



**INSTITUTIONAL REVIEW BOARD FOR THE
PROTECTION OF HUMAN RESEARCH
PARTICIPANTS**

**INSTRUCTIONS for INVESTIGATORS
and
IRB FORMS**

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1. INTRODUCTION

1.a Research Subject to Regulation

In accordance with the [Federal Policy for the Protection of Human Subjects](#) hereafter (“Federal Policy”), all research involving human subjects conducted at or sponsored by a Federal Department or Agency must be reviewed by an Institutional Review Board (IRB). In addition, it is the policy of North Carolina Central University that all research involving human subjects conducted under the auspices of a department, school, or research unit within North Carolina Central University, undergo review by the IRB, regardless of funding status.

The mission of the IRB is to review research involving human subjects to ensure that the risks to human subjects are minimized, and the rights and welfare of human subjects are protected. All research with human subjects must be approved by the IRB or declared exempt from the Federal Policy **before** the research may begin.

Investigators should be aware that specific funding agencies may have requirements in addition to the Federal Policy that must be satisfied before IRB approval can be given. Examples are:

- [Department of Defense](#)
- [Department of Justice, Federal Bureau of Prisons](#)
- Department of Education: [Protection of Human Subjects](#); [Student rights in research, experimental programs, and testing](#); [Family Education Rights and Privacy](#)

Typically, IRB approval is not a prerequisite to apply for federal funding. Investigators are encouraged to read the relevant guidelines closely so that timely submissions are made for IRB approval. **IRB approval for specific projects is for a period of no more than one year.** The IRB must be informed of any changes to approved protocols. New approvals are required when there are significant changes in procedures and scope of the research.

1.b. Defining “Research Involving Human Subjects”

To determine if your proposed activities involve research with human subjects, use the definitions of “research” and “human subjects” provided in the [Federal Policy](#) (45 CFR 46.102) and reproduced below.

“*Research*” means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

IRB Note to Investigators: If the proposed activities are not intended to develop or contribute to generalizable knowledge, it is not research. Generalizable knowledge includes information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge.

Projects that are intended solely for internal assessment purposes, such as quality improvement/assurance, and program evaluations typically do not result in the development of or contribution to generalizable knowledge.

Class projects done solely for educational purposes and not for research purposes need not be reviewed by the IRB. If class projects involve data collection off-campus, then all IRB procedures must be followed.

“Human subject” means a living individual about whom an investigator conducting research obtains

- (1) data through intervention or interaction with the individual,
- or
- (2) identifiable private information.

As defined in the [Federal Policy](#) (45 CFR 46.102), *intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

IRB Note to Investigators: Some activities are clearly “research”, but do not involve human subjects. These may include studies of existing records, publicly available data, data collected for administrative purposes, data already collected from another research study, or biological specimens for which identifying information is not available to the researcher (i.e., they are de-identified or have a coded identifier that cannot be linked back to the participants). Studies that use data for which private information is identifiable or for which the principal investigator or research team have access to a key that links identifying information to a unique code require IRB approval.

After considering the definitions of “research” and “human subjects” above, if you are unsure whether or not your proposed activities involve research with human subjects, you are encouraged to contact the [IRB](#) for advice.

1.c. IRB Membership, Meetings, and Contact information

The composition of the NCCU IRB is governed by Federal regulations and our Assurance. Briefly, it must have at least five members of varying backgrounds and expertise, including at least one person not affiliated with the University and at least one member whose primary concerns are in a nonscientific area. The IRB must not be homogeneous with respect to gender or profession. For a list of current members of the NCCU IRB, contact Undi Hoffler, PhD, Director of Research Compliance, uhoffler@nccu.edu, 919-530-5140.

IRB Meetings

Meetings of the NCCU IRB are normally held on the third Friday of the month.

IRB Contact Information:

To request forms or assistance with the IRB application process, email IRB@nccu.edu. For other questions, contact the Director of Research Compliance or the IRB Chair.

Director of Research Compliance:

Undi Hoffler, PhD
309 Hubbard-Totton Chemistry Bldg,
uhoffler@nccu.edu
919-530-5140

IRB Chair (2010-2013):

Susan Peacock, PhD
1013 BRITE Bldg
speacock@nccu.edu
919-530-6570

IRB Coordinator:

Billy Bryant
IRB@nccu.edu

2. APPLYING TO THE IRB

2.a. General Information

The IRB accepts applications on a rolling basis. The application forms are found in the Appendix to this Manual as Microsoft Word 2007 documents. Applications may be submitted as a single hard copy or electronically. When the IRB receives an application, the IRB will notify the Principal Investigator (PI) by email within two business days that the application was received, and whether the application is complete or has missing parts.

Once an application is complete, it will be reviewed by the IRB. Completed applications received by the 5th of the month will be reviewed and a response issued by the end of the same month. The PI will receive written notification of the IRB's decision to approve or disapprove the proposed research activity, or of modifications required to receive IRB approval. If a protocol is not approved, the PI will receive a statement detailing the reasons for the IRB's decision, and the PI will have an opportunity to respond either in writing or in person.

IRB Note to Investigators: If the PI is a student, the student's Faculty Advisor will receive a copy of all communications between the PI and the IRB.

2.b. Initial Applications

Step 1. Before preparing the application, the Principal Investigator (PI) should begin training in research with human subjects. All personnel who will be directly interacting with research subjects must complete the online training: [CITIprogram](#).

- If your research generates or utilizes [public health information](#) (ie: medical record data) you must complete the HIPAA and Human Subjects Research module within the [CITIprogram](#). Visit [U.S. Health and Human Services- Understanding HIPAA Privacy and Research](#) for more information about using public health information for research purposes.
- Documentation of training in research with human subjects, completed within the previous **two (2)** years, is a required component of the IRB application.

IRB Note to Investigators from other Institutions: the CITI modules required by NCCU may be different than the modules required by the IRB of your home Institution. After logging onto the CITI website, you must "affiliate" with NCCU to know which modules are required by the NCCU IRB.

Step 2. Determine that the planned activities meet the definition of "Research Involving Human Subjects". Refer to the definitions found in the [Federal Policy](#) (45 CFR 46.102) or in Section 1.b of this Manual.

Step 3. Complete the [Cover Sheet](#), found in the Appendix of this Manual. Answer all questions. The PI is the person who will personally conduct or supervise the research study. A student may be listed as PI. **However, if a student is the PI, a faculty advisor must be identified who holds ultimate responsibility for ensuring that the student's project complies with all University, regulatory, and fiscal requirements.** The Investigator's Assurance must be signed by the PI. Electronic signatures are not accepted.

Step 4. Complete [Form A](#), found in [Appendix A](#) of this Manual. All questions **MUST** be answered. Do not alter wording or delete questions. Form A must "stand alone" and should provide complete answers. While you may reference other documents, a response

of “See Attached” is not permitted. **A response of N/A is not permitted on Form A.** If you think that N/A is the appropriate response, then it is possible that your project does not involve research with human subjects. Refer to [1.b. Defining “Research Involving Human Subjects”](#) within this manual, or contact the [IRB](#) for assistance. When answering questions on Form A, avoid technical jargon since the IRB reviewers may not be familiar with the technical jargon of your research area.

Step 5. Complete the [Conflict of Interest Certification](#).

Step 6. Assemble the components of the application in the following order:

- [Cover Sheet](#)
- Summary Sheet – one page, in lay terms. *The summary should describe the purpose and rationale for the study, state the research objectives and what you hope to learn.*
- [Form A](#)
- Research Protocol including questionnaires, internet surveys, instructional tools, scripts for phone interviews, etc.
- Informed Consent document (required).** If applicable, include assent forms, information sheets, and verbal consent scripts.
- Recruitment materials, including final copies of printed advertisements, audio/video taped advertisements, scripts, flyers, letters, email.
- Investigational drug data, if applicable. Include the Investigator’s Brochure and/or package insert for previously approved uses of the drug.
- Letters of support or additional approvals from relevant “gatekeepers” (e.g., school principals, facility directors), if applicable
- Thesis Plan, Chapters 1 and 2 (*NCCU graduate students only*)
- CV of Principal Investigator
- [Conflict of Interest Certification](#)
- Documentation of training in research with human subjects for all personnel who will directly interact with research participants. *Reminder: CITI training must be completed as a NCCU Affiliate within the past 2 years.*

Step 7. When the components have been assembled, submit the application as a single hard copy to the IRB office, 309 Hubbard-Totton Bldg, North Carolina Central University, 1801 Fayetteville St, Durham, NC 27707. Electronic submissions are also accepted. Merge the required parts into a single pdf file and submit by email to IRB@nccu.edu. *Note: this email account cannot accept attachments >10MB.*

2.c. Renewals or Modifications of Approved Protocols

Annual Renewals of Approved Protocols

IRB approval is for a period of one year. If the research activities extend longer than one year, it is necessary to renew IRB approval. To request a renewal of a previously approved protocol, complete and sign [Form B](#) and the [Conflict of Interest Certification](#), found in the Appendix A of this Manual. Submit Form B and the Financial Conflict of Interest Certification as hard copies to the IRB office, 309 Hubbard-Totton Bldg, North Carolina Central University, 1801 Fayetteville St, Durham, NC 27707, or electronically to IRB@nccu.edu no later than one (1) month prior to

the expiration of the initial approval. **Failure to comply with the requirement to renew IRB approval annually will result in suspension of the research activities.**

In addition to submitting [Form B](#) and the [Conflict of Interest Certification](#), the PI should also resubmit documentation of online training in research with human subjects if it has been more than two years since the training was completed. The IRB will send a renewal reminder approximately two months prior to the expiration of IRB approval. This reminder will indicate whether training in research with human subjects needs to be updated. **Annual renewal is not required for protocols that are determined by the IRB to be Exempt from the Federal Policy.** See Section [3.c. Exempt Criteria](#). Exempt protocols *are* subject to the requirement to submit annual status reports (Section 2.d).

Modifications of Approved Protocols:

All modifications to a previously approved protocol must be approved by the IRB prior to implementing the changes. To request a modification of a previously approved protocol, complete and sign [Form B](#), found in [Appendix A](#) of this Manual. Submit Form B as a hard copy to the IRB office or electronically to IRB@nccu.edu.

2.d. Status Reports of Approved Protocols

Ongoing protocols not subject to annual review

Although protocols that are approved as Exempt from the Federal Policy are not subject to the requirement for annual review, the PI must notify the IRB annually of the status of the research. This notification is accomplished by completing [Form C](#), found in [Appendix A](#) of this Manual. The IRB will send a reminder to the PI approximately one month prior to the anniversary of the initial approval.

Completed or discontinued protocols:

When an approved project is completed or discontinued, the IRB must be notified using [Form C](#), found in [Appendix A](#) of this Manual. Submit Form C as a hard copy to the IRB office, 309 Hubbard-Totton Bldg, North Carolina Central University, 1801 Fayetteville St, Durham, NC 27707, or electronically to IRB@nccu.edu. **The requirement to notify the IRB when a protocol is completed or discontinued applies to all protocols, including those that are approved as Exempt from the [Federal Policy](#).** See Section, [3.c. Exempt Criteria](#).

3. IRB REVIEW

There are three levels of IRB Review (full board, expedited, and exempt), determined by the nature of the project, level of potential risk to human subjects, and the subject population. The PI may make a recommendation to the IRB, but the type of review applicable to a particular study is determined by the IRB. Regardless of the type of review, all applications use the same submission forms.

3.a. Full Board Review: Criteria for IRB Approval

If review by the full board is required, the research proposal will be evaluated at the next convened meeting of the IRB. The IRB evaluates protocols based on the following criteria:

- (1) Risks to subjects are minimized
- (2) Risks, if any, to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- (3) Selection of subjects is equitable.
- (4) Informed consent will be sought from each prospective subject, [4.a Informed Consent Process](#).
- (5) Informed consent will be documented, [4.b Elements of Informed Consent](#).
- (6) The research plan makes adequate provision for monitoring data collected to ensure the safety of subjects, if applicable.
- (7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (8) 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.

There are three possible outcomes of IRB review: (1) **“Approved”**, (2) **“Approvable”**, or (3) **“Approval Withheld”**.

- (1) **“Approved”**- Protocols receiving an affirmative two thirds majority vote of the convened members.
- (2) **“Approvable”** – This designation is used if the IRB requires more information or requests specific modifications to the protocol. The “Approvable” designation is used when the requested modifications are minor.
- (3) **“Approval Withheld”**- If the IRB feels that there are major deficiencies in the protocol, or if the eight criteria above are not satisfied, they will withhold approval. If a protocol receives an “Approval Withheld” decision, the PI will be notified in writing of the reasons for the IRB’s decision. The PI will have an opportunity to respond, either in writing or in person, to the IRB’s concerns. There is no avenue for appealing a decision by the IRB.

3.b. Expedited Review

The IRB uses an expedited review procedure to review either of the following:

- (1) Research involving no more than minimal risk, or
- (2) Minor changes in previously approved research

“Minimal risk”, as defined in the [Federal Policy](#) (45 CFR 46.102), means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those

ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The determination of whether a protocol is eligible for expedited review is made by the IRB Chair. If expedited review is used, the research project is evaluated under the same criteria and rigor used for full board review, [3.a Full Board Review](#). The response time for expedited review is the same as for full board review. The difference between expedited review and full review is that the protocol is reviewed by less than the full board, but not less than two reviewers. **If the decision of the reviewers is not unanimous, the protocol will be submitted to the full IRB for review.** *IRB Note to Investigators: Expedited review is NOT appropriate if the research involves a vulnerable population, such as prisoners or persons with disabilities.*

3.c. Exempt Research

If the research project is exempt from the [Federal Policy](#), approval can be granted by the IRB Chair.

IRB Note to Investigators: Normally, research is not exempt if it involves a vulnerable population such as children or persons with disabilities.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories are exempt (See Section [3.c. Exempt Criteria](#)) from the Federal Policy:

- (1) 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.

- (2) *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 subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

IRB Note to Investigators: An exemption for research involving survey procedures, interview procedures or observation of public behavior is not available if the research subjects are children.

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2) of this section, if:
- (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (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 subjects cannot be identified, directly or through identifiers linked to the subjects.
- (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 benefit or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
- (i) if wholesome foods without additives are consumed or
 - (ii) if a food is consumed that contains an ingredient 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.

4. INFORMED CONSENT

*IRB Note to Investigators: Deficiencies in the process of obtaining consent to participate in research, and/or deficiencies in the consent document are the MOST common reasons why the IRB will **withhold** approval of your research. You are encouraged to read the information in sections 4.a and 4.b of this Manual carefully and to contact the [IRB](#) if you have any questions.*

4. a Informed Consent Process

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. The standard consent process is to have the research participant (or a legally authorized representative) sign a document containing the elements of informed consent specified by federal regulations See [4.b Elements of Informed Consent](#). The informed consent document must be written in simple language (6th-8th grade reading level) to be easily understood by persons regardless of scientific background. The consent form should be written in the 2nd person (e.g., *You* are being asked to participate in a research study about . . .). The PI should provide two copies of the consent form, one for the subject to sign and return to the PI, and one for the subject to keep.

IRB Note to Investigators: Readability of the informed consent can be checked using Flesch-Kincaid Grade Level during spell check. To activate this feature: (1) highlight the text, (2) click on spelling/grammar, (3) click on options and (4) check the box corresponding to show readability statistics.

The following are criteria **MUST** be satisfied when obtaining consent to participate in a research study:

- (1) Consent should be obtained **only** under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate.
- (2) The circumstances for obtaining consent should **minimize** the possibility of coercion or undue influence.

*IRB Note to Investigators: The IRB **will not** approve passive informed consent. Failure of a subject to express an unwillingness to participate does not constitute consent to participate in the research.*

- (3) If the prospective subject does not speak English then he/she should be presented with a consent document written in a language understandable to them.

Under limited circumstances the requirement for a signed consent form may be waived by the IRB if either of the following is true: (1) the consent document is the only link between the subject and the research and the principal harm would come from a breach of confidentiality (e.g., a study topic that is so sensitive that mere knowledge of a subject's participation would be damaging) *or* (2) there is no risk of harm to the subject, other than minimal risk and the study involves no procedures for which written consent is normally required outside of a research setting (e.g., a phone survey).

4. b. Elements of Informed Consent

A general rule is that potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. The informed consent document should contain a simple, descriptive title of the research project, and the name and telephone number of the Principal Investigator (PI) and Faculty Advisor if the PI is a student. The elements of informed consent that are required under the [Federal Policy](#) (45 CFR 46.116) are listed below.

You should use this as a checklist when preparing your informed consent document:

- A statement that the study involves research
- An explanation of the general purpose of the research.
- An explanation of the expected duration of the subject's participation.
- A description of the procedures to be followed. If the research involves an experimental treatment for a problem or disorder, that treatment should be identified and any alternative treatments that might be advantageous to the subject.
- A description of any reasonably foreseeable risks or discomforts to the subject. Even if risks are no more than minimal risk this must be stated.
- A description of any benefits to the subjects or to others, which may reasonably be expected from the research. *(May be omitted if none.)*
- A statement describing how confidentiality will be maintained and who will have access to the data.
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- An explanation of how to contact the research team for concerns, complaints, or questions about the research.
- A statement of how to contact someone independent of the research team for concerns, complaints, or questions about the participant's rights as a research subject.

IRB Note to Investigators: The following statement is suggested by the IRB. If you have questions or concerns about your rights as a research subject, you may contact the NCCU IRB Chair at IRB@nccu.edu, 919-530-6570, or the Director of Research Compliance, uhoffler@nccu.edu, 919-530-5140.)

Federal regulations also specify additional elements of informed consent that should be included when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The approximate number of subjects involved in the study.
- A statement describing inducements for participation.

IRB Note to Investigators about HIPAA regulations:

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. HIPAA applies to the following:

*(1) **Research involving the collection and use of medical record information maintained by health care providers** (ie: hospitals, physicians' offices, health care clearing houses, health care plans*

*(2) **Research originating from information within an individual's medical records maintained by health care providers.***

If the research study does not involve the collection and use of medical record information or the generation of information that will be stored within an individual's medical record, it is therefore not subject to additional authorization/ informed consent requirements imposed by HIPAA.

***However**, if your research does utilize or generate public health information or if you have any questions about HIPAA and its applicability to your research, please contact the contact the IRB Chair at IRB@nccu.edu or 919-530-6570, or the Director of Research Compliance, uhoffler@nccu.edu, 919-530-5140.*

4.c. Children's Assent

There are no firm rules regarding when or how a child's assent should be obtained. The IRB considers each protocol on a case-by-case basis. In instances where a child is sufficiently mature to comprehend his/her participation in research, **the child must be offered the opportunity to give assent**. This will be used in addition to the consent form signed by the parent. *Generally*, children seven years of age or older should be given the opportunity to assent to participation in research. Assent of children younger than seven is encouraged if there is reason to believe it would be meaningful.

"Assent" means a child's *affirmative agreement* to participate in research. **A child's failure to object to participate should not be construed as assent**. Affirmative agreement is necessary. Under some circumstances, written assent may be appropriate, but generally verbal assent will be sufficient. When a written form is used, it should contain a simple explanation of the research project, including possible benefits, risks, and safeguards. There is no requirement for securing a child's assent if the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research.

Sample Assent and Informed Consent scripts/letters/forms are provided in [Appendix B](#) of the manual.

APPENDIX A

The forms required by the IRB are found below. Select the appropriate forms as described in Section 2 of this Manual.

[Cover Sheet](#)

[Form A](#) (for *initial* protocol submission)

[Form B](#) (for annual renewals or modifications of previously approved protocols)

[Form C](#) (for notifying the IRB of the status of an approved protocol)

[Conflict of Interest Certification](#)

APPENDIX B

The sample assent and informed consent forms provided in this section are to assist you in your preparation of these documents for your study.

[Script for Assenting a Child 7years old and younger](#)

[Informed Consent Document for Minimal Risk Procedure](#)

[Parental Consent Letter](#)

North Carolina Central University

Application for IRB Approval of Human Subjects Research

Cover Sheet

Title of Study: [Click here to enter text.](#)

Name, Title and Degrees of Principal Investigator (PI):

[Click here to enter text.](#)

Department, address, email and phone number of PI:

[Click here to enter text.](#)

If the PI's title is "Student", provide the name, phone number and email of the Faculty Advisor who bears ultimate responsibility for the research:

[Click here to enter text.](#)

List all other project personnel who will have contact with subjects or identifiable data from subjects. Include an email address for each person who should receive electronic copies of IRB correspondence to the PI. Note: Documentation of training in research with human subjects is required of all personnel listed here.

[Click here to enter text.](#)

Name of Funding Source or Sponsor. If none, state "none".

