



# Clayton State University Institutional Review Board

## Guidelines for the Reporting of Research with Human Subject Participants

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## I. Introduction

### A. Institutional Review Board (IRB) Statement of Purpose

The IRB is responsible for protecting the rights and welfare of human subjects participating in research projects. The IRB acts according to policies set forth by the United States Department of [Health and Human Services Public Health Service Act](#) as amended (45 CFR 46). Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher. Clayton State University (CSU) operates by DHHS-assigned Federal Wide Assurance (FWA) number **FWA00011633**. The CSU IRB number is **IRB00005960**.

Any research that involves human subjects, whether funded internally or from extramural sources, or not funded, that is undertaken by CSU faculty, academic staff or students, supported by or conducted at CSU, must be reviewed and approved by the IRB prior to soliciting subjects or collecting any data from any human subjects. The IRB defines research as a systematic investigation (i.e. having or involving a system, method, or plan) conducted to develop or contribute to generalizable knowledge about the human experience. It is understood that such research may be disseminated by publication or in a public or professional forum.

While the IRB is empowered to review and approve (or disapprove) research involving human subjects, the protection of research subjects from unnecessary or unacceptable risks is a university- wide responsibility. The primary responsibility for the responsible conduct of research falls on the investigators (faculty, faculty associates, academic staff, graduate students, undergraduates, technicians, etc.) who are conducting the research. However, other persons not involved directly (faculty colleagues, department reviewers, department heads, deans, etc.) share in the responsibility to establish and maintain an atmosphere where respect for the rights of individuals and compliance with applicable regulations is the standard.

### B. Regulations

Regulations, built on the ethical principles of research govern much of the research conducted in the United States and *all* research and training involving human subjects at CSU. This section provides an overview of the regulatory framework governing institutions, IRBs, and researchers.

#### *The Common Rule*

The Common Rule is a federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices. The main elements of the Common Rule include: a) Requirements for assuring compliance by research institutions; b) Requirements for researchers' obtaining and documenting informed consent; and c) Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.

#### *Code of Federal Regulations*

The Code of Federal Regulations is a compendium of all federal regulations in the United States. Each federal agency has a Title number; and within each Title, there are chapters and parts. For human subjects' protection in research, the most relevant are 45CFR46, 21CFR50, and 21CFR56 [45CFR46](#) set forth regulations governing research funded by the Department of Health and Human Services (DHHS). [21CFR50](#) and [21CFR56](#) set forth the regulations governing research funded by the Food and Drug Administration (FDA).

***Department of Health and Human Services (45CFR46)***

The Department of Health and Human Services (DHHS) requires institutions that receive grants from the Department to assure that the institution will have a program for the protection of human subjects, a component of which is an IRB, to review all research and training activities within that institution.

This assurance, called a Federal-Wide Assurance of Compliance (FWA), is an enforceable signed agreement between the DHHS and the institution receiving funds. CSU has agreed to enforce 45CFR46 as the minimum standard for all studies across the entire institution, whether or not a study is funded by the government. 45CFR46 has several sub-parts that require additional protections for specified vulnerable populations: prisoners, children, pregnant women and fetuses.

Within the DHHS there are several agencies that function semi-autonomously: National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC).

***Federal Agencies*****Food and Drug Administration (21CFR50 and 56)**

The FDA, an agency under DHHS, adopted the Common Rule in 1991, but it also published several major deviations in order to adapt the rule to its regulatory mandate. The major differences are:

1. No assurance statement or agreement is required from the institution. The primary relationship is between the FDA and the researcher. The researcher agrees to abide by FDA regulations when signing the FDA form 1572, also called an Investigator's Agreement.
2. The FDA regulations cover the operations of the IRB rather than the institutional research administration program. Thus, an FDA warning letter affects only the operation of FDA-regulated IRB actions rather than the institution's entire research administration program.
3. The definition of clinical investigation is different and is narrower than the definition of research provided in 45 CFR 46.

The waivers allowed from the consent process and consent form requirements are different. The penalties for serious or continuing non-compliance can include criminal judgments against the researcher directly. The FDA can and does audit the work of IRBs and clinical researchers.

**Other Federal Agencies**

Several federal agencies fund and regulate their own research, such as the Veterans Administration, Department of Education, and Department of Justice. They are also covered by the Common Rule. However, additional regulations apply.

1. Veterans Administration (38 CFR). An IRB reviewing VA studies must have a member who is a representative of the VA.

2. Department of Education (34 CFR). These regulations allow exemptions specific to the educational setting.
3. Department of Justice (28 CFR). The Department has special concerns surrounding prisoners and confidentiality of data in studies collecting information on illegal activities.

### *International Conference on Harmonization (ICH)*

Movement toward international GCP standards has occurred over the last few years. The ICH, an effort involving the U.S., the European Union, and Japan, published a guideline for Good Clinical Practice. This worldwide document offers uniform standards in clinical studies, definitions of safety and efficacy, manufacturing, and approval.

### *State Regulations*

Each federal regulation makes clear that compliance with the federal regulations will not conflict with pertinent state or local laws or regulations. Georgia's legislature has enacted several laws that set additional legal requirements.

### *Age of Consent*

The basic age of consent for participation in research is 18, which is also the age at which Georgians may enter contracts or consent to medical services. Parental permission must be sought for subjects under 18; exceptions to this requirement may only be granted by the IRB.

### *Legally Authorized Representative*

State as well as federal rules allow consent to be granted, under specific circumstances, by a legally authorized representative instead of by the subject (e.g., parent for a minor).

### *Emancipated Minor*

Georgia law recognizes the concept of the “emancipated minor”. An emancipated minor is a person who is at least 16 but under the age of 18 (See GA Code 15-11-720 (2016)), who is nevertheless considered to be an adult and therefore able to consent for themselves. Special precautions need to be taken to ensure that the participant is, in fact, an emancipated minor.

### *Institutional (CSU) Rules*

Although federal rules define the national minimum standard, implementation is at the local level. Each institution responds in its unique way to the basic requirements. The Federalwide Assurance of Compliance (FWA) forms the basic set of rules for CSU’s institutional program for the protection of human subjects. The information in the FWA is further refined by this Human Subjects Manual, the Faculty Handbook, and various other CSU documents reflecting the institutional culture.

## **C. Individual Responsibilities**

Every person involved in research – subjects, the IRB Officer in Charge, the IRB Chair, the IRB Staff, Principal Investigators, Faculty Sponsors, Student/Staff Researchers, Research Coordinators, Contract Research Organizations, and Sponsors – should understand his or her role on a project in light of the ethical principles described above.

### *Subjects*

Research subjects may be students, faculty, or staff. As research participants who have given consent, subjects also have responsibilities: to tell the truth, to ask for clarification, to follow the protocol, to notify the study personnel of their non-compliance, and to tell the researchers if they wish to withdraw from the study.

### *Principal Investigators (PI)*

The PI will ensure that the PI, co-investigators, research assistants and staff are all properly trained in all aspects of the protocol and that anyone working on the project, CSU faculty, staff, students, and subcontractors will have completed Human Subjects training prior to beginning work on the project. For any research involving human subjects, the PI will submit the protocol for IRB review **prior to beginning any work** on the project **and before contacting any human subjects**.

Any proposed changes to approved protocol will be immediately sent to the IRB for review prior to implementing any changes. The PI is responsible for:

1. Submitting documents in a timely manner for continuing review;
2. Retaining all study records for a minimum of three years following completion of the study.
3. Promptly report any injuries, unanticipated problems, or complaints regarding the research to the IRB; and
4. At the completion of the study, the investigator is required to submit a Project Termination Form and report to the IRB chair summarizing the study and results. This report will be filed with the original application in the Provost's Office.

### *Institutional Review Board (IRB)*

The primary purpose of the committee is to ensure that human subjects are not placed at undue risk of harm during the research process.

A balance between freedom of inquiry for scholars and recognition of the ethical concerns of peers, subjects, sponsors, government agencies, and the public at large shall be maintained by the IRB. The members of the IRB maintain that numerous issues tied to human research merit much further attention by the academic community. The IRB strongly encourages faculty, academic staff members, student groups, departments, schools, and colleges to discuss the ethical responsibilities of scholars as they apply to research to ensure awareness and sensitivity of subjects' needs.

### *Institutional Official*

The Institutional Official signs the Federal-Wide Assurance of Compliance on behalf of the institution and has the authority to determine the practices within that institution. This person is responsible for assuring that the program is functional, adequately staffed and funded, and respected in the research community.

CSU's Institutional Official (referred to throughout this document as IRB OIC, or simply OIC) is appointed by the Provost.

## II. Education in the Responsible Conduct of Research

All individuals engaged in research involving human participants must complete an educational program related to the responsible conduct of research prior to initiation of a research project. At Clayton State University, investigators involved in human subject research are required to complete Human Subjects training.

### A. Faculty

The training is required for the Principal Investigator (PI), Co-Investigators, Student PI, and other key personnel who are responsible for the design and/or conduct of the study. The requirement also applies to sub-contractors, consultants, individual fellowship applicants, study coordinators, and persons who may conduct any research related procedures or health or opinion surveys or interviews.

### B. Students

Graduate and undergraduate student research assistants listed as investigators in the IRB application or who otherwise have a substantial role in data collection or subsequent data analysis are required to complete Human Subjects training.

### C. Staff

Study personnel who handle data or complete activities such as taking transcriptions must complete the training program. Individuals providing only technical services such as setting up a room, or handing out and collecting survey instruments without providing explanations or answering questions about the research or data-gathering instruments are not covered by this requirement; however, they should receive instruction on maintaining the privacy and confidentiality of the research participants as well as the data. The PI is responsible for ensuring that all personnel are properly trained.

### D. IRB

IRB members receive orientation to the responsibilities of IRB service. All IRB members are also required to complete the Human Subjects training course. The IRB training certificate must be dated within three years of appointment to the IRB, and remains in effect for the duration of continuous IRB appointment.

### E. Human Subjects Training

Each investigator included in an IRB application, and other key personnel who are responsible for the design and/or conduct of the study, must complete Human Subjects training. If a current Human Subjects training is not held, the IRB Chair will provide information on training access once the IRB application has been received (prior to study approval). After completing the training, documentation should be emailed to the IRB Chair at [irb@clayton.edu](mailto:irb@clayton.edu). Proposals will not be reviewed until all members of the research team have completed the Human Subjects training and evidence has been documented in the IRB office. Please note that research cannot begin until Human Subjects training has been completed and an approval letter by the IRB Chair for the study has been received. An approval letter will only be provided after verification of Human Subjects training. For a specific research study that has received an IRB acceptance letter, the Human Subjects training certificate remains current for the duration of the project.

## F. Good Clinical Practice (GCP)

The FDA has a series of regulations setting the minimum requirements for principal investigators, researchers, and sponsors. These include rules about drug accountability, source documentation, adverse event reporting and safety reports, responsibilities of sponsors and monitors, monitoring of study activity, data integrity, and financial conflicts. Taken together this set of requirements is known as Good Clinical Practice (GCP). All researchers conducting regulated research should be conversant in GCPs.

## III. Institutional Review Board (IRB) Process

The IRB has the following written policies and procedures for conducting initial and continuing review and procedures for handling modification to research studies. All new human subject research, and modifications to approved research (except when the modification is necessary to eliminate apparent immediate hazards to participants), must be previously reviewed by the IRB. In addition, no previously approved human subject research may be extended beyond the expiration date without continuing review approval by the IRB.

Prior to the execution of any research involving human subjects, investigators shall have completed the mandated education described under “Education in the Responsible Conduct of Research” in this document and completed review by the IRB.

### A. The Review Process

#### *Initial Review*

The IRB reviews applications for research in accordance with federal regulations governing research with human subjects. The Board may also apply such codes of professional ethics as it deems appropriate. These additional codes may or may not be addressed in federal documents. It is the policy of CSU that for any research application to be approved, the Board must determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may be reasonably expected to result;
3. Selection of subjects is equitable given the purposes and the setting of the research,
4. Appropriate informed consent will be sought from each prospective subject or the subject's legally authorized representative, and such consent will be appropriately documented (see Informed Consent Guidelines below);
5. The research plan makes appropriate provision for monitoring the data collected to insure the safety of subjects;
6. Appropriate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data;

7. Where some or all the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included to protect the rights and welfare of these subjects; and
8. When research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations at subpart B, C, or D respectively, of 45CFR46. *See section on Informed Consent.*

The IRB may process a protocol in one of three ways:

1. By exemption certification
2. By expedited review
3. By full review

Any research protocol which does not fall under the category definitions of exempted or expedited research as outlined below, or any protocol as specifically requested by the Board, shall undergo full review.

### ***Decisions of the IRB***

In reviewing research proposals for initial review, continuing review and protocol changes undergoing review, the IRB has the authority to make the following decisions:

**Approved** - Approved as written with no conditions.

**Approved with Modification** - Approved with modifications for minor changes that will be identified to the PI and must be completed and documented prior to beginning the research. A letter requesting the necessary, specific, modifications is sent to the PI. The PI must make the required modifications and submit them to the IRB. For these modifications, the IRB Chair or designated reviewer can, upon reviewing the PI's response(s), approve the research on behalf of the IRB.

If the protocol disposition is "Approved" or "Approved with Contingencies" and the protocol requests inclusion of a vulnerable population(s), special determinations for the vulnerable population(s) are performed at this time.

**Deferred** - Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI. The PI's responses will be reviewed at the next convened meeting of the IRB.

**Disapproved** - The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas.

**Suspended**- All protocols must be ceased immediately upon notification of IRB, and not resume until further notice by IRB. The PI should address the contingencies promptly. Once the PI receives notice that a study is suspended, the PI will have ten (10) days to correct contingencies outlined in the suspension notice and to report in writing to the IRB how contingencies are corrected. If the IRB receives no response within the ten days of issuing the contingencies, the

IRB chairperson shall write a memo to the PI inquiring as to whether he/she intends to continue the protocol. Also, the inquiry shall state that lack of a written response within a two-week period will result in discontinuation of the protocol. The IRB will be kept informed on the non-compliance with contingencies and the administrative actions taken.

Once IRB reviews the written corrections, the PI will be notified in writing of the decision to submit further corrections, resume the study, or to terminate the study.

**Termination** - All protocols must be ceased immediately upon notification of IRB, and not resumed. It is the responsibility of the PI to notify all subjects as to the cessation of the study, and reasons for doing so. Written copies of subject notifications must be submitted to the IRB within one month of notification of study termination.

### *Dissemination of IRB decisions*

Upon review by the Board, the IRB Chair shall notify the PI by email of the Board's decision within 48 hours of review. The letter will also state conditions which must be met, if approval is to be awarded. Approval will not be granted until all specified conditions are met. The letter shall also:

1. Advise the PI to notify the IRB immediately, and in writing, if there are any subsequent changes proposed in the research protocol. No changes may be initiated without IRB review and approval.
2. Indicate the period for which approval is valid (1 year, in most cases).
3. Require the PI to make an application for annual review should the study extend beyond the initial approval expiration date.
4. Direct that during the course of the research, should an adverse event occur which threatens the health, safety or emotional well-being of a participant, or which increases the risks to subjects from that described in the approval documents for the project, the PI must suspend the research immediately and report the incident to the IRB Chair. The IRB Chair will investigate and determine the course of action to follow.

The IRB Chair will retain a copy of the IRB decision for the IRB files and send copies to the PI.

## **B. Procedures to Initiate Review**

Prior to the execution of any research involving human subjects, investigators shall have completed the mandated Human Subjects training, and they shall have completed and submitted to the IRB Chair a copy of the IRB Application form along with a copy of the proposed informed consent statement. The application form must provide the following information:

- Name(s) and department(s) of investigator(s)
- Title of the study
- Signature of responsible faculty member
- Whether or not external funding is proposed
- Begin and end date for the study

- Purpose of the study
- Description of subjects
- Number of subjects to be recruited
- Description of methodology, including a copy of any instruments used
- Potential benefits and risks to the subject
- Anticipated beneficial knowledge resulting from the study
- Qualifications of investigator(s), e.g. a CV or experience in the specific research area
- Description of any deception
- Procedures for protecting the anonymity/confidentiality of subjects
- A copy of any recruiting materials or scripts.
- Method for insuring informed consent, including a copy of the proposed informed consent statement.

### ***Research Determination***

The first step in preparing an IRB application is to determine whether an IRB application is warranted. To accomplish this, the investigator should follow the steps of completing a Research Determination form (<http://www.clayton.edu/provost/irb/forms>). In addition, you should consider reviewing the NIH-provided flow chart for *Research Involving Private Information or Biological Specimens*, available online at: <https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf>.

### **Policy**

Only those activities that meet the definitions of research and human subject under the DHHS regulations and/or those that meet the definitions of clinical investigation and human subject under the FDA regulations will be considered human subjects research. All human subjects research that will be conducted under the auspices of CSU will require prior review and approval by the CSU IRB.

1. Examples of Human Subject Research (this is not intended to be an all-inclusive list):
  - a. Clinical studies that utilize test subjects or their specimens for new devices, products,
  - b. drugs, or materials.
  - c. Research studies that collect data through intervention or interaction with individuals.
  - d. Interaction may include surveys, interviews, questionnaires, and focus groups. Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject's environment (e.g., hot/cold stressors).

- e. Research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individuals to whom the information or specimens pertain, even if the information/specimens were not collected specifically for the currently proposed project.
  - f. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
  - g. Studies that involve living individuals to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space, landscape design, or test chamber.
  - h. Pilot or feasibility projects that will be used to develop or evaluate research procedures or design for a project that will involve human subjects.
2. When an activity does not meet both definitions of research and human subjects, it is not considered human subjects research and no IRB review/approval is required.
3. Examples of Not Human Subjects Research (this is not intended to be an all-inclusive list):
- a. Observational studies of public behavior (including television and open internet chat rooms) do not involve human subjects if there is no intervention or interaction with the subjects, the behavior is not private, or there is no manipulation of the environment in order to stimulate certain types of behavior.
  - b. Data collection for internal departmental, school, or other University administrative purposes. Examples are teaching evaluations and customer service surveys.
  - c. Benchmarking (measurement of an organization's policies, products, etc. and comparison with similar measurements of peer organizations) where the objectives are to analyze peer organizations' practices, determine whether improvements are necessary, and use this information to improve performance.
  - d. Service surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or its clients or for developing new services or programs for students, employees, or alumni. Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.
  - e. Information-gathering interviews where questions focus on things, products, or policies rather than on peoples' own personal thoughts, perceptions, feelings or ideas. Examples include canvassing librarians

about their libraries' inter-library loan policies or periodical purchases, or interviews with company engineers or managers about how a product is made.

- f. Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement. For more information, see IRB Policy on Student Class Projects, <http://research.uga.edu/hso/irb-guidelines/>.
- g. Biographical research involving a living individual that is not generalizable beyond that individual.
- h. Research involving only commercially available, de-identified cell lines or biological materials.
- i. Research involving cadavers, autopsy material or biospecimens from now deceased individuals. Note: Some research in this category, such as use of protected health information and genetic studies involving the collection of information about living relatives, may need IRB review.
- j. Innovative therapies except when they involve "research" as defined by the above criteria. (An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to particular individuals, or when the innovative therapy is investigational.) Note: When innovative therapies differ significantly from routine practice, it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.

Quality assurance or improvement projects and program evaluations are generally not considered research unless there is a clear intent to contribute to generalizable knowledge. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB. (See OHRP's Quality Improvement Activities FAQs at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/>.) NOTE: If a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute nonexempt human subjects research under the HHS regulations.

- k. Case history or case study which is published and/or presented at national or regional meetings is not considered research if the case is limited to a description of the specific features/outcome of the case and do not contribute to generalizable knowledge.

- l. Research involving publicly available datasets or information. Examples: Inter-University Consortium for Political and Social Research (ICPSR), U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), PRAMS, Twitter feeds (tweets), Instagram. Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available.”
- m. Research involving only analysis of data or biological specimens that are not individually- identifiable and were not collected specifically for the currently proposed project.
- n. Oral histories which are NOT intended to draw conclusions, inform policy or generalize findings and for which the sole purpose is to create a historical record of specific personal events and experiences and provide a venue for people to tell their stories (See P&P – Oral History).
- o. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information that focuses directly on the specific individuals about whom the information is collected;
- p. Other types of research that is under IRB are certain public health surveillance activities certain collection and analysis activities conducted by a criminal justice agency; and certain activities conducted by a defense, national security, or homeland security authority.

### *Authorization to Make Determinations*

Each activity undertaken on behalf of CSU must be evaluated by the individual most familiar with the planning and development of the activity. Therefore, it is the responsibility of researchers to make appropriate determinations based on this policy. When an individual makes a self- determination that an activity does not constitute human research, the CSU IRB recommends that the individual document in writing how the determination was made and retain this with his/her study records.

The IRB has the authority to over-rule an investigator’s self-determination or the determination of other institutions or funding agencies. The CSU IRB determination that a planned activity is human subjects research will override an external determination unless the external determination is from the applicable human subjects regulatory agency.

If a determination cannot be made, the investigator must submit the activity/project to the IRB for determination. IRB members are the only CSU individuals authorized to make a formal determination that an activity is human subjects research or not.

### *Initial Review Materials*

Materials should be submitted with sufficient detail for the IRB to make decisions regarding: a) risk; b) potential benefits; c) informed consent; and d) safeguards for human subjects.

Materials should include, but are not limited to:

1. IRB Cover Sheet, required (summary email is sufficient if addressed to [irb@clayton.edu](mailto:irb@clayton.edu))
2. Initial IRB Application (Exempt, Expedited, or Full Review, as appropriate), required
  - a. Applications are available at <http://www.clayton.edu/provost/irb/forms>
  - b. Checklist for each application type, for self-quality-assurance of application materials, is available at <http://www.clayton.edu/provost/irb/forms>
3. Proposed informed consent document, required
4. Letter(s) of Approval from cooperating entities (Letter from district or principal if conducting research in schools)
5. Relevant grant applications
6. Recruitment materials for subjects, required
7. Investigators brochure (a comprehensive document summarizing the body of information about an investigational product), if one exists
8. if study is supported by the Department of Health & Human Services, a copy of the HHS approved sample, informed consent form, and HHS protocol, if they exist.

### **C. Categories of Review**

#### *Exempt Review*

Certain categories of research protocols may be exempt from review. Only the IRB Chair, Committee, or IRB Vice Chair is authorized to determine which protocols may be subject to limited review or may be exempt from review by the Board. Investigators who believe that their research meets the following criteria may request exempt status for their study when it is submitted to the Board, and list the justification. The IRB reserves the authority to require proposal modifications regarding human subject protection before approving the research as exempt.

Note that the exemption DOES NOT APPLY when the research activities include:

1. Prisoners, fetuses, pregnant women or human in-vitro fertilization.
2. The review of medical records when the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects.
3. Techniques which expose the subject to more than minimal risk.

4. The deception of the subject.

### Exempt Categories

The federal categories of research eligible for exemption certification under 45 CFR 101(b) are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - a. research on regular and special education instructional strategies, or
  - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Though the research is exempt, the investigator has an ethical obligation to respect and safeguard students' rights and welfare.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - b. 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), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - a. the human subjects are elected or appointed public officials or candidates for public office; or
  - b. 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:
  - 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 of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies,
- a. if wholesome foods without additives are consumed or
  - b. 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.

In addition, CSU has adopted two categories of exemptions in agreement with exempt policies at University of Georgia (reference: <https://research.uga.edu/docs/policies/compliance/hso/IRB-Exempt-Review.pdf>):

7. Non-federally funded, when the research activities do not conform to one of the six DHHS exempt categories, and involves research of individual or group characteristics or behavior using established qualitative or quantitative data collection procedures that may include benign interventions or performance of non-physically invasive tasks and physical actions by a subject, presentation of stimuli, or manipulations.
- a. Established qualitative data collection procedures include ethnography, action research teams and focus groups.
  - b. Activities may include reading, writing, and card-sorting tasks; eye-tracking technology; computer and video games, internet searches, and photo/video elicitations; game or role playing, simple physical or mental actions; and, non- invasive visual/audio stimuli or tasks where the primary intention is not to affect emotional or physiological responses.
  - c. Benign interventions would be brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and where the Investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
    - i. Example 1: A graduate student researcher in the English Department will ask participants to read on a computer screen twenty (20) words in English and in Latin while eye movements are being recorded.
    - ii. Example 2: A researcher is studying the Kashmiri cuisine among Members of a Tribe in the Himalayas. In the process, the Investigator will immerse herself in the ongoing everyday activities of the community for the purpose of describing the social context, relationships and processes relevant to the cuisine. She will also conduct unobtrusive direct observations, participant observations, structured and unstructured interviews, and focused discussions with Tribal Members.

8. Non-federally funded, when the research activities do not conform to one of the six DHHS exempt categories research and is limited to analysis of existing or prospective information or biological specimens, and information may be recorded by the Investigator in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.
  - a. Research which is FDA regulated are excluded from this category.
  - b. Research with a Certificate of Confidentiality are excluded from this category.
  - c. Studies that typically fall under expedited category 5 may now fall under exempt category 8.
  - d. This category may include information or specimens from children.
    - i. Example 1: A study that is limited to the analysis of coded data that will be collected from participants who have signed up to join a non-research exercise program. It is important for the researchers to retain the codes (indirect identifiers) for the proposed analysis.
    - ii. Example 2: A study will investigate the progression of cancer in individuals exposed to asbestos using existing biological tissues that were obtained from a previous research study. The researchers will retain the identifiers. The proposed analysis is specified in the consent form for initial sample collection.

Human subjects research studies that qualify for exemption are exempt from the requirements of 45 CFR part 46. However, if an investigator decides to modify an exempt human subjects research project in such a way that it would no longer qualify for exemption, the investigator must submit the modified research protocol to the IRB for review prior to implementation of the modified research project. Ongoing exempt research must be re-approved by the IRB every 3 years.

### **Exempt Review Expected Timeline**

An Exempt review application is processed by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair. Once a completed application is received, the PI can expect up to two weeks (10 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least six (6) weeks from the submission of an Exempt IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, time between semesters. The timeline will also be extended during summer semester.

### ***Expedited Review***

Federal regulations permit an expedited review procedure for protocols that meet certain eligibility requirements. Such reviews may be carried out by the Chair of the IRB or by one or more experienced reviewers designated by the Chair from among all qualified members of the Board. In performing expedited reviews reviewers may exercise all of the authorities of the Board with the exception of disapproval. A research project may be disapproved only after full Board review as described in the next section. The Board shall be informed of all expedited

reviews at its next full meeting. Submissions for Expedited Review should be made using Application for Review of Human Participant Research and must include specific permissible category justifying the expedited review.

Research activities that present no more than minimal risk (see glossary) to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities detailed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review used by the IRB — expedited or full. The categories in this list apply regardless of the age of subjects, except as noted. Categories one 1-7 pertain to both initial and continuing IRB review.

### **Expedited Categories**

Federal regulations allow nine specific categories of human participant research to be reviewed through an Expedited Review Procedure. Per 45 CFR 46.110 and 21 CFR 56.110, the research should present no more than minimal risk to human participants and involve only procedures listed in one or more of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
  - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

- b. From other adults and children<sup>1</sup> considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human participants 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB as follows:
  - a. Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
  - b. Where no participants have been enrolled and no additional risks have been identified; or
  - c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Though not guaranteed, expedited reviews may be done twice per month or more often, as needed. The frequency depends on the monthly IRB case load and relevant meeting agendas. The Project Investigator should be aware of these guidelines and plan accordingly.

### **Expedited Review Expected Timeline**

An Expedited review application is processed by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair. Once a completed application is received, the PI can expect up to four weeks (20 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least six (6) weeks from the submission of an Exempt IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, time between semesters. The timeline will also be extended during summer semester.

### **Full Board Review**

Full board review must take place for all protocols that do not qualify as “exempt” or “expedited”, or as otherwise specified by the Board. A quorum of IRB members will review submissions at a regularly convened meeting. The application process remains the same as for the other levels of review, but investigators should note that a Full Review can take up to two months from the time of submission. Initial Full Review may not result in an outright approval of

the research; minor or major revisions and written clarifications are often requested, and the review timeline may be extended to accommodate revisions and subsequent reviews.

### **Full Review Expected Timeline**

A Full review application is prepared by the IRB Chair or Vice Chair, or by another IRB member designated by the IRB Chair, and then reviewed by the full IRB and voted on electronically or during a scheduled session. Once a completed application is received, the PI can expect up to six weeks (30 normal business days during which the university is open and classes are in session) for feedback or a decision from the IRB Chair. If additional information or revisions are requested by the IRB, then the timeline will be extended to allow for reasonable follow-on review once the requested feedback is received by the IRB. CSU advises that investigators plan for at least eight (8) weeks from the submission of the IRB application before they plan to begin executing the study. This timeline will be longer during periods in which classes are not in session, including major holidays, and time between semesters. Full reviews received after April 15 will be prepared for review beginning during Faculty Planning Week in Fall Semester, at which time the review process will begin. Full review applications are not reviewed during Summer Semester, and any received after April 7 do not present enough time for the IRB to conduct due diligence prior to the end of the academic year. In the event that a Full review application is received during the last week of March or first week of April, the PI accepts the risk that a decision may not be reached until Fall Semester if the IRB requires substantial additional information or revisions. PIs are encouraged to plan accordingly, and submit IRB applications well in advance of academic year end.

### ***Continuing Review of Research***

Federal regulations require that the Board conduct continuing review of approved expedited and full Board approved proposals at least once per year. It is the responsibility of the PI to submit all documentation for a review of research for expedited and full board review. PIs must also submit a request for continuation for exempted review. The IRB Chair will send reminders to PIs prior to the review date. The PI is responsible for submitting documents for continuing review in a timely manner to allow continuing approval prior to the expiration of initial approval. Letters of initial approval specify the duration of the approval period or a subject enrollment number as a threshold for determining when continuing review is to occur.

The IRB can begin continuing review from the assumption that all of the categories of initial review are met. The IRB will then focus on new information provided by the PI or otherwise available that would alter prior IRB determinations. The IRB will assess whether there is new information that would necessitate revision to the protocol and/or informed consent. In making this determination the IRB will take into account:

- The nature of any risks posed by the research project and degree of uncertainty of risks involved;
- The vulnerability of the subject population;
- Adequacy of the process for obtaining informed consent;
- The experience of the investigators in conducting research;
- The IRB's previous experience with the investigators (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator);

- The projected rate of enrollment and research progress; and
- Whether the research project involve novel interventions.

### *Lapsed Approval*

In the case that documents are not submitted in time to complete the continuing review process prior to the expiration of IRB approval, the approval lapses. All research activity involving human subjects must stop immediately when IRB approval lapses.

48 hours prior to expiration of IRB approval, the IRB Chair will e-mail notification to the PI, PI Departmental Chair, IRB Chair, and the IRB Officer in Charge. This notice will indicate all research involving human subjects must stop when approval lapses and all correspondence about an overdue protocol from the IRB Chair and the IRB committee will be maintained in the PI's protocol file and in the IRB office.

Research may continue once the review process has been completed and the IRB has re-approved the protocol. During the IRB meeting the IRB minutes should document why the lapse in approval occurred and any corrective actions being taken to prevent repeated instances of IRB approval lapsing.

### **Exempted Protocols and Continuing Review**

Exempted protocols are exempt from continuing review. It is the principal investigator's responsibility to report any changes to research protocol that may change the risk level to human subjects, or otherwise change the conditions (criteria) for which Exemption was initially granted. Any substantive changes in the research protocol will result in a new application for Exempt review. Any questions regarding changes in protocols that may increase risk factors or change otherwise change the qualifications for Exempt status should be directed to the investigator's college IRB representative.

### **Expedited Review for Continuing Review**

Unless an IRB determines otherwise, continuing review of research is not required if: (1) The research is eligible for expedited review in accordance with §11.110; (2) the research is reviewed by the IRB in accordance with the limited IRB review procedure described in several of the exemption categories (specifically, § 11.104(d)(2)(iii), § 11.104(d)(3)(i)(C), §11.104(d)(7), or §11.104(d)(8)); or (3) the research has progressed to the point that it involves data analysis (including analysis of identifiable information or identifiable biospecimens) or access to follow-up clinical data from procedures that subjects would undergo as part of clinical care. If an IRB chooses to conduct continuing review even when these conditions are met, the rationale for doing so must be documented.

### **General Considerations**

A research study that was eligible for initial review under an expedited review procedure will usually qualify for an expedited review procedure at the time of continuing review. However, IRBs should be aware that a research study previously approved under an expedited review procedure in some circumstances will need to undergo continuing review by the IRB at a convened meeting. Full review may be called for in situations where: the investigator has proposed changes to the research project when submitting for continuing review, that involve the addition of activities that do not fall within the scope of any of the categories of research

activities eligible for an expedited review procedure. Likewise, a research project that was not eligible for initial review under an expedited review procedure usually will not qualify for an expedited review procedure at the time of continuing review, except in the following limited circumstances:

1. The research project involves only activities described by expedited review categories (8) or (9); or
2. Research project previously approved by the IRB at a convened meeting progresses to the stage where all of the remaining human subjects research activities involve no more than minimal risk to the subjects and fall within the scope of one or more of expedited review categories (2) through (7).

### **Full Board Continuing Review**

Protocols undergoing full review will be considered and discussed at a regularly convened IRB meeting. Rules and procedures for conducting initial full board review will be in effect for full board continuing review. During continuing review the IRB may take any of the following actions:

1. Approve:
  - a. as submitted, or
  - b. with conditions
2. Defer, requiring significant modifications by PI to be considered at a later meeting
3. Disapprove

IRB Chair shall notify the PI by letter and/or email of the Board's decision within 48 hours of review. The letter will also state conditions which must be met, if approval is to be awarded. Approval will not be granted until all specified conditions are met.

## **D. Monitoring and Oversight**

### ***Continuing Oversight***

IRB approval of the project does not end its overseeing of the project.

### ***Modification to approved project***

Modification is defined as any change to a protocol from what was previously approved during the period for which approval was given. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Should protocol changes be made without prior IRB approval to eliminate apparent hazards to the subject(s), submit a memorandum immediately to the IRB addressing the nature of the change, why it was necessary, and the outcome.

Approval of the modification request is on the advice of the IRB chairperson or a designated reviewer unless the nature of the proposed changes warrants review by the full IRB. If subjects have been enrolled, the IRB may determine the modification relates to subjects' willingness to

continue to participate in the research, and request that the PI relay pertinent information to subjects. The investigator is notified in writing of the IRB's decision.

### *Unanticipated problems, noncompliance, reports of harm*

It is the investigator's responsibility to report to the Board any proposed changes in the research as well as any unanticipated problems that arise involving risk to subjects. Any complaints or concerns by research subjects, university faculty, staff, or students, or members of the community should be addressed using the following procedure. In addition, any reports made directly to the IRB Chair or the OIC will be routed in the following manner:

1. The PI
2. IRB Chair
3. Chair of the IRB
4. The Director of Research & Sponsored Projects
5. The PIs Chair

### *Assurance of Confidentiality*

Appropriate routing of relevant information and communication is critical in successful resolution of these issues. The goal is to protect subject rights or whistleblower rights, and at the same time maintain confidentiality. As such, the following protocol should be followed whenever there is an awareness of such a situation by the CSU administration, faculty, and/or staff: The following individuals should be notified in the order listed above prior to any action taken or contact with the subject.

It is imperative that all parties maintain absolute confidentiality of the subject's identity in communications; subject identifying information should only be included when absolutely necessary to resolve conflicts.

### *Complaint Resolution*

Once notified, the PI shall report to the Chair of the IRB regarding the issue/complaint and options for successful resolution. These parties shall collaborate together to resolve the issue successfully. Once the issue is resolved, The IRB OIC and the PI's Chair will be notified of the outcome.

If deemed necessary, the IRB Chair or IRB Chair may determine that reconsideration of the protocol by the full Board is warranted. If such a determination is made, the procedures governing initial review of protocols will be utilized.

If at any time, the Board becomes aware of:

1. unanticipated problems involving risks to subjects,
2. other serious or continuing noncompliance with 45 CFR 46 or determinations of the Board, including ongoing human subject research which has not been reviewed by the Board,
3. deviation from activities previously approved by the IRB, or

4. report of harm, illness, or any other adverse condition possibly occurring as a result of the study,

it may request a meeting with the PI and/or suspend the research until the problem can be further evaluated. In these circumstances, the Board may impose sanctions on an individual by suspending the individual's right to conduct or supervise research involving human subjects, taking possession of the data collected by the non-compliant individual, withholding or revoking academic credit to a student researcher, and recommending discipline of a faculty member by the University. This list is provided by way of example only, and is not intended and should not be construed as exhaustive, in that individual situations may call for specific actions and remedies not identified herein.

Under these circumstances, letters will be immediately sent, by the IRB Chair, to the Authorized Institutional Official (IRB Officer in Charge [OIC], appointed by the Provost), College Dean, OHRP, and sponsoring agency. Reporting of any further sanctions subsequently recommended by the Board will be sent by the IRB Chair within 24 hours of being advised by the Board.

### *Verification of Information*

At times the IRB may need verification that no material changes have occurred since previous IRB review, from sources other than the investigator. This determination can be made in situations where:

1. The IRB doubts the veracity of the information provided by the investigator.
2. The information provided by the investigator is internally inconsistent and the inconsistency cannot be resolved through discussion with the investigator.
3. The information provided by the investigator is inconsistent with other information known to the IRB and the inconsistency cannot be resolved through discussion with the investigator.
4. Complaints from research participants that appear not to be adequately addressed by the investigator
5. The investigator has been found to be in serious or continuing noncompliance in the previous year.
6. Studies have an unusually high dropout rate

Any other situation where the IRB requests verification from sources other than the investigator that no material changes have occurred since previous IRB review. The IRB with the assistance of the IRB Officer in Charge must determine the method of verification from other sources to ensure that no unapproved changes have occurred since the previous IRB review. This may be accomplished by:

1. Conducting audits or inquiries to collect information, and/or
2. Having the IRB or its designee observe the informed consent process and conduct of the research, and/or
3. Examining contents of manuscripts or reports resulting from protocol activities.

## E. Human Subject Research without Prior IRB review

No research involving human subjects is to be conducted without IRB review. Any reports of human subject research without prior review by the IRB, whether reported by the PI, other faculty, administrators, staff, students, or subjects will be investigated. Any reports will be sent immediately to the IRB Chair and to the IRB Officer in Charge.

### *Determination of Alleged Infractions*

The IRB Chair will interview the investigator to gather additional information to determine if any University rules or policy have been violated. If it is determined that no infractions have occurred, no further action will be taken. If it is determined that University rules or policy have been violated, the PI and the PIs Department Chair will be immediately notified in writing what procedures must be followed to comply with University policy regarding human subject research.

The following actions will be taken:

1. Non-approved Exempt research: The PI is required to immediately suspend all research activity. For research to continue, the PI must submit an application to the IRB within 7 days. If the research will not be continued, the PI will submit a report documenting the research that was done without IRB approval. This documentation should include a description of the research protocol, number of subjects involved, and any results of the study. No data collected during unapproved research may be used for publications or presentations.
2. Non-approved non-exempt research: The PI is required to immediately suspend all research activity. For research to continue, the PI must submit an application to the IRB within 7 days. The IRB application will be handled in according to normal IRB procedures. The minutes of the IRB meeting will reflect that the application was submitted as a result of determination by the IRB that he PI had been conducting human subject research without IRB approval. If the research will not be continued, the PI will submit a report documenting the research that was done without IRB approval. This documentation should include a description of the research protocol, number of subjects involved, and any results of the study.

If the investigator fails to submit an application or report within the designated time, the IRB will send a written report, including description of the IRB actions to the Department Chair or next higher level of administrative authority for appropriate action within 3 days. Failure of the department chair to act or comply is reported to the IRB Officer in Charge with a recommendation for appropriate actions.

### *Determination of an alleged repeated infraction of Institutional Policy*

The procedures outlined in “Determination of Alleged Infractions” above will apply for a repeated alleged infraction. If it is determined by the IRB Chair and IRB Chair that a second or additional infraction has occurred, the IRB will promptly notify the IRB Officer in Charge and the Department Chair, with the recommendation that the investigator’s privilege to do research be suspended at once, that the funding agency be notified of the suspension, and that unused funds

be returned. It is also recommended that patients on therapeutic studies be changed to alternate therapy as soon as possible.

## F. Evaluating Investigator and Institutional Issues

When appropriate, the reviewing IRB should consider issues regarding the investigator and the institution(s) where the research is being conducted during its continuing review, such as the following:

1. Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, change in medical license status, or increase in number of research studies conducted by the investigator);
2. Evaluation, investigation, and resolution of any complaints related to the investigator's conduct of the research;
3. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and applicable regulations, State and local law, or standards of professional conduct or practice; and
4. Reports from any third-party observations of the research carried out under 45 CFR 46.109(e).

**Failure by the investigator to initiate this annual review prior to the expiration date of the approval shall result in immediate termination of the research.**

## G. Investigator's Right of Appeal

It is the policy of CSU that the final decision regarding approval or disapproval of all protocols rests with the IRB. In accordance with federal regulations, no research involving human subjects may be conducted under CSU's auspices without the prior and continuing approval of the Board. Any investigator who disagrees with a decision of the Board may request a hearing before the duly-convened IRB to appeal its decision. Relevant arguments and/or witnesses may be presented on behalf of the investigator. The investigator may also request that the Authorized Institutional Official be informed of the appeal. However, final decision rests with the Board.

## H. Student Research and Faculty Responsibility

Research conducted by students, such as thesis research and some class projects, requires the approval of the IRB prior to execution. It is the responsibility of faculty supervising research by students or staff to ensure that approval of the Board is obtained by submitting the application, if needed. Individual projects conducted primarily for instructional purposes within the context of a formal class, and **not designed to contribute to generalizable knowledge** (not intended for presentation or publication outside of the university community), do not meet the definition of "research" as defined in the federal guidelines. Thus, they do not require review by the Board, provided the instructor is prepared to accept professional and ethical responsibility for all research projects conducted in conjunction with the class. Under these conditions, a single form may be submitted for the class assignment. The instructor is responsible for completing Human Subjects training and instructing all students in proper protection of human subjects, federal regulations, and ethical standards. Faculty are also responsible for monitoring the ethical propriety of these projects and applying the criteria listed in this document.

Faculty supervising students who are conducting class-based activities involving human subjects should request IRB review of the activities. In most cases, this can be accomplished by submitting a single request for IRB review of the class project.

Faculty supervising students who are conducting human subject research that will likely be incorporated in a thesis or dissertation project should submit a request for IRB review since this may contribute to generalizable knowledge by being disseminated through a presentation or publication.

Additionally, faculty supervising students who conduct research should submit a request for IRB review if it meets the criteria for research. Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In other words, the IRB defines research as a systematic investigation (i.e. having or involving a system, method or plan) conducted to develop or contribute to knowledge about the human experience. It is understood that such research may be disseminated by publication or in a public or professional forum. In addition, based on the principle that CSU IRB exists to protect the rights and safety of individuals who participate as research subjects in projects administered by university faculty, staff and students, the IRB will review protocols for projects involving interviews recorded for research purposes.

Engaging in human subject research without IRB approval has serious ethical implications and violates university and federal policies. When there is a chance of public dissemination (i.e. presentation/publication outside of the university) the supervising faculty member should apply for IRB approval of the student's specific project. Data collected during classroom assignments without IRB approval may not be used for publication or presentation to professional audiences. This data may not be used for thesis or dissertation work.

Faculty supervising student research for IRB approval will follow the formal initial and continuing review processes and procedures. The student's research submission must be accompanied by the signature of the supervising faculty member. Students must first make submissions to the supervising faculty member. The supervising faculty member should review the application materials, apply an electronic signature, and then the supervising faculty member should make the submission to the IRB.

Students conducting research that involve human subjects are also required to complete Human Subjects training. Faculty who teach Research Methodology courses may also use Human Subjects training for students in their classes.

