

**Application for Initial Review
Institutional Review Board (IRB)
Chicago State University**

Principal Investigator							
Department							
Department Address							
Email Address							
Phone Number							
CSU Extension							
Study Coordinator/Additional Contact Person:							
Study Coordinator/Additional Contact Phone:							
Project Title							
I am requesting (please check one):		<input type="checkbox"/> Exempt		<input type="checkbox"/> Expedited Review		<input type="checkbox"/> Full Committee Review	
Please see Page ? to determine eligibility							
Gender Breakdown (if known):		<input type="checkbox"/> Male		<input type="checkbox"/> Female			
If your study proposes to include any of the following study subjects, indicate in the box below include the proposed number of each:				If your study proposes to include any of the following items, indicate in the box below:			
<input type="checkbox"/> Minors (under age 18)				<input type="checkbox"/> Human Tissue Sample			
<input type="checkbox"/> Pregnant Women/Fetuses				<input type="checkbox"/> Other			
<input type="checkbox"/> Prisoners							
<input type="checkbox"/> Cognitively Impaired							
Assurance:							
<p>The undersigned assures that protocols involving human subjects described in this application are complete and accurate and are consistent with applicable protocols submitted to any external funding agencies. All protocol activities will be performed in accordance with Chicago State University institutional guidelines and any applicable State and Federal regulations. Research conducted by CSU researchers falls under the purview of the University even when conducted elsewhere. Research at international sites must receive approval by the local equivalent of the IRB. The IRB requires documentation of this "local approval" before they can receive IRB approval. <u>No activities involving the research of human subjects can be initiated without prior review and approval by the Chicago State University Institutional Review Board.</u></p>							
Signature of Principal Investigator						Date	
Signature of Department Chair(s)						Date	
						Date	
If this is a Student Project, Signature of Supervising Faculty						Date	
Signature of Department Chair(s)						Date	
Primary Reviewer						Date Received	
Approved by IRB Chair				Date		IRB Number	

**Application Instructions/Checklist
Institutional Review Board (IRB)
Chicago State University**

Please make sure that your application contains the following materials, where appropriate.
Improper submissions will result in delayed reviews.

1. Original Signed, Dated and **Completed Application Form for Initial Review** including all relevant appendices and appropriate signatures. Submit the original plus one copy of the original and one electronic copy. A separate list indicating all enclosures/attachments is extremely helpful.
2. Copies of **letters granting permission to conduct research** (e.g., letters from principals, CPS administrators, department chairs, program directors, organization heads that may be given access to membership lists etc.)
3. Copies of all **recruitment materials** (advertisements/flyers).
4. Copies of **recruitment scripts** and any **verbal instructions** that are given to participants.
5. Copies of **consent forms and assent forms** for minors with the ability to give assent, containing the name and contact information of the principal investigator and the CSU IRB chair, Dr. Rachel Lindsey, 773-995-3788, rlindsey@csu.edu to be contacted if there are questions about subjects' rights. (See "Informed Consent Guidelines").
6. Copies of all **data collection instruments** that will be used, i.e. questionnaires, interview questions, discussion guides, etc.
7. Copy of PI's **curriculum vitae and resume** for other coordinators or study personnel.
8. Copy of a current (within the last two years) **Protecting Human Research Participants** certificate. (NIH Webcourse Link on our Website.)
9. Approval from the **IRB of the PI's home or degree granting** institution, if other than CSU.
10. Copies of **Grant/Contract applications and proposals**, where applicable.

**Submit application materials (and any questions) to:
Dr. Esther Jenkins, IRB Co-Chair
HWH - 241
(773) 995-2196**

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I.	Research Plan: Provide a brief summary, in non-technical language, of the proposed research. Include the purpose and relevance of the study, design of the study, and expected outcomes.
II.	Performance Site and Proposed Dates: a. Provide the name and location of the site(s) where the study will take place. Attach a letter giving permission for the research from the appropriate person. b. Indicate the beginning and end dates of the project.
III.	Subjects, Recruitment and Consent Process: a. Subjects: Exactly who will be in your study? Give the number, demographic characteristics, how they are identified and selected, inclusion and exclusion criteria. Will subjects be compensated for their participation? If so, how? b. Recruitment: Who will approach subjects, where, and exactly what will be said to the potential participant regarding the study. <i>Attach a copy of your recruitment flyers and/or script</i> c. Consent: Clearly describe your procedure for obtaining informed consent and/or assent (for youth younger than age 18). Where will this be done and who will be responsible for obtaining consent? If other than the PI, this person's vita and Ethics Training Certificate must accompany this application. Attach a copy of all consent and assent documents.

