution/facility (e.g. other university, K-12 school, nursing home, prison, etc.) and
b. describe the type of involvement of each institution (e.g. recruitment, enrollment/consenting, study procedures, follow-up, data analysis).
c. Indicate if IRB approval/site permission is attached (indicate yes, no, or pending). You will need to obtain IRB approval from every collaborating institution that has an IRB before you can initiate research there.

3. If the PI, Student Researcher or other Key Personnel has an affiliation/appointment with an Institution listed above, please explain:

Section 6. Human Participants

1. Will your sample of participants include Saint Anselm College Students or Employees?

☐ No ☐ Yes ☐ N/A

2. How many participants do you plan to enroll or charts/records to be reviewed?

At SAC	Male:	Female:	Total:
At all Sites	Male:	Female:	Total:

3. Provide an estimated duration of individual subject participation (insert not-applicable for chart/record reviews):_____

4. Age Range – Check all that apply:

☐ 0 – 7 (Include parental consent form)

☐ 8 – 17 (Include child's assent form and parental consent form)

☐ 18 - 64

☐ 65 and older

5. Identify any special participant population(s) that this study will involve.

Check **all** that apply: (Place an "X" in the column next to the name of the special population.)	☐	Minors under the age of 18	☐	Persons in a Sedated/Traumatized/Crisis State
	☐	Prisoners or Juvenile Offenders	☐	Non-English Speaking
	☐	Pregnant Women/Neonates	☐	Individuals Living with AIDS/HIV
	☐	Persons Over Age 65	☐	Persons with Cognitive, Social, Economic, or Educational Disadvantages
	☐	Other (Please identify):		

Section 7. Recruitment Procedures

1. Please indicate all methods that will be used to recruit participants and attach all recruitment materials: *(check all that apply and attach all recruitment materials)*:

☐ Letters/Emails

☐ Media/Internet Ads, Press Releases. If so, in which publications will they appear?

_____

☐ Flyers/notices to be posted *(describe below)*:

_____

☐ Other *(describe)*:

_____

☐ Verbal. If recruiting participants in person or by phone, please attach the script for what will be said to participants.

2. Will the PI conduct all recruitment activities? ☐ No ☐ Yes ☐ N/A

If no, please name the specific individuals who will recruit participants and attach their training documentation:

3. Please describe the inclusion/exclusion criteria for the study:

4. By whom (e.g., PI, research assistant, medical personnel) will the inclusion/exclusion criteria be determined?

5. Are any subjects excluded on the basis of race, ethnic group, understanding of English, socioeconomic status, education or gender? ☐ No ☐ Yes ☐ N/A

If yes, please provide clear scientific rationale for the exclusion.

6. Conditions that may result in removal of subjects from the research (check all that apply):

☐ Not Applicable	☐ Participant Withdrawal
☐ Adverse Effect	☐ Participant uncooperative or non compliant
☐ Investigator's judgment	☐ Other (describe):

7. Will participants receive inducements before or rewards after the study?

☐ No. ☐ Yes. (Note: this information must be outlines in the consent document.)

If yes above, please describe including type of payment and schedule.

8. Will participants be responsible for any of the costs (including travel) related to the research?

☐ No.

☐ Yes.

If yes , please explain.

Section 8. Research Plan

1. Does this study involve any of the following? (Check all that apply)

☐ Use of private records (medical or educational)
☐ Covert Observation
☐ Use of Picture and/or Voice
☐ The collection of personal or sensitive information in surveys or interviews (e.g., sexual attitudes or preferences, use of alcohol or drugs, information related to illegal conduct)
☐ Procedures which may risk physical/mental harm to the participant

	Induction of mental and/or physical stress
	Manipulation of psychology or social variable such as sensory deprivation, social isolation, stresses, mood induction
	Changes in diet or exercise
	Use of drugs
	Possible invasion of privacy of participant or family
	Use of a deceptive technique (if use of deception is part of the experimental protocol, the protocol must include a "debriefing procedure" which will be followed upon completion of the study, or withdrawal of the participants.)
	Presentation of materials that participants might consider offensive, threatening, or degrading
	Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
	Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.

2. Please provide details on all procedures checked above: How are they integral to the study?

3. Please attach the research design of the project, addressing <u>each</u> of the points below. Attach all relevant materials:

a. Introduction and Purpose

- State the problem and hypothesis. Provide the scientific of scholarly reason for this study and background on the topic. Attach appropriate bibliographic information.
- List the purpose(s) of the study (what you are hoping to learn as a result of the study)

b. Design, Procedures, Materials and Methods (Quantitative and qualitative):

- Describe sampling procedure, design, and sample size (including estimates of the number of participants you will contact or invite and anticipated response rate).
- Describe research design, conditions and randomization procedure (e.g., experimental, quasi-experimental, control groups, assignment to groups) – be specific.
- Describe data collection methods (Procedures) and/or activities in which the participants engage – be specific.
- Describe the specific materials or tools that will be used to collect the data – be specific.
- Explain how you will analyze the data; describe the analysis type and procedures including statistics– be specific.

- Describe how data will be reported (e.g., aggregated, pseudonyms for participants) and where data will be stored. If applicable, describe what will happen to video and/or audio recordings at the end of the study.

4. The research involves the following *(check all that apply)***:**

☐	Chart review - retrospective	☐	Interview/ Focus Group/ Oral history
☐	Chart review - prospective	☐	Audiotaping/ Videotaping
☐	Survey/Questionnaire	☐	Intervention (Behavioral, Psychological, Physical)
☐	Medical Procedures	☐	Tests, inventories, measuring instruments
☐	Database Analysis		
☐	Other (describe):		

5. Does the study include the administration of any substances (e.g., medication, vitamin, caffeine, etc.), devices or equipment?

☐ No. ☐ Yes. (If yes, provide a detailed description of the substances and procedures used):

6. Procedures and data will be conducted by *(check all that apply)***:**

☐	PI	☐	RI
☐	Co-Investigators	☐	Research Assistants
☐	Other (describe):		

Section 9. Risks and Benefits

1. Please give your overall estimate of the level of these risks:
Minimal Risk: Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Physical	☐ **Minimal**	☐ **Greater than Minimal**	☐ **Not Applicable**
Psychological	☐ **Minimal**	☐ **Greater than Minimal**	☐ **Not Applicable**
Social	☐ **Minimal**	☐ **Greater than Minimal**	☐ **Not Applicable**
Economic	☐ **Minimal**	☐ **Greater than Minimal**	☐ **Not Applicable**

2. Please explain briefly why you consider the risks associated with the study to be reasonable in relation to its benefits?

3. Will participants receive any direct benefit from the research?

☐ No. ☐ Yes. (Note: this information must be outlines in the consent document.)

If yes above, please describe including type of payment and schedule.

4. Will the research yield generalizable knowledge that will benefit society or individuals?

☐ Not Applicable ☐ No. ☐ Yes. *(Please describe):*

Section 10. Informed Consent Process

1. Type of Consent *(check all that apply)***:**

☐ **Written Informed Consent**
☐ **Waiver of Informed Consent (Submit Consent Waiver) and proceed to Section 11.**

2. Please describe the process for obtaining informed consent, or if children are involved, for obtaining permission of the parents and assent of the child-subject (i.e., how and where will informed consent be obtained):

3. List the study personnel who will be obtaining informed consent from subjects or their legally authorized representatives:

4. Will anyone other than the subject be authorized to provide consent or permission for the subject's involvement in the research (e.g., parents, court ordered guardian, spouse, etc.)?

☐ **No** ☐ **Yes** *(please explain)***:**

5. Please describe how informed consent will be obtained from subjects who do not read or understand English; identify any languages likely to be encountered; and attach a copy of a translated and authenticated informed consent document:

6. Will all adult subjects have the capacity to give informed consent? ☐ No. ☐ Yes.
If no, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined. (NOTE: In research involving more than minimal risk, capacity to consent should be determined by a psychiatrist, clinical psychologist, or other qualified professional not otherwise involved in the research. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.)

Section 11. Confidentiality of Data

1. **Will researchers have access to identifiable private information about subjects or potential subjects before consent is obtained?** ☐ **No** ☐ **Yes** *(please explain)***:**

2. Will researchers obtain identifiable private information about anyone other than the target subject (e.g., family members, friends, colleagues, classmates)? ☐ **No** ☐ **Yes** *(please explain)***:**

3. Describe how/where informed consent documents and study data will be stored, and identify the persons that will have access to them:

4. Describe procedures to ensure the privacy of subjects and maintain the confidentiality of data/information (e.g., how/where data will be stored (location with room number), who will have access to the data/codes, what will happen to the data when the research is complete, will data be archived, if so, for how long and in what medium):

5. If data with identifiers will be released, specify the person(s) or agency to whom this information will be released:

6. Does the research involve storage of identifiable private information for use in future studies (e.g., submission to a repository) ☐ **No** ***(Section 12)*** ☐ **Yes**

If yes, please provide the following information:

a. What identifying information will be required?

b. Where and for how long will the data be stored?

c. Is the storage facility an on-site or off-site location?

d. Will participants be able to request that their information be withdrawn from the bank or repository? ☐ **No** ☐ **Yes**

If no, please explain the reason.

7. Does the research involve the use and/or disclosure of individually identifiable information that is maintained electronically or in any other formats? ☐ **No** ☐ **Yes***(explain)*

Section 12. Investigator's Statement of Assurance

Principal Investigator Certification

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project. I agree to accept responsibility for the conduct and supervision of this research and the protection of human subjects as required by state and federal law and regulation.

- The protocol will be performed by qualified personnel according to the Saint Anselm College IRB approved protocol,
- All changes in the protocol and consent form will be approved by Saint Anselm College IRB before they are initiated,
- Legally effective informed consent will be obtained from human subjects if applicable, and
- Adverse events will be reported to the Saint Anselm College IRB in a timely manner.
- If I leave the Saint Anselm College, I will assure that all appropriate documents, constituting a final report, are submitted to the IRB for review.
- I will complete the required educational program on ethical principles and regulatory requirements in a timely manner.
- I understand the Initial Review is valid up to one year and I will need to submit a request for continuance each subsequent year.
- I will submit a report to the IRB when the study is completed.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Signature of Principal Investigator **Date**

Responsible Investigator Certification

By my signature as responsible investigator on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.

In addition,

- I agree to meet with the investigator on a regular basis to monitor study progress,
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them,
- I insure that the investigator will promptly report significant or untoward adverse effects to the Saint Anselm IRB in a timely manner,
- If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate staff member to assume responsibility during my absence and I will advise the IRB by letter of such arrangements, and
- I ensure that the investigator will complete the required educational program on ethical principles and regulatory requirements in a timely manner.
- I understand the Initial Review is valid up to one year and will need to submit a request for continuance each subsequent year.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Signature of Responsible Investigator **Date**

FOR IRB USE ONLY

☐ **Approved by Expedited Review**

☐ **Approved by Convened (Full) IRB (as proposed)**

☐ **Approval includes Consent Waiver**

☐ **Disapproved**

Comments:

Signature of IRB Chair or Designee **Date**

Name: