**East Georgia State College**

**Application for Human Subjects Research Projects**

**EGSC Institutional Review Board**

**Directions:** Select the appropriate gray fields below by first clicking in the field. Then, type in your information when the field is highlighted by a darker shade of gray.

**Project Director or Investigator:**      Phone:       Date:

**Institution:**      Department:

**Project or Grant Title**:

**Project Status**:       New Project       Revision to Previously Approved Project

      Periodic Review of Continuing Project

**Project Start and End Dates:**      -      Where will the work be done?

**Project Type (Check the one that applies.)**

      Faculty research       Federal grant application

List source:

      Student research (under faculty direction)       Nonfederal grant application

List source:

      Student class project (under faculty direction)      Thesis or dissertation

If class project, list class/course no.

Other, specify:

**Does your project involve participants or individuals from any of these special/vulnerable**

**populations? (Check all that apply.)**

     Children under 18 years of age     Economically disadvantaged

     Individuals with intellectual disabilities     Elderly

     Prisoners     Individuals with physical disabilities

**Subjects Research Project/Study Checklist (Check as appropriate.)**

 **YES NO**

1.         Does this project or study involve collection of data that identifies individuals (e.g.,

 cohort databases include SSN# data on individuals, surveys, or interviews identifiable by

 name or student number etc.)?

2.         Will data identifiable by individual be shared with anyone (such as in a performance

 report for a funding source, conference presentations, published articles and reports,

 etc.)?

3.         Are the participants being offered one or more of the incentives to participate (such as

 money, extra credit for the class, etc.)? List the incentive(s) here:

4.         Is participation in this project or study voluntary for the individuals participating in the

 program or study?

5.         Will participants be fully informed about the benefits and any risks?

6.         Will participants be videotaped during the project or study?

7.         Will participants’ privacy and personal information be protected? Briefly explain how

 privacy and information will be protected:

8.         Will participants be debriefed following completion of the project or study?

9.         Will participants, prior to the project, indicate informed consent to participate by

 completing and signing a written form? Sample is included? Yes No

10.         Does the funding source have any potential for financial or professional benefit from the

 outcome for this study or project? If yes, please explain.

11.         Are data sources clearly identified (such as interviews, survey, existing project data such

 as services received, reports, grades, existing school records, focus group, etc.)?

**Check all that apply and estimate total number of individual participants in each relevant category**

**about whom you will be collecting data on for your project or grant:**

      College Students       General Public

       Faculty       Children and Youth under 18

       Staff       Other (specify category and number)

Comments (optional):

**I. Abstract Describing Project and Purpose:** Briefly describe (a) the project or study and (b) what

human participants will experience during the proposed study or project. Describe all strategies or

experimental methods to be used, design and program activities. Indicate what data, measures, or

observations will be collected and used in the study or for the project. If any questionnaires, tests, or other

instruments are to be used, include a brief description and one copy of the instruments. **Note to Grant**

**Projects Directors:** In the case of educational or training grants, data collected about the participants

served, assessment testing, pre- and posttesting and other aspects of project evaluation plans are

critical.

**II. Methodology:** Specify who the project participants or research subjects will be. Indicate how they

will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document.

State how much time will be required of each participant or subject. Describe procedures to which

individuals will be subjected. Use additional pages if necessary.

**III. Voluntary Participation:** Specify the steps that will be taken to insure that each individual’s

participation is voluntary. State what, if any, inducements will be offered for their

participation.

**IV. Confidentiality of Data and Privacy Protection:** Describe the methods to be used to safeguard the

privacy of your participants and ensure the confidentiality of data obtained, including plans for

publication, disposition and destruction of data, including that of computer, print, videotape, and audio

materials.

**V. Informed Consent:** Attach a copy of all consent forms to be signed by the participants and/or any

statements to be read to or provided to the participant.

**VI. Risks to Participants:** a) Describe any potential risks to participating individuals—physical,

psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as

side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to

human participants, list emergency backup procedures that are in place such as medical or counseling

interventions.

**VII. Benefits:** (a) Describe the benefits and/or any compensation that the participating individuals can

expect and (b) describe the gains in knowledge that may result from the project or research study.