[Click here to enter text.](#)

Proposed time span of research: From [Click here to enter a date.](#) To [Click here to enter a date.](#)

Does this research involve a vulnerable population that requires special protection by the IRB, such as pregnant women, prisoners, children, mentally or physically challenged, economically disadvantaged, or non-English speaking?

No Yes

If yes, [click here to describe.](#)

PI's recommendation for IRB Review (select one):

- Full Board Review
- Expedited review for projects involving no more than minimal risk
- Determination of Exempt

Category for exemption: *(Include all that apply. Refer to [3.c. Exempt Criteria](#))*

INVESTIGATOR'S ASSURANCE: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies. I will obtain IRB approval before making any changes or additions to this project. I will report all unanticipated problems or adverse events involving risk to human subjects to the IRB. I will follow the IRB approved consent process for all subjects. I will notify the IRB when this research study is completed or discontinued. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this application is accurate and complete.

Signature of Principal Investigator

Date

FACULTY ADVISOR (if PI is a student): I accept ultimate responsibility for ensuring that this project complies with all regulatory, University, and fiscal requirements.

Signature of Faculty Advisor

Date

DEPARTMENT CHAIR (not required if PI is a student): I certify that this research is appropriate for this Principle Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. I support this application, and hereby submit it for further review.

Signature of Department Chair
(or Chair's designee if Chair is PI or otherwise unable to review)

Date

Print Name of Department Chair or designee

Department

For IRB Use Only:

Protocol Number: _____

Approved Exempt under category _____ Approval Withheld Withdrawn

IRB Chairperson

Date

**North Carolina Central University
Application for IRB Approval of
Research Involving Human Subjects**

FORM A

All questions on Form A must be answered. Do not alter wording or delete questions. Form A must “stand alone” and should provide complete answers. A response of “See Attached” is not permitted. A response of N/A is not permitted.

1. **Research Title:** [Click here to enter text.](#)

2. **Summary:** Provide a brief, non-technical description of the study, to be used in IRB documents as a description of the study (50 – 100 words).
[Click here to enter text.](#)

3. **Participants:** Who will be your research participants and how will they be recruited? Describe who will do the recruiting and how subjects will be contacted. Recruitment materials must be submitted with this application.
[Click here to enter text.](#)

4. **Study Design:** Describe the research study design and procedures. Include a sequential description of what subjects will be asked to do; how data will be collected, and how the results will be analyzed.
[Click here to enter text.](#)

5. **Benefits to subjects and/or society:** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained. If there is no direct benefit to the individual subject, it must be disclosed here and on the consent form.
[Click here to enter text.](#)

6. **Attendant Risks:** Describe risks and measures to minimize risks. Include risk of psychosocial harm (embarrassment, emotional distress, breach of confidentiality), economic harm (loss of employment, loss of professional standing, loss of standing within the community). Describe how the procedures used reflect respect for privacy, feelings, and dignity of subjects, avoid unwarranted invasion of privacy, and minimize risks as much as possible.
[Click here to enter text.](#)

7. **Confidentiality:** Describe the procedures to assure confidentiality in the use, storage, and disposal of the primary data. If electronic storage of data is used, describe safeguards to protect confidentiality.
[Click here to enter text.](#)

8. **Informed Consent:** Describe the *process* of obtaining informed consent from subjects. If children will be research subjects, describe the provisions for obtaining parental permission and assent of the child. Do not include the Consent Document here.

[Click here to enter text.](#)

9. **Inducements for Participation:** Describe all inducements to participate, monetary or non-monetary. If inducements are used, explain how the inducements are not coercive.

[Click here to enter text.](#)

10. **Costs to research subjects:** Include travel, parking, child care, etc. If there are no costs to subjects other than their time to participate, indicate this.

[Click here to enter text.](#)

North Carolina Central University
Application for Renewal or Modification of
Ongoing Research Involving Human Subjects

FORM B

Principal Investigator: [Click here to enter text.](#)

Project Title: [Click here to enter text.](#)

IRB#: [Click here to enter text.](#)

Date of initial approval: [Click here to enter a date.](#)

Date of this request: [Click here to enter a date.](#)

Research Project Site: [Click here to enter text.](#)

Number of Participants Enrolled Since Initial IRB Approval:

Total Subjects Required to Complete Project(s):

Risk Classification:

More than minimal risk No more than minimal risk

Describe any significant preliminary findings.

[Click here to enter text.](#)

Describe any adverse events, including those were foreseeable and described in the initial application. Attach all adverse event reports to this Form, even if previously submitted to the IRB. If none, state “none”.

[Click here to enter text.](#)

Describe any unanticipated problems involving (a) risks to subjects or others (such as the parents of minor subjects), (b) withdrawal of subjects from the project and/or (c) complaints about the project. If none, state “none”.

[Click here to enter text.](#)

Summarize any recent literature findings or other relevant information that bears on the issue of risks or benefits associated with this research project.

[Click here to enter text.](#)

North Carolina Central University
Notification of Status of Research Involving Human Subjects

FORM C

Principal Investigator: [Click here to enter text.](#)

Project Title: [Click here to enter text.](#)

IRB#: [Click here to enter text.](#)

Date of initial approval: [Click here to enter a date.](#)

Research Project Site: [Click here to enter text.](#)

Current Status:

Completed

Discontinued

Ongoing

Date Completed or Discontinued: [Click here to enter a date.](#)

If discontinued, state reason(s): [Click here to enter text.](#)

Describe any unforeseen risks or unanticipated results from this research. If none, state “none”.
[Click here to enter text.](#)

Describe any adverse events, including those were foreseeable and described in the initial application. Attach all adverse event reports to this Form, even if previously submitted to the IRB. If none, state “none”.

[Click here to enter text.](#)

Signature:

Principal Investigator

Date

Faculty Advisor if PI is a student: I accept ultimate responsibility for ensuring that the PI complies with the University’s conflict of interest policies and procedures.

Conflict of Interest Certification

The following questions apply to **all investigators and study staff** engaged in the design, or reporting of results of this project **and/or their immediate members**. For these purposes, “family” includes the individual’s spouse and dependent children. “Spouse” includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations.

1. Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have:
 - (a) A personal interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? Yes No
 - (b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? Yes No
 - (c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? Yes No
 - (d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? Yes No
2. Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team? Yes No
3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, processor technology studied in this project? Yes No

If the answer to any of the questions above is *yes*, the PI will be contacted by the Director of Research Compliance for conflict management. List name(s) of all research team members for whom any answer to the questions above is *yes*:

Certification by Principle Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of all members of my research team who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above. I understand that as Principle Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.

Signature of Principle Investigator

Date

Faculty Advisor if PI is a student: I accept ultimate responsibility for ensuring that the PI complies with the University’s conflict of interest policies and procedures.

Signature of Faculty Advisor

Date

APPENDIX B

Example of an Assent Script for a Child Less than 7 years of age

Hello, my name is _____

My friends and I are doing a study to learn _____

We are asking you to help because we do not know very much about _____

If you agree to be in our study, we will ask you _____

What we learn from you may help other children with _____

It is possible you will feel _____

At anytime you may ask us questions.

If you feel like skipping a question or if want to stop YOU CAN.

This is not a test so there is no right or wrong answer. Tell us what what you think.

Example of an Informed Consent Document for a Minimal Risk Procedure

Confidential

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: The Relationship between Use of Alcohol and Depression in a Sample of College Students

Principal Investigator: John Doe, PhD
Department of Psychology
401 Taylor Education Building
North Carolina Central University
Durham, NC 27707
(919) 555-1212
jdoe@ncu.edu

You are being asked to participate in a research study. To join the study is voluntary. If you decide to be in this study, you will be one of approximately 200 people who will participate. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about whether you want to participate in this research.

Background and Purpose:

The purpose of this research is to examine the relationship between use of alcohol and levels of depression in a sample of college students. Research participants for this study are being recruited from undergraduate classes at North Carolina Central University. You must be 18 years of age or older to participate in this research study.

Duration and Location:

Participation in this study will occur over a one day period in the First Summer Session, 1997, in a classroom here at North Carolina Central University. Your participation will last for approximately one hour.

Procedure:

In this study you will be asked to complete a questionnaire regarding your alcohol use, and the Beck Depression Inventory (BDI), which measures an individual's level of depression. The principal investigator will give you a date, time and location to come and complete the alcohol use questionnaire and BDI. The questionnaire and BDI will be administered by the principal investigator in a group setting of about 40 students.

