The Citadel's Institutional Review Board
Operating Procedures

Procedures Approved and Adopted by IRB September 2023

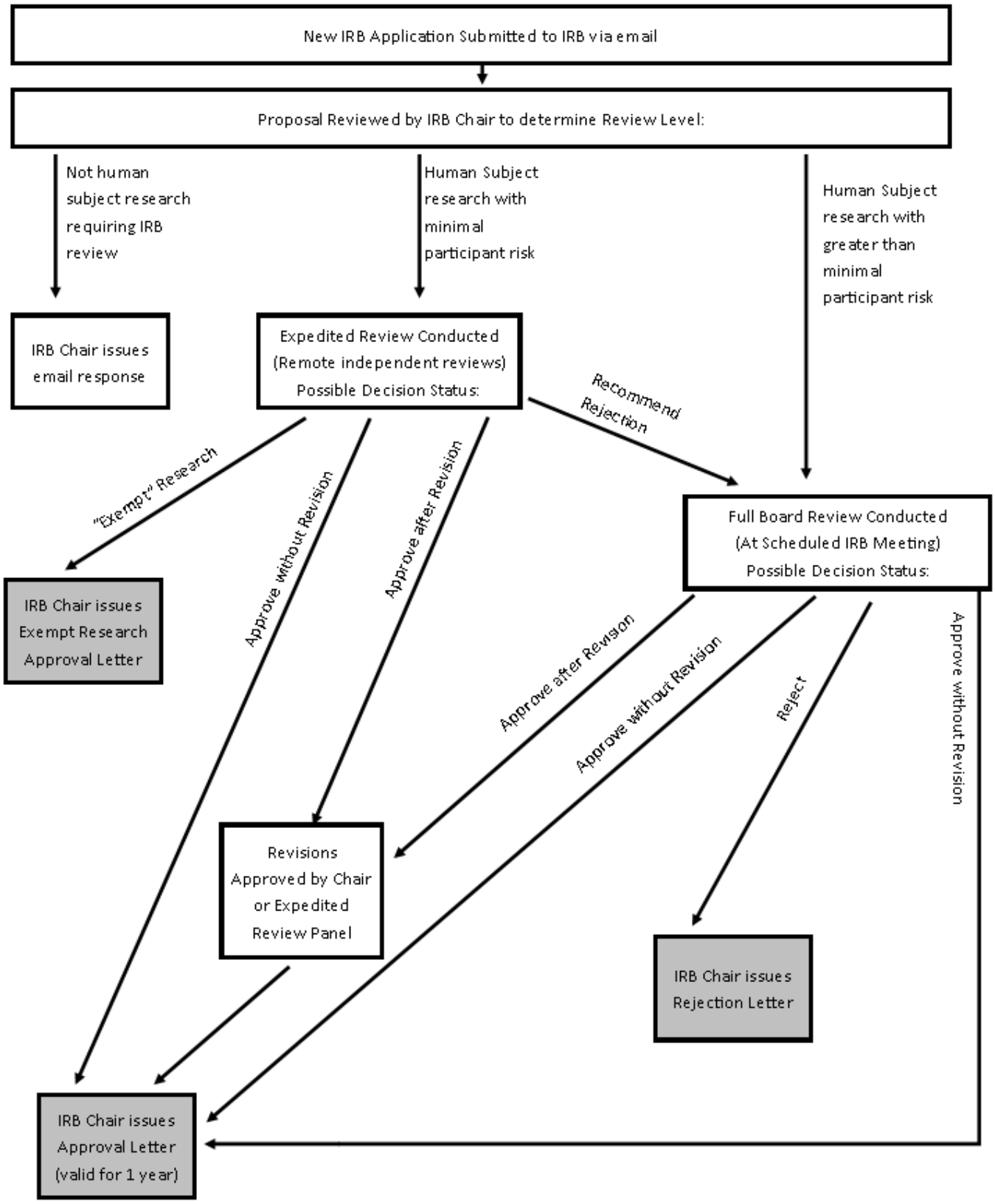
Contents

The initial expedited review process takes approximately 2-3 weeks during the Fall/Spring Semesters and 4-5 weeks during the Summer.
Proposals involving "greater than minimal risk to subjects" are reviewed at IRB Meetings which occur 4 times per year. Dates are posted on the IRB webpage.

To submit to the IRB:

1. Utilize the appropriate template(s) or form(s) from the IRB webpage.
2. Save documents in Word or PDF format.
3. Email documents to citadelirb@citadel.edu

New IRB Application Review Process Flowchart:



1. IRB Operating Procedures

The Citadel conforms to the regulations specified in Title 45 Part 46 (Department of Health and Human Services) and Title 34 Part 97 (Department of Education) of the Code of Federal Regulations (45 CFR 46, 34 CFR 97) effective January 2018, concerning the protection of human subjects involved in research. In order to conform to the federal regulations, The Citadel has established an Institutional Review Board (IRB) whose primary responsibility is to ensure compliance with The Citadel's "RP-10 Human Subjects in Research Policy" as well as with applicable state and federal regulations, which are currently in force or which may be introduced in the future.

1.1. Composition of the Institutional Review Board

The Citadel's Institutional Review Board (IRB) is required per RP-10 Human Subjects in Research Policy, and based on those requirements listed in 45 CFR 46.107a, to be comprised of at least five (5) voting members including at least one scientific area expert, non-scientific expert, and one non-institutional affiliate.
It is practice at The Citadel that IRB membership is comprised of one representative from each school, the chair, and a nonaffiliated Citadel member (total of seven voting members). The Chair will be appointed by the Assistant Provost for Research who also acts as an *ex officio* member of IRB. Deans are responsible for nominating IRB voting and non-voting members with approval of members by the Assistant Provost for Research or another designee of the Provost.

Standard Voting Membership Positions:

- Chair
- Representative- School of Engineering
- Representative- School of Science and Mathematics
- Representative- Zucker Family School of Education
- Representative- School of Humanities and Social Sciences
- Representative- Tommy & Victoria Baker School of Business
- Representative- Non-Citadel Affiliate
- *Ex officio* member- Assistant Provost for Research

If there are fewer than five voting members on the board, review of submissions will pause until the board is repopulated.

If such a time arises that the number of IRB applications and reviews necessitate expanded voting membership (and cannot be supplemented via non-voting members), the board may set forward a proposal for how the additional members are to be selected, subject to approval from the Provost.

1.2. Pool of Reviewers (Non-voting Members)

As specified in 45 CFR 46.107e, an IRB may invite additional non-voting members to serve as experts on specific topics. The Citadel IRB will use these non-voting members in reviewing specialized protocols and/or during periods of high protocol volume. Any time a non-voting member is appointed as a reviewer on an expedited review, the second reviewer must be a voting member of the IRB.
It is recommended that the pool be composed of one additional representative from each School, although departments typically submitting a high volume of protocols may be asked to appoint additional faculty to join the pool. The Chair will coordinate with appropriate department chairs and/or deans to appoint pool members.

1.3. IRB Member and Reviewer Qualifications

IRB members must have documented academic training and/or research experience to justify their expertise and qualifications in their field.
IRB members who serve as representatives from the schools should be full-time faculty or researchers within that school.
The IRB Non-Citadel member cannot be affiliated with The Citadel nor any of their direct relatives. Like all other IRB members, they should have documented academic training and/or research expertise.
Beginning Fall 2023, all members of the IRB and those in the pool of reviewers are required to complete human subjects training through a program approved by the Assistant Provost for Research. As of Summer 2023, the Citadel utilizes training modules from the CITI Program, but this is subject to change.

- The IRB Chair must complete the "IRB Chair" Module in addition to the modules required for IRB voting membership.
- IRB voting and non-voting members are required to complete the "IRB Members" Module.
- IRB non-voting members must complete the Humans Subject Research Training Module affiliated with their expertise (either Biomedical Research or Social & Behavioral Research). Voting members must complete both modules to ensure that they are equipped to review the range of protocols submitted by Citadel researchers.
- Training certificates will be stored in the IRB Sharepoint system and are valid for up to 3 years.

1.4. Duties of IRB Chair

The IRB Chair will:

1. Work with the Assistant Provost for Research to ensure that the IRB membership:
    a. Is at least 5 voting members; Including at least one scientific area expert, non-scientific expert, and one non-institutional affiliate
    b. To the greatest extent possible, reflects diversity at The Citadel with respect to gender, ethnicity, and professional discipline
    c. Contains sufficient non-voting members to complete reviews of proposals in a timely manner reflecting their research disciplines
2. Be responsible for all direct communications with the IRB received via email or other channels from Citadel affiliates and non-affiliates, including IRB submissions and inquiries. These should be replied to in a professional and timely manner.
3. Serve as designated signer for all Approval Letters from the IRB, except in cases where the Chair has a conflict of interest. These should be signed by the Assistant Provost for Research.
4. Ensure that IRB meetings are conducted in a professional manner and that all views and concerns of members are considered. The Chair may designate a non-voting individual to be responsible for taking meeting minutes during the meeting.
5. During Full IRB Reviews, Chair is responsible for ensuring all key aspects of regulatory compliance are discussed by the Board and addressed by the investigator. The Chair invites subject matter experts to inform discussion as needed. The Chair will call for votes and tally results. After Review, the Chair will issue a formal decision letter to the investigator.
6. During Expedited Reviews, the IRB Chair will designate IRB members to complete the reviews, share any documents related to the proposal, and establish deadlines for review completion.
7. Be responsible for maintaining records of all proposals per the standards discussed in section 1.17 of this document.
8. Be responsible for initial classification of all new proposals received.

9. May independently assess and approve singleIRB, Protocol Renewal, Protocol Amendment, and Adverse Event Reporting submissions. However, the Chair may reserve the right have IRB members conduct an Expedited or Full IRB review as deemed necessary by the Chair.

1.5. Duties of IRB Members

IRB voting members must:

1. Be responsive in a timely manner to inquiries from the IRB Chair via email or other communication tools
2. Attend and actively participate in IRB meetings
3. Review protocols as assigned by the Chair, via both Expedited and Full IRB Review processes, or disclose justifications for turning down a review to the Chair
4. Disclose Conflict of Interest to the IRB Chair, if any occur
5. Act as expert in their school for IRB process and assist fellow faculty in IRB preparation upon request
6. Assist in identification of replacement of IRB member when stepping down from the Board

IRB non-voting members (reviewers) are not subject to items 2 and 6.

1.6. IRB Committee Meetings

The IRB will hold scheduled meetings four (4) times each calendar year. These meetings will be publicized on the IRB webpage as well as in Faculty Senate. Location information will be provided for those who wish to attend public portions of the meeting.

IRB meetings are open to voting and non-voting members of the IRB. The Citadel community is welcome to join for parts of the meeting but may not be present during closed committee deliberations as part of the Full IRB Proposal Review process.

Meetings will consist of the following:

a) The Chair will call the meeting to order and present numerical data on Protocols and Reviewed Proposals since the last meeting
b) The Chair will review any regulation, policy, or procedure changes that may affect the IRB
c) Feedback from Committee Members will be heard
d) If any have been submitted, the IRB will conduct Full IRB Reviews of Proposals

Meetings may be held in person or video call (Zoom) at the discretion of the Chair.

The Chair will designate an individual to keep minutes during the meeting. This may be an IRB member or an appropriate member of staff. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

After the meeting, the minutes will be distributed to the IRB via email for review. Amendments must be submitted to the IRB Chair within two weeks of distribution.

1.7. Process for Review Level Classification

Proposals submitted to the IRB will be received by the IRB Chair. The Chair will conduct an initial review of the submission in order to (a) confirm that the proposal meets the requirements for "research" utilizing "human subjects [45 CFR 46.102], (b) confirm all necessary forms and documents have been provided and (c) identify if the research meets the requirements for expedited review or will require a full panel review. In order to qualify for expedited review, the submission must fall into one of the 16 categories listed below.

Note: The Chair is responsible for identifying submissions that do not meet the criteria for "human subject research" and thus do not require IRB review. This includes "Quality Improvements" activity determination. Such submissions will receive an email notification that they do not require IRB review, however they will be encouraged to (a) seek peer review within their own department/office and (b) ensure safety and welfare of participants are safeguarded.

At The Citadel, in order to maintain a high level of research integrity and protection of subjects, even research that could be classified as Exempt will receive expedited review though unless major concerns are raised by the reviewers, the proposal will automatically receive an Exempt Approval Letter.

HHS specifically identifies that "**Quality Improvement** Activities" do not meet the definition of research in many scenarios. Activities that are undertaken for the purpose of documenting and improving processes within the institution do not require IRB review. Quality Improvement activities may be published under certain circumstances without comprising "research."

Exempt Research must fall into one or more of the categories below. Special populations (pregnant subjects, fetuses, and incarcerated individuals) must meet additional criteria to be categorized as exempt. Children *may be* included in exempt research, except for in Categories 2 and 3 where the researcher cannot participate in the activity being assessed in order to be categorized as exempt. ***Proposals containing both exempt and non-exempt items cannot be classified as exempt.***

Exempt Research Categories: (Paraphrased from Subpart A of 45 CFR 46)

1. Research in established or commonly accepted educational settings involving *normal educational practices or assessment of instructors*. Research cannot adversely affect student's opportunity to learn required content.

   Example: Comparison of different instructional strategies across two sections of a course
2. Research where *only interaction is an educational test, survey procedure, interview, or observation of public behavior* (including visual or audio recording).
   - Data must be obtained and stored in such a manner that the subject's identity cannot be readily ascertained OR any data disclosure would not reasonably place subject at risk for civil/criminal liability or damage to financial status, employability, education, or reputation.
3. Research where *benign behavioral intervention* is performed in conjunction with subject data collection through verbal or written responses. Benign interventions must be brief in duration, harmless, painless, not likely to have significant adverse lasting impacts, and will not be offensive or embarrassing to the subject.
   - May include audiovisual recording if subject consent obtained prior to intervention.
   - Data must be obtained and stored in such a manner that the subject's identity cannot be readily ascertained OR any data disclosure would not reasonably place subject at risk for

civil/criminal liability or damage to financial status, employability, education, or reputation.
    - No research involving deception may be exempt unless the subject provides prior consent to be unaware of or misled regarding aspects of the research during the experiment

Example: Subjects solve a puzzle under varying noise conditions then answer a survey

4. *Secondary research* not requiring consent given one or more of the following:
    - Identifiable data/biospecimens are already publicly available
    - Investigator receives/records data/specimens such that subjects cannot be identified and the investigator will not attempt to contact or re-identify subjects from the data used
    - Research under specific criteria for public health activities (see Subpart A of 45 CFR 46)
    - Research on behalf of a Federal agency using federal data (see Subpart A of 45 CFR 46)
5. Projects conducted or supported by Federal agencies to *assess public benefit or service programs* including procedures to obtain benefits or possible changes or alternatives to existing programs.
6. *Taste and food quality* evaluation and consumer acceptance. Food must be wholesome and without additives or food consumed contained ingredients at or below levels already approved by FDA, EPA, or USDA.
7. Storage and maintenance for *secondary research* for which broad consent is required.
8. *Secondary research* for which broad consent is required. Unlike Category 4, this research would involve use of identifiable private information/specimens. Research can still be exempt if broad consent for storage, maintenance, and secondary research was obtained from subject at time of collection and stored in line with policy. IRB should still conduct review to ensure that research is in line with broad consent obtained and investigator will not have contact with individual subjects (barring external legal requirements to do so).

Expedited Review is allowed when research activity poses (1) no more than minimal risk to human subjects AND (2) is in a listed category. Expedited categories can apply regardless of subject age but may not be used for classified research. When identification of subjects and/or responses could reasonable put them at risk of civil or criminal liability or affect their financial standing, employability, reputation, etc., appropriate protections MUST be in place so that risk for breach of confidentiality is no more than minimal.

Expedited Review Categories: (Paraphrased from 63 FR 60364-60367)

1. Clinical studies of *medical drugs or devices* where investigational new drug applications or device exemption application are not required OR the device is cleared for marketing and being used in accordance with cleared labeling.
2. Collection of *blood samples* no more than 2x per week and within the volume limits provided in the policy.
3. Collection of *biological specimens via noninvasive means*, including: hair and nail clippings, teeth lost or removed through routine patient care, external secretions (including sweat), saliva, and mucosal and skin cells through scraping or swabbing. Additional examples in policy.
4. Collection of *biological data through noninvasive* means routinely used in clinical practice (cannot involve sedation nor x-rays or microwaves). Examples: sensors applied to the surface of the body, weighing or testing sensory acuity, MRI, ECG, EEG, ultrasound, moderate exercise, muscular strength testing flexibility assessment, body composition assessment

5. Research involving *materials collected solely for non-research purposes* (such as medical treatment data or specimens for medical diagnosis)
6. Collection of *data from voice, video, digital, or image recordings* made for research purposes
7. Research on *individual or group characteristics or behavior* OR research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methods.
8. Continuing review of *research previously approved* under Full IRB ("greater than minimal risk") when: (a) research is no longer enrolling new subjects AND all clinical interventions are complete AND only long-term follow-up of subjects remains, OR (b) no subjects enrolled and no additional risks identified, OR (c) remaining research activities are limited to data analysis

1.8. Criteria for IRB Approval

(Paraphrased from 45 CFR 46.111)
IRB review should, at minimum, assess the following:

1. *Risks to subjects are minimized* by using *sound research design*, utilizing existing diagnostic/clinical processes when possible. Research design is sound enough to reasonably expect to answer the proposed research question(s).
2. *Risk to the subject is reasonable* related to the benefit to the subject and the importance of the knowledge gained by the study.
3. There is *equitable selection of subjects.*
4. Special care must be taken to *protect against harm to populations vulnerable to coercion or undue influence* – children, prisoners, individuals with mental deficiencies, and economically or educationally disadvantaged persons. This may be in subject selection, study design, or consent protocols.
5. *Informed consent sought* from each subject and/or subject's legal authorized representative (Note, some exceptions apply)
    a. Informed consent sought before research begins
    b. Subject must have time to discuss and consider whether to participate or not
    c. Information in consent forms must be written in language understandable to the subject
    d. Consent forms should include the contents as described in 46.116 b
6. *Informed consent* is appropriately *documented*.
7. Adequate provisions are in place to *protect the privacy of the subjects* and maintain confidentiality of data.

1.9. Process for Expedited Reviews

Expedited Reviews consist of two IRB members (at least one of whom must be a voting member) conducting an independent review of the submitted proposal.

Reviewers will submit a completed Action Form to the Chair. The Action Form will document:

1. Comments and Suggested Revisions
2. *Classification Status* of the Proposal as "Exempt" or "Minimal Risk"
3. Reviewer *Decision*: Accept, Revisions Needed, or Reject

After the two Action Forms have been submitted to the IRB Chair, the Chair will compile feedback for the investigator and utilize the more conservative Classification and Decision statuses. If significant variation in status exists between the two reviews, the Chair will determine the appropriate status.

When research is assessed by both reviewers as Exempt, the IRB Chair will issue an Exemption Approval Letter to the research investigator with the constructive feedback from the review. This feedback is not required to be enacted but is intended to improve the quality of research and protection of human subjects at The Citadel. Proposals that are exempt do not require annual renewal.

When research is in the "Minimal risk" category, and both reviewers select the "Approve" status, the IRB Chair will directly issue an Approval Letter. If revisions are required, the Chair will inform the research investigator of the required revisions. Once revisions are made and approved (either by the Chair or another review) an Approval Letter will be issued. This research is approved for one year, after which renewal must be requested if the research is ongoing.

Note: Per 45 CFR 46.110.2, a proposal cannot be rejected via an Expedited Review. If one or more reviewers state that the proposal should be rejected, the proposal would be turned over for Full IRB review and/or the IRB Chair would communicate with the research investigator to help them modify or improve the proposal.

1.10. Process for Full IRB Review

When the IRB Chair determines that a greater than minimal risk is present for subjects and/or the research does not fall into one of the 18 Exempt or Expedited categories, the proposal will receive full committee review. Additionally, if the reviewers on an expedited review indicate that full panel review is required or they vote to reject the proposal, a full panel review will occur.

Full panel review is conducted by all voting members, excluding those with a conflict of interest. All members will receive the proposal for independent review at least two weeks in advance of the scheduled IRB meeting. Additional non-voting experts from the reviewer pool may be asked to participate, though they are unable to vote on the final decision. Voting is conducted by a hand vote, but may be done by secret ballot on request of the IRB members.

Research investigators will be informed that their proposal is undergoing full committee review and requested to be available if the committee has questions during the next IRB meeting. The research investigator will receive a video call (Zoom) link to join the meeting. In some scenarios, the investigator may be asked to join in person, but would be in a separate room until requested to join the meeting.

During the IRB meeting, the Chair will take an initial vote from the members as to the status (accept, require revisions, reject). Then discussion among the IRB members will occur to identify common concerns or questions. These may be addressed within the IRB or via conversation with the research investigator. The research investigator will only be present in the meeting to answer questions. They may also be present to hear the final decision, but will not be present for voting.

The three voting options during a Full IRB review are Approval, Revise, or Reject. For the decisions of Approval or Reject, the simple majority (>50%) of votes must be in that option. If a majority cannot be reached, a decision for Revision will be issued. For example, in a seven-member IRB, if four votes for Approve and three votes for Revision, the final decision would be Approve. However, if a member has a conflict of interest and abstains from the vote and a 3-3 split vote occurs, the final decision would be Revision.

When the outcome of the final vote is to Revise, the IRB must further decide how the revisions will be reviewed. The three options are: (1) review by Chair, (2) review by expedited review, (3) review by Full IRB. For revisions that must be approved by the full IRB, this can be done by independent asynchronous review with decisions recorded on the Action Form. All eligible voting members must approve of the revisions via the Action Form. If one or more members do not approve of the revisions, the revised proposal will be processed via the next IRB meeting.

1.11. Process for Cooperative Research

As specified in 45 CFR 46.114, cooperative research projects are those involving more than one institution. Each institution is responsible for safeguarding the rights and welfare of human subjects, however many research projects are subject to singleIRB (sIRB) requirements. This means only one institution must conduct an IRB review and other institutions may enter into an agreement to rely on another institution's IRB review to avoid duplication of effort.

The research investigator may select which institution conducts the review, however it is recommended that if 50% or more of research activities involving human subjects are conducted at or by Citadel affiliates, then The Citadel IRB is responsible for the review.

If the review is conducted at The Citadel, the research investigator is responsible for sharing the associated documentation, including the Approval Letter, with the other institution(s). If those other institutions request additional documentation that requiring signatures or information from The Citadel IRB, these should be sent to <citadelirb@citadel.edu> and will be reviewed and completed by the IRB Chair.

If the review is completed at another institution, The Citadel IRB, will maintain a record of the decision made by the other institution. Research investigators should submit a copy of their proposal documents and Approval Letter from the other institution, along with the "Cooperative Research with singleIRB at Another Institution" form found on the IRB website via email to <citadelirb@citadel.edu>. The IRB Chair will maintain records of active human subject research at The Citadel subject to sIRB and reserves the right to request an additional Citadel IRB review if the Chair does not concur with the findings of the other institution's IRB.

1.12. Process for Protocol Renewal

Approval of non-exempt protocols are only valid for one year after issue. Research investigators are responsible for requesting renewal of on-going research for an additional year of approval.

Research investigators should complete and submit the "Research Proposal Renewal" form found on the IRB website via email to <citadelirb@citadel.edu>.

If the research protocol is unchanged but ongoing, the Chair will grant an Approval Letter for the renewal.

If changes are being requested along with the renewal, the "Research Proposal Amendment" form should also be completed and submitted. The review will proceed in line with the guidelines below.

1.13. Process for Protocol Amendment

Research investigators who plan to deviate from the research protocol as submitted and approved previously must submit a "Research Proposal Amendment" form via email to <citadelirb@citadel.edu>.

For minor changes to previously approved research submitted during the year when the protocol has been approved, the review process will be carried out by the IRB Chair with appropriate records of decisions and justifications being maintained.

The IRB Chair may also opt to process the Amendment using the Expedited Review Process, above, rather than making an independent decision.

Minor changes to protocols may include, but are not limited to:

- Addition, removal, or replacement of survey questions without alteration of subjects' privacy and welfare
- Alteration of research investigators such that the subject expertise of the research team is not compromised
- Addition, removal, or replacement of data analysis methods

1.14. Process for Adverse Event Review

It is the responsibility of the investigator to submit an Adverse Event Reporting form to the IRB via email following any adverse events. The form will receive immediate review by the IRB Chair who may request suspension of the research pending IRB review depending on the severity of the adverse event.

- For unexpected significant harm, Chair request research suspension pending full IRB review
- For unexpected minimal harm, Chair request research suspension pending expedited IRB review
- For expected harm (first event), Chair documents but allows research to continue
- For expected harm (repeated or frequent), Chair may request full IRB review to compile possible modifications to increase safety

Adverse events are cases of physical, psychological, social, legal, or economic harm to human subjects or breaches of subject privacy related to their data/information. These may be expected or unexpected based on the study design.

In the event of *unexpected* harm, the IRB may require modification of the protocol to maintain approval in order to reduce the chances of a repeat event. The IRB may also terminate the research if the newly identified risk to the subjects are too great. [45 CFR 46.113]

Adverse events that are *expected* to occur as a part of the research should also be documented. These will be tracked and if they are occurring at a much greater risk than anticipated in the original approval, modification or termination of the research may occur.

1.15. Process for Sanctioning Unapproved Research

In the event the IRB is informed of human subject research by a Citadel affiliate that has not been reviewed by the IRB, the following will occur:

1. A letter to cease research activities will be sent to the research investigator(s) as well as their

department head(s) and the Assistant Provost for Research
2. The researcher may submit for IRB approval of research of projects that involve no more than minimal harm to subjects but review of the application by the IRB will include the information that it was begun without IRB approval – approval may be offered contingent on using no data prior to IRB approval
3. If research is found to involve possible greater than minimal harm to subjects, the research investigator(s) may be sanctioned by the IRB in conjunction with the Assistant Provost for Research with final approval of sanctions from the Provost

Sanctions from IRB may include but are not limited to:

- Obtaining new consent from all subjects
- Notifying all subjects of non-compliance
- Require additional human subjects research training prior to research resuming
- Require more frequent review of on-going/future research activities to ensure compliance with federal guidelines

Additional sanctions may be imposed by the Assistant Provost for Research or the Provost consistent with other Citadel policies.

1.16. Process for Protocol Close-Out

The research investigator is responsible for reporting completion of work to the IRB, for record keeping purposes. This is required for all non-exempt research and encouraged for exempt research.

Closeout letters will be created by the investigator using the provided form on the IRB webpage and submitted via email to the IRB Chair. This document will be stored with other files related to the proposal. The IRB will be informed that the protocol is no longer active.

1.17. Documentation Requirements

The IRB will maintain and update a webpage under The Citadel's Office of Research and Grants website. This will include current versions of application forms. As required by 45 CFR 46.108a2, biographical information on all IRB members can be found on the IRB webpage.

Biographical information for each IRB member will include at a minimum: name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of the governing board, and/or paid or unpaid consultant,

The main contact for the IRB is via email using the <citadelirb@citadel.edu> address. This address is accessible by the current Chair and allows continuity of contact and records throughout leadership transitions.

The IRB stores the following documents related to their operations for a period of at least three years after the completion of the related research protocols: [45 CRF 46.115]

1. Submitted IRB Research Proposals including sample consent forms
2. singleIRB record forms

3. Research Proposal Amendment Forms
4. Research Proposal Renewal Forms
5. Reports of Adverse Events affecting subjects
6. Minutes of IRB meetings
7. Copies of correspondence between IRB and research investigators
8. Rational for reviewer determinations (Action Forms)
9. Copies of CITI training certificates for IRB Chair, members, and human subject research investigators

2. Instructions for Research Investigators

2.1. Who must submit IRB Research Proposals for review?

Human subject research conducted by faculty or students must be submitted for review. This includes both Honor's and Master's theses research that involves human subjects.

Research studies from students or non-Citadel affiliates must be sponsored by a permanent member of Citadel faculty or staff before the research proposal is reviewed.

Cooperative research projects spanning multiple institutions may elect to have another institution as their IRB of record, however Citadel PIs must complete the "single IRB Form" to keep a record with Citadel IRB.

No research project which involves human subjects may begin prior to receiving approval.