IV.	Procedure: Describe the data collection process.
V.	Measures: Describe/List Medical/Psychiatric/Psychological devices/instruments to be used in the study. Attach copies of any measures/questionnaires/questions.
VI.	Risks: Describe any potential risks to the subjects. <u>Explicit consideration must be given to all risks</u> . For example, physical, psychological, emotional, legal, social or financial risks to the participants. Risks related to privacy and confidentiality should be considered as well. <i>Please explain any and all procedures taken to minimize risk.</i>
VII.	Benefits: Describe potential benefits to study participants and/or humanity that may result from participation in the study. Compensation for participation is not a benefit.

VIII.	Confidentiality: Please describe how confidentiality of data will be protected. Include any discussions of de-identifying data, storage of data, subject lists, tapes etc., and eventual destruction of raw data.
IX.	Alternatives to Participation: Describe any alternatives to participation including currently Accepted practices or treatments. Non-participation is a reasonable alternative.

X.	Other Issues: Please describe any potential conflict of interest or financial benefit that the invest benefit from or any other relevant information deemed relevant to IRB consideration.
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Request for Expedited Review

Some research activities may be eligible for *expedited review* procedures. Under **expedited review**, the review is carried out by the IRB chairperson and/or co-chairperson or by other reviewers designated by the chairperson rather than the full committee. All rules of full review apply: need for consent documents (unless waived) and for periodic reports to the IRB.

Expedited reviews may be requested for research that involves no more than minimal risk and fits in one or more of the specified categories indicated below. **Please indicate the expedited categories that apply to your research:**

- The research involves no more than minimal risk (probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

AND

- 1) Research on non-investigational (FDA-approved) drugs and devices for approved use.
- 2) Collection of blood samples (blood volume limited in non-healthy adults, pregnant women, and children)
 - 3) Collection of biological samples (hair, nail clippings, sweat, urine, saliva.
- 4) Collection of data through non-invasive means routinely employed in clinical practice (weight, moderate exercise, ECG, EEG, MRI etc.
- 5) Research involving materials (data, records, specimens) that have been collected; or will be collected solely for non-research purposes.
- 6) Collection of data from voice, video, digital or image recordings made for research purposes.
- 7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, etc.

PLEASE EXPLAIN WHY YOUR PROJECT SHOULD BE EXPEDITED AND HOW IT FITS INTO THE INDICATED CATEGORY.

Request for Exemption from Continued IRB Review

Some research qualifies for exempt review which means that it is exempt from full review of the board and from continued IRB review. Under an exempt review material is reviewed by the IRB Chair and Co-Chair and/or a designated member of the IRB. Exempt projects may or may not have a signed consent form, but where feasible must always have a consent process with enough information to allow the research subject to make an informed decision about participation in the study (see waiver of documented consent under “Informed Consent Guidelines”). **Exempt review requires submission of an application, IRB review and approval prior to initiation of research.**

Please indicate the exempt categories that apply to your research:

- Research represents negligible or no risk to subjects AND
- 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 comparison among instructional techniques, curricula, or classroom management methods practice.
- 2) Research involving the use of educational tests, survey procedures (cognitive, diagnostic, aptitude, achievement), interview procedures or observation of public behaviors **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.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) surveys, procedures, interview procedures, or observation of public behavior that is not exempt under #2 if: 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
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimen if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects can not 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 benefits 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 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 FDA or EPA or the Food Safety and Inspection Service of the USDA.

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PLEASE EXPLAIN WHY YOUR PROJECT SHOULD BE EXEMPT AND HOW IT FITS INTO THE INDICATED CATEGORY.

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Investigator Agreement

Please read and **initial** each of the following items in the space provided:

	I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor and the CSU IRB, except when necessary to protect the safety, rights, or welfare of the research participants.	
	I agree to personally conduct or supervise the described investigation.	
	I agree to ensure that all of the requirements relating to the recruitment and consent process are met.	
	I agree to report to the sponsor and the CSU IRB any adverse experiences and/or events that occur during the course of the experiment.	
	I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations consistent with and in meeting the above commitments.	
	I agree to maintain adequate and accurate records in accordance with IRB regulations and to make those records available for inspection in accordance with those regulations.	
	I agree to ensure that I will submit a request for initial and continuing review and approval to the CSU IRB within the appropriate period of review.	
	I agree to report promptly to the IRB any and all changes in the research activity and all unanticipated problems involving risk to the participants and/or others.	
	I agree to submit a copy of the final report of the results and a summary of those results upon completion of the study.	
	I have completed training in "Human Participant Protection" and agree to follow the ethical and legal obligations outlines in this training.	
<p>CSU IRB reserves the right to audit any/all IRB approved protocols to inquire about the progress of the study, inspect consent documents, inspect data, and/or observe the consent and recruitment process utilized. The Principal Investigator must cooperate fully with the IRB staff in making such visits.</p>		
Signature of Principal Investigator		Signature of Supervising Faculty
Print Name		Print Name
Date		Date