## I. Considerations for Special Populations

### *Research involving pregnant women, human fetuses, or neonates*

The IRB will document and maintain records in meeting minutes regarding research involving pregnant women, human fetuses, or neonates.

#### **Pregnant Women or Fetuses**

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- c) Any risk is the least possible for achieving the objectives of the research;
- d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions **of subpart A of this part**;
- e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions **of subpart A of this part**, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;
- f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the **provisions of subpart D of this part**;
- h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- j) Individuals engaged in the research will have no part in determining the viability of a neonate.

### Neonates

1. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
  - a. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

- b. Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
    - c. Individuals engaged in the research will have no part in determining the viability of a neonate.
    - d. The requirements of paragraph (b) or (c) of this section have been met as applicable.
  2. Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:
    - a. The IRB determines that:
    - b. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
    - c. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
    - d. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
  3. Nonviable neonates. After delivery, nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:
    - a. Vital functions of the neonate will not be artificially maintained;
    - b. The research will not terminate the heartbeat or respiration of the neonate;
    - c. There will be no added risk to the neonate resulting from the research;
    - d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
    - e. The legally effective informed consent of both parents of the neonate is obtained **in accord with subpart A of this part**, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the **requirements of this paragraph (c)(5)**, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized

representative of either or both of the parents of a nonviable neonate will not suffice to meet the **requirements of this paragraph (c)(5)**.

- f. (d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of **subparts A and D of this part**.

## **J. Research involving prisoners**

The IRB will document and maintain records in meeting minutes regarding research involving prisoners. The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners.

Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB policies and procedures apply and the additional ones outlined in this policy. The IRB may approve research involving prisoners only if these special provisions are met.

1. A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
2. A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
3. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research; or
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research.

For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk in the Common Rule (45 CFR 46). The definition for prisoners requires reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons.

Consent forms for studies involving prisoners as subjects must state that participation will not affect the prisoner's probation, parole, or treatment at the facility. The contact information in consent forms must be appropriate for that population and must include mailing addresses.

### ***Measures to be Taken When a Current Research Participant Becomes a Prisoner***

If a participant becomes incarcerated after enrolling in a research study, the Investigator must report this event immediately to the IRB in writing. This is not required if the study was previously approved by the IRB for prisoner participation.

The full, convened IRB will review the current research protocol in which the participant is enrolled, taking into special consideration the additional ethical and regulatory concerns for a prisoner involved in research.

## **K. Research involving children**

The IRB will document and maintain records in meeting minutes regarding research involving children. The consent document (or parental permission document) should be fully informative, reflect information conveyed verbally about the study, and be written in a language and at readability level appropriate for the participant or parent. An 8th grade reading level is recommended for the general population. Most word processing packages can assess the readability of a document.

Unless the IRB has waived any or all of the elements of consent required by Federal regulations, the following elements must be explained verbally and must be included in the consent form.

These elements are:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the individual's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation will be provided for participation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and

8. A statement that participation is voluntary, refusal to participate will involve no loss of rights, benefits, or services to which the participant is otherwise entitled, and the participant may discontinue participation at any time without loss of rights, benefits, or services to which he/she is otherwise entitled.

Use of the Parental Permission and Child Assent Forms ensures that all of the required elements of consent are addressed. To aid in efficient protocol review, the paragraph titles in the model consent documents should be retained. If the consent or permission form is more than one page, an area in the lower right hand corner of every page should be included for the participant's or parent's initials.

A copy of the consent document should be provided to the participant or parent; he/she does not need to sign the copy. The original consent/permission form should be stored in a secure location separate from data collected about participants and retained for at least three years (or longer if required by an external funding agency).

### *Child Assent*

When the participants in non-exempt research are between the ages of 5-18, the IRB requires a participant assent process after parental permission has been granted.

**Ages 5-12.** This assent script should be modified as necessary so that it can be easily understood by the particular participant population. Children in the 5-13 age range must give affirmative assent to participate. The lack of a negative reply is not sufficient to assume assent. Unless otherwise specified by the IRB, the child's signature indicating assent is optional.

**Ages 13-18:** The Informed Consent normally used for adults may be modified and used as an assent form for children ages 13-18. A signature should be obtained from those minor participants who are 13 and older.

**Under 5 Years of Age:** Unless specifically required by the IRB during its protocol review and approval process, no formal assent process is required for children under 5 years of age. As appropriate, the researcher may ask the child if he/she wishes to play a game or complete some other activity, but these young children exhibit their assent or refusal to participate through their behavior.

Children who do not assent should never be forced or coerced by their parents or the researcher to participate unless the study is providing some direct benefit to the child that cannot be attained through any other means. This type of situation rarely occurs in social/behavioral research.

When a consent form requires the signatures of research subjects and/or their parents or legal guardians, a copy of the signed form must be given to the subject/parent/guardian and a copy must be retained by the researcher for a minimum of three years after completion of the project. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects as described in 45 CFR Part 46.117.

For exempt research, the researcher is expected to provide information to prospective subjects about the research. This information should include:

1. A statement of the purpose of the research
2. An explanation of the procedures of the study
3. Details of any foreseeable risks, benefits and compensation

4. A clear explanation that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject either refuse to participate or decide to discontinue participation (at any time).
5. Contact information for the investigator and faculty advisor if the investigator is a student.

In some cases, it may not be practical to provide this information to prospective subjects. In these cases of exempt research, investigators should provide an explanation of why it is impractical to provide this information to potential subjects to the IRB Chairs.

## **IV. Informed Consent and Broad Consent Guidelines**

Informed consent constitutes the very essence of protecting the rights of subjects. Obtaining the informed consent of a potential human subject (or the subject's legally authorized representative) for participation in non-exempt research is a federally mandated safeguard to ensure the protection of the rights and welfare of all individual subjects. Consent forms should contain information that a "Reasonable Person" would want in order to make an informed decision. The IRB will carefully review the proposed method for obtaining informed consent and the content of the document prepared for participants' signatures.

### **A. Elements of Informed Consent**

For research that is not exempt from IRB review, the informed consent form must include the following information:

1. The title of the study, information on the purpose(s) of the research, a description of the method(s) and procedure(s) to be followed, including the intention to publish or disseminate the results of the study, and the amount of time the subject will spend in actual project participation.
2. A description of any reasonably foreseeable risks or discomforts to the subject, including expected total time of participation. If disguised or deceptive procedures are to be used, a plan to debrief participants must be explained to the IRB.
3. A description of any benefits to the subject or to others as a result of the information obtained from the research.
4. A disclosure of appropriate alternative procedures that may be advantageous to the subject when making an informed decision whether or not to participate in the research (this pertains primarily to medical research and drug trials).
5. A description of the measures to be taken to insure the confidentiality of data and the anonymity of individual subjects, if applicable, as well as any circumstances under which confidentiality CANNOT be guaranteed.
6. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility OR

7. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies
8. The name and phone number of a contact person(s) who will be available to answer any questions the subject or his/her legally authorized representative may have regarding the research (student investigators must include the name, address, and phone number of his/her faculty supervisor), and "Questions regarding the protection of human subjects may be addressed to the IRB Chair, CSU, Morrow, GA 30260, irb@clayton.edu."
9. A clear explanation that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject either refuse to participate or decide to discontinue participation (at any time).
10. Disclosure of costs to the subject, if any, because of his/her participation in the research; disclosure of compensation/reward to the subject, if any, for his/her participation in the research.
11. For projects of more than minimal risk to subjects, a statement must be included that describes how the costs of medical care or other therapies required as a result of injury or mishap incurred while participating in the research will be handled. The Consent Form should also include information about the availability and extent of on-site medical treatment should an injury occur.
12. The approval and expiration date for the consent form once approval of the project has been granted.
13. The consent form must not include a statement releasing the investigator, sponsor, institution or its agents from liability or negligence.

Additional Elements included if appropriate:

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what condition.
3. For research involving biospecimens, a statement whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

These requirements are not intended to preempt applicable federal, state, or local laws which require additional information to be disclosed in order to be legally effective. The consent form shall document that the subject understands the information contained therein, and has had an opportunity to have any of his/her questions answered.

## B. Procedure to waive signed consent

The IRB meeting minutes will document any approval to the consent procedure which does not include or alters the required elements of informed consent based on the following conditions being satisfied:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may waive some or all of the elements of informed consent provided the IRB finds:

1. The research is conducted by, or subject to the approval of state or local government officials and is designed to study or examine: a) public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes or alternatives to those programs; or, d) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.
3. The research could not practicably be carried out without accessing or using information or biospecimens in an identifiable format.

## C. Broad Consent Guidelines

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in the following cases for certain types of exempt research:

1. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an institutional review board (IRB) conducts a limited IRB review and makes certain determinations.
2. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
  - a. Documentation of informed consent or waiver of documentation of consent was obtained;
  - b. An IRB conducts a limited IRB review and makes certain determinations; and
  - c. The investigator does not include returning individual research results to subjects as part of the study plan (although the investigator is not prevented from abiding by any legal requirements to return individual research results).

A research is also allowed to use broad consent to be obtained as an alternative to traditional informed consent for the non-exempt storage, maintenance, and secondary research use of identifiable private information or

identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes). To obtain broad consent, the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative to obtain broad consent

1. A description of any reasonably foreseeable risks or discomforts to the subject
2. A description of any benefits to the subject or to others that may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
5. When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
6. When appropriate, for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen);
7. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the Broad Consent would permit the types of research conducted;
8. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
9. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
10. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
11. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
12. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

### *Waiver of Parental Permission:*

Federal regulations provide the four basic criteria for waivers of any of all of the elements of informed consent. The same criteria apply to waivers of parental permission (and also to child assent). To waive or alter any or all elements of informed consent, **the IRB must find and document that all** of the following criteria have been met:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practically be carried out without the waiver or alteration (inconvenience and expense are not acceptable factors - scientific validity would be acceptable);
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

## V. External Researcher Guidelines

If you are not affiliated with CSU), and you would like to conduct research with CSU faculty, staff, or students, or include CSU participants in your data collection plan, you will need to follow the External Researcher Guidelines. Minimally, you will need to do the following:

1. Submit all IRB materials, including your letter of approval from your home institution.
2. Complete and sign the Clayton State University Unaffiliated Investigator Agreement (available in the forms section of the CSU IRB website, <http://www.clayton.edu/provost/irb/forms>)
3. Complete the required Human Subjects training. Training must be current at the time of the application date.
4. Secure a full-time CSU employee to serve as your "local contact" for the purposes of your research.
5. Obtain approval from the correct CSU department, college, or administrator for permission to recruit their faculty, staff, or students.

### A. Procedure

Researchers who are unaffiliated with CSU but wish to recruit participants on the CSU campus, must request permission from the IRB before recruiting alumni, students, or employees at CSU (via poster, flyer, email announcement, newspaper ad, or any other method of recruitment). Unaffiliated researchers must submit one copy of the full packet of materials submitted to the IRB at their own institution, including the letter of IRB approval for the project, to the CSU IRB Office. Researchers who do not have an IRB at their home institution should submit all required documents, using CSU application materials found at <http://www.clayton.edu/provost/irb/forms>, to the CSU IRB. The packet should include, but may not be limited to, the IRB protocol application, consent form or information sheet, recruitment flyer or ad, instruments or measures to be used, and any supporting documentation.

For research activities that qualify as exempt from IRB review, evidence must be provided from the home institution that exempt status has been granted. The IRB Chair or their designee will review the request and issue a letter of permission to recruit on campus. The IRB reserves the

right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair decide that the nature of the study requires the independent scrutiny of the IRB to protect its students and employees. Further, the IRB may require that the investigator receive written permission from the CSU Provost or other CSU officer to conduct a study on campus.

The CSU IRB only considers the protection of human subjects; it does not grant authority for the investigator to conduct the research at CSU. Therefore, the authority to conduct research on the CSU campus must also be obtained from the appropriate university official relative to the research to be conducted. For assistance in obtaining this approval, contact the CSU Provost Office.

## VI. Glossary of Terms

**Anonymity-** means that the identity of a subject cannot be matched to his/her response.

**Confidentiality-** refers to the treatment of individual information gathered during the conduct of the research. An individual discloses information to the investigator with the expectation that the information will not be divulged to others in a manner inconsistent with the understanding of the original agreement.

**Data Collection-** refers to any research procedure that is intended to elicit from or record the actions, reactions, attitudes, and/or behavioral manifestations of subjects participating in a research project.

**Exempt Research-** refers to human subject research activities that fall into one or more of the federally defined exempt research categories. Exempt research does not mean the research protocols are exempt from IRB review, only that the research may not require a full IRB review, and may not be subject to other IRB requirements, such as annual reviews or informed consent. It is strongly suggested that informed consent be used whether required or not.

**Expedited Review-** refers to the review by the IRB Chair or designate of research proposals which involve minimal risk or no-risk.

**Full IRB Review-** refers to the review of proposals conducted during an IRB meeting at which a quorum has been established.

**Human Subject-** refers to a living individual about whom a researcher obtains either identifiable private information, or data through intervention and/or interaction with the individual.

**Informed Consent-** refers to the voluntary agreement by an individual or an individual's legally authorized representative to participate in a particular study without any element of force, fraud, deceit, duress, or any other form of constraint or coercion. Valid consent requires voluntary action, competence, informed decision, and comprehension of terminology.

**Intervention-** includes both physical procedures by which data are gathered (for example, venipuncture) 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 (for example, a medical record). 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.

**Institution-** is defined in 45 CFR 46.102(b) as any public or private entity or agency (including federal, state, and other agencies).

For purposes of this document, an institution's *employees or agents* refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

**Minimal Risk-** means that the probability and magnitude of harm(s) or discomfort(s) anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

**Research-** refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In other words, the IRB defines research as a systematic investigation (i.e. having or involving a system, method or plan) conducted to develop or contribute to knowledge about the human experience. It is understood that such research may be disseminated by publication or in a public or professional forum. In addition, based on the principle that CSU IRB exists to protect the rights and safety of individuals who participate as research subjects in projects administered by university faculty, staff and students, the IRB will review protocols for projects involving interviews recorded for research purposes.

**Vulnerable Populations-** refers to subjects such as children, prisoners, pregnant persons, or any population that may be relatively or absolutely incapable of protecting their interests through the informed consent process.

Clayton State University would like to acknowledge the outstanding work of the IRB of the University of West Georgia (UWG). UWG's IRB manuscript "Guidelines for the Review of Research Involving Human Subjects", and the guidelines and procedures therein, formed the basis for this guideline manual. UWG's document was last retrieved on March 31, 2017, from:

[https://www.westga.edu/academics/research/orsp/assets/docs/UWG\\_IRB-Guidelines.pdf](https://www.westga.edu/academics/research/orsp/assets/docs/UWG_IRB-Guidelines.pdf)

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