Risks and Discomforts:

The risks and discomforts involved in this study are believed to be minimal. You may experience some discomfort in answering questions about your alcohol use and mental health. The likelihood of any serious problem is believed to be low.

Benefits and Payment:

Research is designed to gain new knowledge that will be beneficial to society. By participating in this research, you will be contributing to society's understanding of the relationship between alcohol use and depression. You will also receive information regarding available treatment services if you need assistance in dealing with alcohol abuse or depression. In addition, you will receive \$10 upon completion of both the alcohol use questionnaire and BDI. This study does not provide funding to participants for treatment services.

Right to Refuse or Withdraw from the Study:

Your participation in this study is voluntary. You may refuse to participate, or may discontinue your participation at any time without penalty. The Investigator has the right to stop your participation at any time.

Use of Research Results:

The data obtained in this study will assist investigators in understanding the relationship between alcohol use and depression in college students, and will help steer future research in this area. The data may be used in publications or for teaching purposes.

Privacy and Confidentiality:

In order to assure anonymity, participants will be instructed NOT to put identifying information on the questionnaire and BDI. All data collected will be coded and not have the participant's name on it. Upon completion of the questionnaire and BDI, participants will place the material in

a slot in a closed box such that the investigator will not be able to identify the individual responses of a given participant. To ensure confidentiality, the signed consent forms will be stored in a locked file in Dr. Doe's office, 401 Taylor Education Building. Participants will not be identified in any report or publication.

Questions about the Study:

If you have any questions, complaints or concerns about this study, you may contact the Principal Investigator listed on the first page. This study has been approved by the Institutional Review Board (IRB) at North Carolina Central University. If you have questions about your rights as a research participant, or if you have complaints or concerns about this study, you may contact the IRB Chair at IRB@nccu.edu or 919-530-6570, or the Director of Research Compliance, uhoffler@nccu.edu, 919-530-5140.

Title of Study: The Relationship between Use of Alcohol and Depression in a Sample of College Students

Principal Investigator: John Doe, PhD

Participant's Agreement:

I have read the information provided above and voluntarily agree to participate in this study. My signature certifies that I am 18 years of age or older.

Printed Name of Research Participant

Signature of Research Participant

Date

Example of Parental Consent Letter

Dear Parent or Guardian:

I am conducting a research product on how children think and develop strategies in games. I request permission for your child to participate. The study consists of two 20-minute sessions where children will play Tic-Tac-Toe on the first day and a Guessing Game on the second day. The goals of the study are to detail the strategies of game-playing used by children of different ages, and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity. The project will be explained in terms that your child can understand, and your child will accompany me only if he or she has expressed a willingness to do so. Children usually enjoy games, so I expect that they will be interested and enthusiastic about participating; however, any child who expresses a desire to return to the classroom will be escorted back immediately. During the two-

20-minute game-playing sessions, the children will be videotaped by my research assistant. Only I and members of my research staff will view the tapes. At the conclusion of the study I will erase the tapes. Children's responses to the game-playing activities will be reported as group results only. In addition to your child's participation in the game-playing activities, I will need to look at the school's records to obtain your child's birth date and mathematics scores on the Iowa Tests of Basic Skills.

Participation in this study is voluntary. Your decision whether or not to allow your child to participate will not affect the services normally provided to your child by the school. At the conclusion of the study, a summary of group results will be made available to all interested parents and teachers. Should you have any questions or desire further information, please call me at (919) 555-1212. This study has been approved by the Institutional Review Board (IRB) at North Carolina Central University. If you have questions about your rights as a research participant, or if you have complaints or concerns about this study, you may contact the IRB Chair at IRB@nccu.edu or 919-530-6570, or the Director of Research Compliance, uhoffler@nccu.edu or 919-530-5140.

Retain this letter after tearing off and completing the bottom portion and returning it to your child's school. Thank you in advance for your cooperation and support.

Sincerely,

John D. Doe
Associate Professor
Department of Psychology
North Carolina Central University

Title of Study: The Relationship between Game Strategies and Thinking in Children

Principal Investigator: John Doe, PhD

Participant's Agreement:

I have read the information provided above and voluntarily agree for my child to participate in this study.

Printed Name of Research Participant (Child)

Signature of Parent

Date

Printed Name of Parent