**VIII. Human Subjects Research Protection Exemption Categories:** Federal law 45 CFR 46.101(b)

identifies the six (6) EXEMPT **categories listed below using the language found in the legislation.**

*Check all that apply to your project or study and explain why your proposed project or study falls into the*

*category.*

**NOTE:** The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses,

pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.101(b)(2), for research

involving survey or interview procedures or observation of public behavior, does not apply to research

with children, except for research involving observations of public behavior when the investigator(s)

do not participate in the activities being observed.

**Special Note to Grant Project Directors:**

In most cases, your grant projects are not what we traditionally think of as research studies. Nevertheless,

the participant data, pre- and posttests of student learning, and other information you generate, compile,

analyze, and report on in carrying out project activities and project evaluation are now considered Human

Subjects Research by federal funding agencies. As you review the exemption categories listed below,

think about the data you are collecting and reporting for the participants you serve and other data you will

be using for project evaluation purposes.

     (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.

*Please provide an explanation as to how your research falls into this category:*

     (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.

*Please provide an explanation as to how your research falls into this category:*

    (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 (b)(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.

*Please provide an explanation as to how your research falls into this category:*

    (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.

*Please provide an explanation as to how your research falls into this category:*

    (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: a) public

benefit or service programs; b) procedures for obtaining benefits or services under those programs; c)

possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or

levels or payment for benefits or services under those programs.

*Please provide an explanation as to how your research falls into this category:*

     (6.) Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods

without additives are consumed or b) if a good 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 Inspective Service of the U.S. Department of

Agriculture.

*Please provide an explanation as to how your research falls into this category:*

**Attachments: Attach all that apply to your proposal. (Check the ones you’ve included with**

**proposal.)**

    Informed Consent Form(s): first page(s) on letterhead

    External support proposal or award letter

    Letters of approval from cooperating entities

    Research methods (research design, data source, sampling strategy, etc)

    Questionnaires, surveys, or other data-gathering forms

    Letters, flyers, questionnaires, etc., that will be distributed to the study subjects

    Copy of thesis/dissertation, approved proposal, or prospectus

 If the research is part of a research proposal submitted for federal, state, or external funding, submit a copy of the FULL proposal.

**Notes:**

1) The information should be in sufficient detail to allow the IRB to determine if the study can be classified as EXEMPT under Federal Regulations 45 CFR 46.101(b).

2) Be sure to send electronic copy of the application and materials to David Gribbin, Chair of the EGSC Institutional Review Board at [dgribbin@ega.edu](file:///F%3A%5CInstitutional%20Review%20Board%5CIRB%20Forms%5Cdgribbin%40ega.edu). If you have questions, call (478) 289-2047.

**Certification and Signatures**

***In making this application, I certify that*:**

   1) I have read and understand the protocol and method of obtaining informed consent, as outlined by the EGSC IRB Guidelines, and will follow them during the period covered by this research project.

    2) I intend to comply with the letter and spirit of EGSC IRB Policies.

    3) I agree to comply with federal, state, and local laws regarding the protection of human participants in research.

    4) I will submit any future changes to the research project to the IRB for review and approval prior to implementation, as these may alter the exempt status of the project.

    5) I agree that any new findings that develop during the course of this study that may affect the risks and benefits to participants will be promptly reported to the IRB in writing.

    6) I agree that any adverse events that occur in the course of this study will be promptly reported to the IRB in writing.

    7) I agree and understand that records of the participants will be kept for at least three (3) years after the completion of the research.

    8) I may begin research when the IRB gives notice of its approval.

**Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MM/DD/YYYY

**Printed Name:**

**Co-Investigator (Name):**

**Approval by Faculty Sponsor (e.g., dissertation, thesis, special project).** I confirm the accuracy of this application. I accept responsibility for the conduct of this research, the supervision of human participants, and the maintenance of informed consent documentation as required by the IRB.

**Signature of the Faculty Sponsor \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

MM/DD/YYYY

**Printed Name:**

**Approval by the College** (Department/Division Chair, Vice President, or Other Primary Administrator). I confirm the accuracy of the information stated in this application. I am familiar with and I approve of the procedures that involve human participants.

**Signature of Department/Division Chair, Vice President, or Other Primary Administrator:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_MM/DD/YYYY

**Printed Name:**

**For IRB OFFICE Use Only:**

    This application has been reviewed by the EGC IRB as (exempt, expedited, full):

    Approved

    Approved, Subject to Restrictions:

    Tabled (insufficient information for IRB to make a final decision):

    Disapproved:

Authorizing Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name: