Institutional Review Board of Centenary University

DRAFTED
Nov. 22, 2010

APPROVED BY SENATE
February, 2011

APPROVED BY FACULTY
March, 2011

APPROVED BY VPAA
April, 2011

APPROVED BY LEGAL
April, 2011

APPROVED BY CENTENARY COLLEGE BOT
July, 2011

EDITS FOR UNIVERSITY TRANSITION
April 2017

EDITS TO REFLECT CITI TRAINING & APPLICATION REVISIONS
April 2018; April 2021

EDITS TO ENHANCE PARTICIPANT DATA SAFETY
November 2021

ADDITION OF IRB APPLICATION FOR SECONDARY DATA ANALYSIS
November 2022

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MISSION STATEMENT

The Institutional Review Board (IRB) of Centenary University strives:

- To promote ethical research;
- To protect research participants' rights;
- To facilitate research and research careers;
- To ensure compliance with federal regulations; and
- To protect the interests of the institution.

BYLAWS
INSTITUTIONAL REVIEW BOARD (IRB) OF CENTENARY UNIVERSITY

Article 1 – Names and Offices

1. The name of this committee shall be the Institutional Review Board (IRB) of Centenary University.
2. The official mailing address of the IRB shall be *Centenary University, 400 Jefferson Street, Hackettstown, New Jersey 07840*. The contact email shall be irb@centenaryuniversity.edu. The contact person shall be the IRB Chair.

Article 2 – Purpose

1. The mission of the IRB is assisting researchers and Centenary University administration to protect the rights and welfare of human research participants.
2. Specifically, the IRB is responsible for:
    a. Clarifying if research is **exempt** from IRB review
    b. Initial and continuing review of **non-exempt** research
    c. Ascertaining if proposed research meets the federal guidelines for human research participant protections as well as all Centenary University policies
    d. Provision of assistance and information to all current or potential researchers at Centenary University
    e. Developing, maintaining, and adjusting all policies regarding human research participants research
    f. Adjudicating and/or reviewing any problem arising from research with human participants at Centenary University
    g. Reporting to the VPAA any serious and/or continual non-compliance with requirements set forth by the IRB

Article 3 – Membership

1. The IRB will consist of FIVE (5) total members.
2. Four (4) full-time faculty members from the following academic departments and school: Business Media & Writing, Education & Humanities, and the School of Natural, Health, Social & Behavioral Sciences. These departments/school at Centenary University have faculty trained and familiar with social science methodology.
3. The fifth member will be from the community (e.g., Hackettstown or surrounding areas). This member will be selected by the President and/or Vice President of Academic Affairs in consultation with the IRB and Senate.
4. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
5. The IRB membership term for **faculty members** will be three-years. The IRB membership term for the **community member** will be one-year. However, the community member can serve multiple one-year terms for as long as the member, the IRB, and Centenary University desire.
6. At inception, the IRB shall meet on *an as needed basis*. If/when the number of research proposals consistently submitted to IRB warrants a change to more frequent meeting times the IRB (in consultation with the Senate) shall make such a change.

Article 4 – Chair

1. At the first IRB meeting of the academic year the IRB will elect a Chair via simple majority vote of IRB members. The Chair will serve for a 1-year term determined by the IRB (in consultation with the Senate) and cannot exceed three (3) consecutive academic years.
2. Only the faculty members of the IRB are eligible to serve as Chair.
3. At the end of each academic year the Chair will write and distribute (to the Senate and VPAA, an annual report of all IRB matters attended to during the academic year).

Article 5 – Resources

1. Centenary University will make available to the IRB the necessary resources for carrying out essential duties such as an on-campus mailbox and email account designated for IRB use and accessible by the Chair. Web-space for IRB forms, policies, contact information, and other pertinent information will also be made available.
2. At the start of each semester a classroom/meeting room (booked by the Chair using the standard University procedures) will be made available as a standing reservation for the IRB to use should the need for a full review and/or meeting arise at any point during the semester.

Article 6 – Amendments

1. Subject to the approval of all IRB members (and in consultation with the Senate) these By-Laws may be altered, amended, or repealed at any regular or special meeting of the IRB.

IRB of Centenary University
Policy for Human Research Participants

GENERAL STATEMENT

This policy contemplates that research that meets the requirements of this policy shall be approved and not rejected for reasons that fall outside the purview of this policy. The IRB shall not consider general policy or political reasons as a basis for making its decisions.

This policy applies to any research activity conducted at or sponsored by Centenary University that involves human participants. It is relevant whenever an investigator conducts research where:

- Data are obtained through intervention or interaction with an individual *or*

- Data are obtained via private information by which an individual could be identified.

The policy is therefore applicable to research involving living human beings whose physical, emotional, or behavioral conditions, responses, tissues, or fluids are investigated for research purposes (that is, for any reason other than the sole purpose of benefiting the participant as an individual). It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain nonpublic information about individuals or groups, as well as the study of existing public or privately held records where the identity of individuals is known.

The policy is applicable to studies of all sample sizes and regardless of whether the research is undertaken is externally funded or not. Pilot projects, student research, independent study projects, and course projects must follow this policy if they involve research with human participants and are not otherwise exempt under IRB policy.

This policy **does not apply** to routine course work, workshop, or curriculum development using accepted educational practices sponsored by Centenary University or to services provided by professionals to their clients. This policy also does not apply to student, or other, research projects that are not published, or publicly disseminated, and thus do not contribute to generalizable knowledge (as that term is used in applicable federal regulations governing human participant research).

For the purposes of the IRB of Centenary University, publication or public dissemination shall **not** include:

- The oral presentation of student research projects in classrooms as part of a course,

- At undergraduate research colloquiums or other campus events where the primary purpose of the presentation is not to disseminate information to individuals or groups outside the Centenary University community.

The presentation of student research or other research projects at external conferences or at campus events where the presentation of the information to individuals from outside Centenary University is a primary purpose of the event or the placement of the research on file at the Centenary University library **shall be** considered the publication and/or public dissemination of the research.

COMPLIANCE WITH APPLICABLE LAWS

In accordance with Centenary University policy governing the use of human participants in research, all human participants research under the auspices of Centenary University will be performed in accordance with *Title 45 Code of Federal Regulations, Part 46 (45 CFR 46).* Any research involving drug/alcohol abuse treatment will also be conducted in accordance with *Title 42, Part 2 – Confidentiality of Alcohol and Drug Abuse Patient Records.* In addition, Centenary University will also adhere to all applicable federal, state and local laws and regulations.

REVIEW OF RESEARCH

All research involving the collection of information involving human participants for the purpose of advancing knowledge that is not exempted by this policy must be reviewed and approved prior to commencing such studies.

The requirements of this section apply to any research project conducted at Centenary University or elsewhere, or anyone affiliated with Centenary University (i.e. all faculty, staff, undergraduate, and graduate students).

CATEGORIES OF IRB REVIEWS

The following categories of review shall be applied to research proposals involving human participants:

Exempt Review

a. Research activities where there are no apparent risks for the involved human participants as outlined in the Exempt Review Criteria set forth in 45 C.F.R. Section 46.101(b).

b. The determination of whether a research activity meets the exemption criteria set forth in subparagraph 1 (c) below shall be made by the IRB Chair/Designee.

c. Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from full review by the IRB:

(1) As outlined in the AAUP white paper *Research on Human Subjects: Academic Freedom and the Institutional Review Board (2006)* any "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places" (p. 11). *Autonomous adult* is defined as a participant at least 18 years of age and not a member of one of the listed protected populations in 45 CFR, Section 46: Fetuses, pregnant women, neonates, or human in vitro fertilization (45 CFR Section 46.201 et seq.), prisoners (45 CFR Section 46.301 et seq.), or children (45 CFR Section 46.401 et seq.).

(2) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is

recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

a. Full review is required for existing datasets consisting of participants from one or more of the protected populations

b. Full review is required for any existing drug/alcohol abuse related dataset **not in the public domain**

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Full Review

a. All proposals that do not meet the criteria for exempt review shall be considered as a full review that requires all members of the IRB to review. Such proposals must be reviewed and approved by majority vote of the IRB prior to any involvement of human participants in the research.

b. Any research involving drug/alcohol abuse must adhere to one of the following two scenarios:

(1) If the Centenary University researcher is collecting original data, specific mention must be made as to how the data will be kept confidential as outlined in *Title 42, Part 2 – Confidentiality of Alcohol and Drug Abuse Patient Records* (290-DD3, EE3)

(2) If the Centenary University researcher is working in collaboration with another researcher/agency and obtaining pre-existing data **not in the public domain**, the Centenary University researcher must include a letter of support from the principle researcher that specifies the dataset is voluntarily being shared with the Centenary University researcher, and in accordance with *Title 42, Part 2 – Confidentiality of Alcohol and Drug Abuse Patient Records* (290-DD3, EE3) the data are confidential and that the principle investigator is providing the data to the Centenary University researcher for the purposes of scientific research.

APPROVAL/REJECTION

Exempt Status

The IRB Chair reviews any proposal classified as exempt to ***simply verify*** that the proposed research falls under one or more of the exempt conditions. If the proposal is found exempt an approval letter (written by the IRB Chair) is forwarded to the Principle Researcher and human research participation may begin immediately.

If the IRB Chair finds the proposed research to not fit one or more of the exempt conditions, the Chair sends a letter to the Principle Investigator asking that either the research proposal (1) be amended (in a manner outlined

by the IRB Chair) to meet exempt status or (2) be revised and resubmitted as a full review proposal. No human research participation on this project may commence until the proposal (in either an exempt or full review format) is approved.

Full review for a proposal qualifying as exempt may be granted if such a review is mandated by an external funding source. Such a request should be made in writing to the IRB Chair in advance of submitting the proposal.

If the Chair is the investigator of a proposal, a pre-determined alternate IRB member determines exempt eligibility.

All exempt status reviews shall produce a decision in no more than 15 business days from submission.

Full Review

If a proposal comes to the IRB in need of full review the entire five-member IRB will convene to review and discuss the proposal. If a simple majority (at least three votes in favor) find the proposal has sufficiently followed all pertinent human participant protections the research is accepted. An approval letter (written by the IRB Chair) is forwarded to the Principle Researcher and human research participation may begin immediately. If a majority cannot approve the proposal the IRB Chair will communicate the decision in writing.

The letter will list the proposal problem(s), possible solution(s), and stress that the IRB is available to assist the researcher(s) in revising the proposal.

All full reviews shall produce a decision in no more than 30 business days from submission.

AMENDMENTS

Once accepted, if the proposal is amended in any manner (including additional researchers or an exempt proposal becoming non-exempt status) an amendment form must be forwarded to the IRB. If necessary (e.g., exempt study amended to now be non-exempt) the IRB will convene to review the amended project.

RESEARCH ETHICS TRAINING

All potential researchers (and research assistants) must complete the **free** Collaborative Institute Training Initiative **(**CITI) online ethics training. A certificate of completion for each researcher/assistant listed on the IRB must be included as an appendix to the IRB application. These trainings should, at minimum, include the Basic Researcher and Responsible Conduct of Research courses.

All IRB members must complete the CITI online ethics training for IRB members. All IRB member certificates will be kept on-file by the IRB Chair.

Certificates will expire 3 years after completion date.

STUDENT SUBMISSION OF PROTOCOLS

Students submitting a research proposal (as the lead investigator) must have a faculty sponsor that verifies the student is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct the particular study.

Both the student and the faculty sponsor must have taken the CITI online ethics training.

INSTRUCTIONS FOR CITI TRAINING

-Click on https://www.citiprogram.org/index.cfm?pageID=14 and select "register".
- Select affiliation (type Centenary University and the option will pop up). Do NOT choose independent learner registration.
- Agree to terms of service and affirm affiliation with Centenary by checking the boxes.
- Hit "continue" button to create your CITI username and password.
- Create username and password.
- Choose country of residence (US).
- Choose "yes" or "no" for the option to purchase continuing education credits for the CITI training.
- Fill out demographic info.
- Select training modules. Modules #1 (Human Subjects Research basic training) and #7 (Responsible Conduct of Research) are required for IRB submission. In both cases, you will choose the specific module most applicable to your discipline and research agenda (*EdD students and Chairs are required to take the Social Sciences Basic/Refresher and RCR*)
- Click "finalize registration".
- Click "view courses"
- A list of your selected courses will appear. Click "start now" to begin a course.

You do not need to take the entire training at once. The system will allow you to log out and return where you left off. Once completed, you will receive a certificate for the course, which you will print out and include with your IRB application.

CONTINUATION REVIEWS

The IRB shall conduct continuing reviews of **non-exempt research** at intervals appropriate to the degree of risk, but at least once per year. Scheduling of reviews will be addressed in the IRB meeting and communicated to the Principle Investigator in the approval letter.

RECORD RETENTION

Federal regulations require that all records relating to the IRB and to human participant activities be retained for at least three years after completion of the research. Records, including signed consent forms and collected data, must be accessible for inspection at any time and for copying by authorized representatives of Centenary University or the agencies sponsoring the research.

INSTITUTIONAL OVERSIGHTS

Only the IRB of Centenary University has the authority to approve, suspend, terminate, or disapprove of a research proposal/program housed at and/or sponsored by Centenary University.

However, the IRB **does not** oversee any research operations conducted by the Office of Institutional Research for University purposes.

The IRB has the authority to suspend or terminate approval of any research conducted at or sponsored by Centenary University that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and to the appropriate institutional officials.

For any research supported by the United States Department of Health & Human Services (e.g., National Institutes of Health) that is terminated or suspended, federal regulations mandate that the Secretary of Health & Human Services be notified as well.

IRB CONSULTATION

Any and all communication regarding the IRB process and or applications, etc. must go through: irb @centenaryuniversity.edu. All faculty members of the IRB are available for consultation during any component(s) of the proposal process or project implementation. Such consultation will be made directly between the researcher(s) and IRB member(s) and need not mandate an IRB meeting.

RESEARCH PARTICIPANT DATA SAFETY REQUIREMENTS

All data collected under IRB-approved protocols must ensure data security in order to protect research participants/subjects. In IRB applicantions utilizing anonymity, participants should not be able to be reidentified through the use of email addresses, IP addresses, and/or similar means of identification. Concurrent with this requirement, Google Forms will not be allowed as a survey data collection tool. Microsoft Forms, Surveymonkey, or Qualtrics are all acceptable to use for research data collection, so long as collection of identifiers are not selected when appropriate.

Data collected under IRB-approved protocols must also be stored securely and may not be accessed, intentionally or unintentionally, by unauthorized third-parties. To ensure data security, data should minimally be stored in a password protected drive to maintain a basic level of privacy for study subjects and optimally be encrypted to prevent unauthorized access. Storage on cloud-based servers, such as Google Drive, or on a computer with a password login alone are not considered secure (i.e., password protection on the drive/folder is required). Generally, consent forms should be stored separately from participant data to reduce the risk of reidentification.

MULTI-SITE COLLABORATION

Regardless of acceptance by the IRB of Centenary University, all projects done in collaboration with other institutions that require IRB review must provide a certificate of IRB approval from the other institution(s) prior to commencement of human research participant research. In addition, the IRB of Centenary University will forward an IRB approval letter to the other institution(s).

IRB CALANDER OF REVIEW

The IRB will meet to review applications ONLY during the Academic Calendar. The IRB will **NOT** operate during the summer months or winter break period (June through August, late December through early January). Any research in need of exempt or full-review should be submitted no later than **April 1st** (or first business day thereafter) for full reviews or **April 15th** (or first business day thereafter) for exempt reviews, so human research participation may occur in the summer.

Institutional Review Board of Centenary University
E-mail: **irb@centenaryuniversity.edu**

DIRECTIONS: Application for Review of Human Subjects Research

1. **If you have additions/revisions to a previously approved application, please submit an addendum.**
2. For new applications, please take a moment to review the policy on IRB submissions as well as the appropriate federal guidelines.
3. Download and save this form into Microsoft Word. Place cursor on the gray boxes and type. The box size will expand as you type. Examples and instructions for individual questions appear in italics. The application MUST be completed using the Microsoft WORD program. NO handwritten or PDF versions of applications will be accepted.
4. Please be sure to complete EVERY item in the application or it will be returned as incomplete. It is important to note that applications will not be considered for any form of IRB review until the application is deemed complete. Principal Investigators are strongly encouraged to plan their research accordingly to allow sufficient time to carry out the project upon completion of the IRB review process.
5. For student research, the faculty advisor/supervising professor should review the protocol prior to submission to ensure that it is complete, and that it is scientifically and ethically sound.
6. The application must be delivered electronically in one PDF document (including supplemental materials and CITI certificates) via e-mail to irb@centnaryuniversity.edu.

Review Categories and Timeline

a. **Exempt:** Within 15 business days of receiving the complete application, the Principal Investigator will be informed via electronic letter of the Outcome of IRB Review.
b. **Full Review:** Within 30 business days of receiving the complete application, the PI will be informed via electronic letter of the Outcome of IRB Review.
c. The IRB can offer guidance on the appropriate research review category.

Centenary University IRB Protocol Application Checklist

[ ] Application is filled out in its entirety and submitted in one PDF (please leave no blanks; use "n/a" if an item is not applicable)

[ ] You are listed as the Principal Investigator (PI)

[ ] Your faculty/dissertation advisor (if applicable) is listed as the Co-PI

[ ] You have completed the CITI training within the last three years AND you have attached your certification to the application https://www.citiprogram.org/index.cfm?pageID=14

[ ] Your advisor (if applicable) has completed the CITI training within the last three years AND you have attached their certification to the application

[ ] You have signed and dated the application (see page 8)

[ ] Your advisor (if applicable) has signed the application (see page 8) and supervisor's consent (page 12)

[ ] Administrative letter of support if using Centenary University data (Please note that permission is required for any campus-wide CU data collection or retrieval of CU data. This permission must be granted before IRB submission – complete "permission to use CU data form" and submit to the Vice President for Academic Affairs (VPAA).

[ ] Off-campus collaboration letter of support and/or IRB approval from outside institution

[ ] K-12 research approval form/letter (Please note that each site may have different protocols for approving external research, and it is up to the researcher to contact schools/districts/administrators to get permission from the appropriate authority i.e. BOE, superintendent, principal)

[ ] You have attached the following appendices (as applicable):
- [ ] Consent form(s)
- [ ] Assent script(s)
- [ ] Recruitment materials (emails, letters, posters, verbal scripts, etc.)
- [ ] Data collection tools (surveys, interview questions, manipulation materials, etc.)
- [ ] Debriefing script(s)

Please note that applications that are missing substantial information or have grammatical errors that impede the committee's ability to ascertain meaning may be returned to you.

Please allow 15 business days for exempt applications and 30 business days for full board applications. Please consider this when developing your study timeline.

Submit all application materials (in one PDF) to IRB@centenaryuniversity.edu

IRB of Centenary University

400 Jefferson Street
Hackettstown, NJ 07840
Submit applications to: IRB@centenaryuniversity.edu
Application for Review of Human Subjects Research

TYPE OF REVIEW REQUESTED

[ ] **EXEMPT** [ ] **FULL REVIEW**

A. IDENTIFYING INFORMATION

1. Principal Researcher's Contact Information:
   Name(s): Address:
   Phone Number: E-mail:

2. Co-Researcher(s) Contact Information (*students should include faculty advisor's info here*):
   Name(s): . Address: .
   Phone Number: . E-mail: .

3. Department:

4. Dissertation supervisor's name and email (*if EdD student*):

5. Research Category: (Please mark an X in the appropriate box)

[ ] Faculty research	[ ] Senior Thesis	[ ] Research from another institution
[ ] Graduate student research	[ ] Undergraduate student research	[ ] EdD dissertation research
[ ] Honors thesis	[ ] Undergraduate independent study	[ ] Other, please specify:
[ ] Master's Thesis		

6. Title of the Study:

B. HUMAN PARTICIPANT PROTECTIONS REQUIRED TRAINING

1. I have attached the CITI Training Certificates for all PI's and co-researchers: [ ] Yes [ ] No

C. SUPERVISING PROFESSOR'S CONSENT (*required for all student research – see page 13*)

1. I have attached my supervising professor's consent form: [ ] Yes [ ] No [ ] N/A

D. RESEARCH PROJECT DESCRIPTION

1. In approximately 500 words, please describe the purpose of the study (*What is the central research question and/or hypothesis that this study examines? What is the goal/objective of this study?*) and a brief rationale for the study (*Why is this study needed? How does it fit in with existing research? What new knowledge will this study potentially add?)*:

E. SAMPLING METHOD AND PARTICIPANT REQUIREMENTS

1. Sampling Method
   [ ] Random
   [ ] Convenient
   [ ] Purposive
   [ ] Snowball
   [ ] Other (explain) _____

2. Participant Characteristics
   a. Projected number of participants _____
   b. Age range _____
   c. Gender _____

   d. What are your inclusion criteria?

   e. What are your exclusion criteria?

3. What is the population from which you will select participants for the study?
   Please mark an X in all appropriate box(es)

[ ] Centenary University Students	[ ] Non-English Speaking Persons
[ ] Centenary University Employees	[ ] Physically Disabled
[ ] General Public	[ ] Mentally Disabled
[ ] Pregnant Women	[ ] Prisoners
[ ] Children/Minors	[ ] Economically Disadvantaged
[ ] Institutionalized Persons	[ ] Alcohol/Drug Abuse
[ ] Critically or Terminally Ill	[ ] Elderly
[ ] Public School Employee	[ ] Other, please specify:

   a. Please describe your role, if any, as it relates to the participants in your study, other than that of Principal Researcher (*for example, are you collecting data from colleagues or students in a district in which you are employed? Are you a student collecting data from other students?)*

4. Access to Participants (*How will you gain access to participants? Be specific.*)

5. Participant Recruitment (*How will you recruit participants? Who will do the recruiting? How will participants initially learn what the study is about? <u>Please note that all recruitment materials need to be included at the end of the application</u>*):

   Please mark an X in the appropriate box(es).

[ ] Flyers/Posters	[ ] Telephone
[ ] Letter	[ ] Internet
[ ] E-mail	[ ] Newspaper
[ ] Radio	[ ] Social Media

   [ ] Other (please specify) _____

6. Participant Expectations (*Please generally describe a typical participant's experience from the beginning until the end of the study. Detailed information regarding measurement tools will be asked elsewhere.*):

7. Participant's Total Estimated Time Commitment:
   .

8. Setting for Data Collection (*e.g., school, hospital, clinic, home, lab, etc. Be specific.*): .

9. Timeline for the Study (*month and year; e.g., 9/10 – 5/11*):
   Expected Start Date: Expected Completion Date:

10. Does this research involve the IRB approval of one or more participating institutions or organizations other than that of Centenary University?
    [ ] Yes (*Please include appropriate documentation*) [ ] No

    If you answered "yes" to question 10:

11. Contact Person:
    Name(s): Address:
    Phone Number: E-mail: .

F. INFORMED CONSENT/ASSENT PROCEDURES

1. Will this study seek consent from participants?
   [ ] Yes
   [ ] No
   If consent will not be sought, please explain why and what procedure you will use to ensure the participant understands his/her/their rights.
   .