Note: Not all activities meet the definition of "human subject" and "research" requiring IRB review and approval. Be sure to review the guidelines below and consult the IRB Chair to determine if your work may be excluded.

2.2. What training is required for research investigators?

All research investigators, including student researchers, must submit proof that they have completed human subject research training.

As of Summer 2023, the training service used is CITI Program. Investigators are required to complete at least the Human Subjects Research Course and the Responsible Conduct of Research Course relevant to their research area(s):

- Biomedical Research
- Social & Behavioral Research
- Research with data or lab specimens only

These can be added by answering Question 1 and 2 in the survey under "Add a Course" in the CITI Program when the account is Citadel affiliated.

Additional modules may be completed for Conflicts of Interest, Good Clinical Practice, and Information Privacy Security. These additional modules may be required by the IRB before approval is granted dependent on the content of the proposed research.

2.3. What types of research must be reviewed?

IRB review is required for all activities that meet the criteria for "research" using "human subjects" as outlined below:

- Research is a systematic investigation designed to develop or contribute to generalizable knowledge. This includes research development, testing, and evaluation. Some public health surveillance, criminal investigation, and homeland security/defense activities are excluded. Additionally, activities that collect and use information on and for specific individuals rather than to obtain more generalizable knowledge are not deemed as research. [45 CFR 46.102l]

- A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains, uses, studies, or analyzes information or biospecimens. [45 CFR 46.102e]

HHS specifically identifies that "Quality Improvement Activities" do not meet the definition of research in many scenarios. Activities that are undertaken for the purpose of documenting and improving processes within the institution do not require IRB review. Quality Improvement activities may be published under certain circumstances without comprising "research". If you are not sure if your activity is a "Quality Improvement" please email the IRB Chair, <citadelirb@citadel.edu> for guidance.

Additionally, student class assignments that are conducted during a single semester in fulfillment of class learning objectives *without* the generation of new knowledge or scholarly publication may not require IRB review. Such assignments are designed to teach research methods through student interaction with individuals ("human subjects") rather than to address scholarly research questions. These assignments differ from student thesis-type activities. Instructors should take special care to ensure that all students realize the potential for harm and take all possible steps to eliminate risk. If you are not sure if your classroom activity could be excluded under these criteria please email the IRB Chair, <citadelirb@citadel.edu> for guidance.

All *research* involving *human subjects* must be reviewed. Human subjects research will fall into one of three general classifications. These classifications are Exempt Research, Minimal Risk Research**,** and Greater Than Minimal Risk Research. *The IRB Committee, not the researcher, determines whether a particular research project is exempt, minimal risk, or greater than minimal risk.*

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 46.102j]

Exempt research and Minimal risk research must fall into one of 16 listed categories in order to qualify for Expedited Review. The Expedited Review process involves review of your submission by two IRB members using evaluation criteria specified by 45 CFR 46. Additional criteria may be applied if you are conducting research that falls under the purview of FDA. The reviews will be compiled by the IRB Chair. If your proposal is in one of the exempt categories, you will receive an Exemption Approval Letter and compiled constructive feedback from the IRB Chair. If your proposal is not exempt, you may be asked to submit revisions in order to obtain an Approval Letter.

Research judged to pose greater than minimal risk to human subjects and not meeting criteria for

expedited review will receive Full IRB review. These proposals will be evaluated by all voting IRB members without a conflict of interest at the next IRB meeting. These meetings only occur four times per year and proposals submitted less than 2 weeks before an upcoming meeting will have review postponed until the following meeting. Research investigators will be invited to be present to address questions at the IRB meeting and will receive verbal notification of the voting results, but will not be in the room during voting itself. Full IRB review will result in one of three outcomes, (1) Approval of the Protocol as submitted, (2) Revisions required prior to approval or (3) Rejection.

2.4. What are the elements of Informed Consent?

An essential provision of federal regulations is informed consent. Informed consent is defined as "...the legally effective informed consent of the subject or the subject's legally authorized representative" **[45 CFR 46.116]**. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject, or the representative, shall be in language understandable to the subject or the representative.

In some research, it may be necessary, for the success of the research, to not fully inform individuals because disclosing information will affect the results of the study. In these instances, it is necessary to clearly explain in the research proposal why the information will not be provided and how individuals will be debriefed at the conclusion of the research. All research involving deception or lack of full disclosure must be reviewed, even research that may otherwise be judged as Exempt. **[45 CFR 46.116]**

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. **[45 CFR 46.116]**

Particular attention to informed consent must be exercised with vulnerable populations, such as children, prisoners, pregnant women, mentally disabled subjects, or subjects that are economically or educationally disadvantaged. **[45 CFR 46.111 (b)]**

The IRB may require that additional information be presented to participants as part of the informed consent procedure if the information would meaningfully add to the protection, rights, and welfare of the subjects. **[45 CFR 46.109(b)]**

In seeking informed consent, the following basic elements shall be provided to each subject **[45 CFR 46.116 (a)]**:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be

advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Sample Informed Consent forms and templates can be found on the IRB website.