2. What type of document(s) will be used to obtain consent? (*Please include a copy with this application*)
   [ ] Signed consent form [ ] Parental Consent Form
   [ ] Letter of Consent [ ] Child Assent
   [ ] Online consent statement [ ] Other, please specify: .

3. Will this study seek verbal assent from participants?
   [ ] Yes
   [ ] No

   If verbal assent will be sought, please explain why and what procedure you will use to ensure the participant understands his/her/their rights:

G. MANIPULATIONS, MEASURES, AND QUALITATIVE DATA COLLECTION

1. Manipulation Information (*Will this study include a manipulation?*):
   [ ] No
   [ ] Yes
   If "yes," please describe in detail the manipulation being used. *(Please append a copy of the relevant materials—what participants will see—to this application.)*
   .

2. Measure Information (*What will participants be asked? Provide the name of any instrument(s) being used <u>and</u> a citation/reference; Please append a copy of relevant materials—what participants will see—to this application; If your measurement tool in copyrighted or requires permission for use, please include appropriate documentation at the end of the application).*

3. Qualitative Data Information (*What will you ask participants? e.g., Focus group discussions, interview questions, field notes, list of discussion topics, any "starter" questions for each topic, etc.): (Please append a copy of relevant materials —what participants will see—to this application.)*

4. Feedback (*What information will be provided to participants concerning their results?*):
   .

H. DATA COLLECTION AND CONFIDENTIALITY

1. Please indicate if you will use any/all of the following:
   [ ] N/A [ ] Audio recording [ ] Video recording [ ] Other, please specify: .

2. Is this an anonymous study?
   [ ] Yes [ ] No

   If "yes," please explain how anonymity is assured? If using Microsoft Forms or a similar program, please explain specifically how this program manages data and ensures anonymity.

   If "no," please explain, in detail, the plan to protect participant information (for example, use of identification numbers). Also, please explain why retaining identifying information is necessary; also, explain who will have access to this information:

3. Where, how, and for how long will the data from the study be stored? (*If stored on a laptop computer, where is it stored and who has access? All research records must be stored for a minimum of three years. Describe how you will ultimately dispose of your records after this time. If you do not plan to destroy research records, please provide a justification and how you will ensure confidentiality*)
   .

4. Will signed informed consent forms be kept separately from the data? [ ] Yes [ ] No [ ] N/A

   If yes, where will the informed consent forms be kept?

I. RISKS TO RESEARCH PARTICIPANTS

Risks can be either physical, psychological, legal, or social. Most research has some risk. Please describe even minor risks (e.g., potential embarrassment, anxiety, feeling left out, etc.) Include those aspects of the procedure that might cause unusual discomfort or inconvenience to the research participants, including the impact on their self-esteem or self-image.)

1. Potential Immediate Risks

2. Potential Long-Range Risks

3. If there are immediate or long-term risks to the participant, how will you mitigate these risks?

J. BENEFITS TO RESEARCH PARTICIPANTS

1. Describe any benefits participants may receive as participants in your study.

2. Will participants be compensated for their time?
   [ ] No
   [ ] Yes, please explain: .

K. DECEPTION

1. Will you be utilizing deception?
   [ ] No (Please skip to section L.)
   [ ] Yes

2. What is the nature of the deception involved? Will this be significant to participants? (*If possible, please provide citations for published research that has used similar methods*.)
   .

3. Why is this deception necessary (*please describe consent procedures related to the deception, including plan for minimizing risk*)?
   .

4. Deception Debriefing (*Describe the procedure you will use to debrief your subjects regarding the deception. How will you explain the deception to participants?*):
   .

L. DEBRIEFING

1. Will you debrief participants?
   [ ] Yes
   [ ] No *(Please consider that it may be advisable, depending on your research design, that participants receive a full debriefing for educational purposes, to answer any questions, and/or to provide an additional opportunity for participants reveal if the study caused any feelings of discomfort.)*

2. Debriefing Procedure (*How will debriefing take place? When? Where? Individually or in groups? Please be specific and include debriefing materials*):

M. RESEARCHER RESPONSIBILITIES

As a researcher you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations imposed by the IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved application.

2. Adhere to ethical codes and applicable policies and procedures of Centenary University, the sponsoring agency, relevant professional organizations and cooperating institutions (if any).

3. Do not implement changes in the approved study or consent form without prior IRB approval by completing an Addendum Form (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects).

4. If written consent is required, obtain the written informed consent from human subjects or their legally responsible representative. Store informed consents and data in a secure but separate place for a minimum of three (3) years.

5. Promptly report (to the IRB Chair) all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within five (5) working days of occurrence. All fatal or life-threatening events or events requiring hospitalization must be reported to the IRB Chair in writing within 48 hours after discovery.

6. Submit the Annual Review Form when directed to do so to the current IRB Chair.

7. Retain required records for a minimum of three (3) years.

_____ _____

Signature of Principal Researcher Date

_____ _____

Signature of Dissertation Advisor (if applicable) Signature of Co-Researcher

_____ _____

Signature of Co-Researcher Signature of Co-Researcher

Supervising Professor's Consent

I am the supervising professor for the student submitting this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound. Furthermore, I believe that the student has the necessary training, experience and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles. I agree to:

- Oversee and monitor the conduct of this research by communicating regularly with the student investigator;
- Assist with the resolution of any problems or concerns encountered during the research;
- Assure that the IRB is notified in the event of an adverse event or protocol deviation.

I have reviewed the IRB checklist and application and certify that it is complete and reflective of the student research plan.

I understand that as supervising professor I am responsible for the conduct of this research.

_____ _____

Signature of Supervising Professor Date

Supervising Professor: .
Phone Number: .

Address: .

E-mail: .

IRB of Centenary University
400 Jefferson Street
Hackettstown, NJ 07840
E-mail: **irb@centenaryuniversity.edu**

RESEARCH IN K-12 SCHOOLS

The IRB requires that research conducted in K-12 schools be approved by schools, school district authorities, or research committees (if applicable). Documented approval is required for both new applications and changes in existing studies.

1. Identify school district and/or name of school(s):

2. Does the school district have its own Institutional Review Board or research evaluation policies?
   The IRB recommends contacting the school district to determine this.

   ☐ Yes. Include documentation of approval.
   ☐ No. Include documentation of the approval to conduct research at the site, given by the superintendent or principal on school letterhead. This is <u>not</u> a consent document.

3. Who are the participants in the proposed research?
   ☐ Teacher. Include a proposed teacher's informed consent form.
   ☐ Student. Include a proposed parental consent and student assent forms.
   ☐ Administrative Personnel. Include proposed informed consent form and describe personnel.

4. If students are participants, explain what role the teacher plays in the project:

5. If any researcher is employed by the district in which data is being collected, please explain your role as both an employee and your role in the proposed research study:

A site approval letter (to be attached to this application) needs to outline, in significant detail (similar to the level of detail contained in an informed consent document), the study components and be signed by an appropriate K-12 official.

IRB of Centenary University
400 Jefferson Street
Hackettstown, NJ 07840
E-mail: **irb@centenaryuniversity.edu**

Request for Addendum to an Approved Project
Addendum must be approved prior to implementation

Please submit this form and, as appropriate, revised forms and/or surveys. Highlight or use bold font to indicate where changes/additions occurred on the revised documents.

Researcher(s):

Supervisor Signature (if applicable) **E-mail**:

Title of Project:

Prior Approval: Exempt Review □ Full Board Review □

1. Description of modification (check all that apply).

Modification to currently approved **procedure**		Modification to currently approved **Informed Consent**	
Modification to **research team** (if yes, please attach NIH training certificates)		Modification to **survey/questionnaire**	
Modification to **title** of project		Other (e.g., advertisement)	

2. Check as appropriate.

This modification **does not** increase risks to participants enrolled in this study		This modification **does** increase risk to participants enrolled in this study.	

3. Briefly describe rationale for the modification.

_____ _____
Signature of Principle Researcher **Date**

IRB Approval

_____ _____
Approval Signature of the IRB Chair **Date**

IRB of Centenary University
400 Jefferson Street
Hackettstown, NJ 07840
E-mail: **irb@centenaryuniversity.edu**

ANNUAL REVIEW FORM
(If necessary, a separate sheet of paper may be used for reply)

Project Title:

Researcher's Name(s) and E-mail:

Researcher's Phone Number:

Status of the study (check one): Active _____ Completed _____
(Date of completion)

A. Have there been any changes in your procedure?

B. Have you encountered any risks to subjects or other adverse, unanticipated reactions?

C. If you answered "YES" to the previous question, how were they handled?

D. Do you propose to make any changes to your protocol this year?
(*If yes, please submit an addendum form at the appropriate time, in addition to the Annual Review Form).

Principle Researcher's Signature(s): _____ Date: _____

_____ Date: _____

Centenary University IRB Protocol Application for Secondary Data Analysis Checklist

[ ] Application is filled out in its entirety and submitted in one PDF (please leave no blanks; use "n/a" if an item is not applicable)

[ ] You are listed as the Principal Investigator (PI)

[ ] Your faculty/dissertation/thesis advisor (if applicable) is listed as the Co-PI

[ ] Your data set is either publicly available or the information has been recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

[ ] If the data set has been provided by a colleague, a letter of support approving you to utilize these data has been attached to the application. This approval letter must include evidence of prior IRB approval for the collection of these data.

[ ] You have completed the CITI training within the last three years AND you have attached your certification to the application https://www.citiprogram.org/index.cfm?pageID=14

[ ] Your advisor (if applicable) has completed the CITI training within the last three years AND you have attached their certification to the application

[ ] You have signed and dated the application (see page 28)

[ ] Your advisor (if applicable) has signed the application (see page 28) and supervisor's consent (page 29)

IRB APPLICATION FOR SECONDARY DATA ANALYSIS

A. IDENTIFYING INFORMATION

1. Principal Researcher's Contact Information:
   Name(s): Address:
   Phone Number: E-mail:

2. Co-Researcher(s) Contact Information (*students should include faculty advisor's info here*):
   Name(s): . Address: .
   Phone Number: . E-mail: .

3. Department/School:

4. Dissertation/thesis supervisor's name and email:

5. Research Category: (Please mark an X in the appropriate box)

[ ] Faculty research	[ ] Senior Thesis	[ ] Research from another institution
[ ] Graduate student research	[ ] Undergraduate student research	[ ] EdD dissertation research
[ ] Honors thesis	[ ] Undergraduate independent study	[ ] Other, please specify:
[ ] Master's Thesis		

6. Title of the Study:

B. HUMAN PARTICIPANT PROTECTIONS REQUIRED TRAINING

1. I have attached the CITI Training Certificates for all PI's and co-researchers: [ ] Yes [ ] No

C. SUPERVISING PROFESSOR'S CONSENT (*required for all student research – see page 28*)

1. I have attached my supervising professor's consent form: [ ] Yes [ ] No [ ] N/A

D. DATA SOURCE

1. Name of dataset:
2. Source of dataset (e.g., colleague, public data):
   a. If colleague, please provide a letter of support approving you to utilize these data. This letter must also include evidence of prior IRB approval for the collection of these data
   b. If a public dataset, please provide the website where these data are located.
3. Brief description of dataset (e.g., population, setting):
4. Brief description of the variables:
   Note: *For Exempt Review, the information must be recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.*

5. Brief description of the dataset storage plan:
   Where, how, and for how long will the data from the study be stored?
   Note: Data that is not in the public domain must be stored in a password protected, encrypted drive (Cloud servers are not considered secured method of data protection). In addition, all data must be stored for a minimum of three years. Describe how you will ultimately dispose of your data after this time. If you do not plan to destroy this data, please provide a justification.

E. RESEARCH PROJECT DESCRIPTION

1. In approximately 500 words, please describe the purpose of the study (*What is the central research question and/or hypothesis that this study examines? What is the goal/objective of this study?*) and a **brief rationale for the study (***Why is this study needed? How does it fit in with existing research? What new knowledge will this study potentially add?)***:**

F. RESEARCHER RESPONSIBILITIES

As a researcher you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of these data, and strict adherence to any stipulations imposed by the IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved application.

2. Adhere to ethical codes and applicable policies and procedures of Centenary University, the sponsoring agency, relevant professional organizations and cooperating institutions (if any).

3. Submit the Annual Review Form when directed to do so to the current IRB Chair.

4. Retain required records for a minimum of three (3) years.

_____ _____

Signature of Principal Researcher Date

_____

Signature of Dissertation/Thesis Advisor

_____

Signature of Co-Researcher

Supervising Professor's Consent

I am the supervising professor for the student submitting this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound. Furthermore, I believe that the student has the necessary training, experience, and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles. I agree to:

- Oversee and monitor the conduct of this research by communicating regularly with the student investigator;
- Assist with the resolution of any problems or concerns encountered during the research;
- Assure that the IRB is notified in the event of deviation in study protocol.

I have reviewed the IRB checklist and application and certify that it is complete and reflective of the student research plan.

I understand that as supervising professor I am responsible for the conduct of this research.

_____ _____

Signature of Supervising Professor Date

Supervising Professor: .
Phone Number: .

Address: .

E-mail: .