2.5. What criteria are used to evaluate IRB Research Proposals?

The IRB will ensure that all research proposals meet the technical requirements of the law. In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied.

- The risk to subjects are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose subjects to risk. **[45 CFR 46.111 (a) (1)]**
- The risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result from the research. **[45 CFR 46.111 (a) (2)]**
- The selecting of subjects is equitable. **[45 CFR 46.111 (a) (3)]**
- Informed consent will be obtained from each prospective subject and, if necessary, from the subject's legally authorized representative. **[45 CFR 46.111 (a) (4)]**
- Informed consent will be appropriately documented. **[45 CFR 46.111 (a) (5)]**
- The research plan makes adequate provisions for monitoring the data collected to insure the safety of subjects. **[45 CFR 46.111 (a) (6)]**
- Where appropriate, there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data about or from these subjects. **[45 CFR 46.111 (a) (7)]**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. **[45 CFR 46.111 (b)]**

IRB Committees have authority, under Federal guidelines, to approve, disapprove, or require modifications of a research project **[45 CFR 46.109(a)]**, including evaluation of the design and procedures being proposed.

The IRB has authority to suspend or terminate approved research that is not being conducted consistent with the approved procedures or the law. **[45 CFR 46.113]**

2.6. How do I submit the IRB Research Proposal?

The Citadel's Templates for IRB Research Proposals can be found on the website for The Citadel's Office

of Research & Grants. Commonly used forms include:

- New IRB Proposal Submission
- Cooperative Research with singleIRB at Another Institution
- Approved IRB Proposal – Amendment Request
- Approved IRB Proposal – Renewal Request

Submission Steps:

1. Complete the documents in a word processor. Content may be submitted as a single document or multiple documents in Word or PDF format.
2. Email the completed IRB Research Proposal and associated documents to <citadelirb@citadel.edu>
3. You will receive an email message confirming receipt of the proposal within two business days.

2.7. When will I be notified of the IRB Committee's Decision?

If the proposal is processed via Expedited Review, you will be notified of the IRB Committee's decision approximately 2-3 weeks (during Fall and Spring semesters) after submitting the proposal. During the Summer, expedited reviews may take up to 4-5 weeks.

If processed via Full IRB Review, the decision of accept or reject would be issued at the IRB Meeting with the formal letter to follow from the IRB Chair. If the decision at the meeting requires revisions, additional time will be required. Remember that if submitting a proposal that is not in one of the 16 exempted or expedited categories, your proposal will need to be submitted at least two weeks ahead of the next IRB Meeting for consideration.

2.8. What do I do after my Proposal is Accepted

Your acceptance letter is valid for 1 year after issue.

After 1 year, you must do one of the following:

- Submit a close out letter to the IRB discussing completed work
- Submit a request for renewal and/or addendum to the existing Protocol

Templates for both options can be found on The Citadel Office of Research & Grants webpage

Note: Research proposals that received an "Exempt Approval Letter" do not require renewal as long as the activities are enacted exactly as stated in the proposal. However, for record keeping purposes, at the one-year mark, a "close out letter" should be submitted even if research is ongoing.

2.9. How do I document an Adverse Event?

It is the responsibility of the investigator to submit an Adverse Event Reporting form to the IRB via email following any adverse events. The form will receive immediate review by the IRB Chair who may request suspension of the research pending IRB review depending on the severity of the adverse event.

Adverse events are cases of physical, psychological, social, legal, or economic harm to human subjects or breaches of subject privacy related to their data/information. These may be expected or unexpected based on the study design.

In the event of unexpected harm, the IRB may require modification of the protocol to maintain approval in order to reduce the chances of a repeat event. The IRB may also terminate the research if the newly identified risk to the subjects are too great. [45 CFR 46.113]

Adverse events that are expected to occur as a part of the research should also be documented. These will be tracked and if they are occurring at a much greater risk than anticipated in the original approval, modification or termination of the research may occur.

2.10. How do I request approval for changes to a previously approved protocol?

Research investigators who plan to deviate from the research protocol as submitted and approved previously must submit a "Research Proposal Amendment" form via email to <citadelirb@citadel.edu>.

For minor changes to previously approved research submitted during the year when the protocol has been approved, the review process will be carried out by the IRB Chair with appropriate records of decisions and justifications being maintained.

The IRB Chair may also opt to process the Amendment using the Expedited Review Process, rather than making an independent decision if the changes are greater than minor.

Minor changes to protocols may include, but are not limited to:

- Addition, removal, or replacement of survey questions without alteration of subjects' privacy and welfare
- Alteration of research investigators such that the subject expertise of the research team is not compromised
- Addition, removal, or replacement of data analysis methods

Researchers should not alter how they enact a protocol until approval has been obtained from IRB.