

IRB SUBMISSION WORKSHEET

INSTRUCTIONS: Not all research involving humans will require IRB submission or approval. Only activities meeting the regulatory definitions of (a) “research” and (b) “human subjects” and where (c) Claflin University (CU) is “engaged” in the conduct of human subjects research require CU IRB review and approval.

This form may be used as (1) a tool to help you determine whether you may need to file a New Study Submission to the CU IRB, and/or (2) documentation of formal notice that the CU IRB is not “engaged” in “human subjects research” requiring CU IRB review/approval.

SECTION 1: DETERMINATION OF “RESEARCH”	
Research – “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”	
<p style="text-align: center; color: blue;">RESEARCH</p> <p>Activities ‘designed to develop or contribute to generalizable knowledge’ are those activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.</p> <p>The project may be “research” If it:</p> <ul style="list-style-type: none"> intends to advance general knowledge in the academic, scientific, or professional community; is conducted using a research design that will lead to scientifically valid findings; and the subjects are not expected to benefit personally from the knowledge gained. is completed to obtain a Baccalaureate, Master, or PhD degree. 	<p style="text-align: center; color: blue;">NOT RESEARCH</p> <p>Projects may be systematic but not “research.” Some examples of not “research” include:</p> <ul style="list-style-type: none"> classroom projects solely to fulfill course requirements and the intention is to not share the results beyond the University community; QI/QA or program evaluation activities designed to improve the quality or performance of a department or program where it is not the intention to share the results beyond the local community. ***See QI/Eval questions below; Most of the subjects who participate in the project are expected to benefit from the knowledge gained and the main goal of the project is to improve services; Oral history activities, in general, are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge. Only those oral history projects that conform to that regulatory definition of research need to submit their research protocols for IRB review.
Use the information above to answer the following questions.	
<p>1. Do the proposed activities involve a systematic approach? A “systematic” approach involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens; and analysis.</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If NO, please explain why the proposed activities do not involve a systematic approach: <Type Here></p>	

2. Is the intent of the proposed activities to *develop or contribute to generalizable (scholarly) knowledge****?

YES

NO

If **NO**, please explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge:

<Type Here>

***If you think your project may be considered *a Quality Improvement project or Program Evaluation ONLY and WILL NOT contribute to generalizable knowledge* please confirm by answering either the QI/QA or Evaluation questions below. Either ALL QI or ALL Evaluation questions must be YES to be considered a Quality Improvement Project or a Program Evaluation.

Quality Improvement/ Quality Assurance	Program Evaluation
<p>QI 1. The project is being initiated/conducted based on the request and needs of a department, institution, or organization for internal purposes only. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>E 1. The evaluation is being initiated based on the request and needs of a partner organization or department for internal purposes only. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>QI 2. The study is NOT designed to expand knowledge of a scientific discipline or scholarly field of study. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>E 2. The intent of the evaluation is to improve a specific program and/or to meet funder requirements. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>QI 3. All activities are “routine care” or “standard practice” and conducted by staff where the project will take place. Untested methods and/or interventions are NOT being evaluated. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>E 3. The program being evaluated is evidence based (already shown to be effective). Untested services, programs and/or interventions are NOT being evaluated. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>QI 4. The project does NOT involve a control group or randomization or blinded interventions. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>E 4. The evaluation does NOT involve randomization of participants, but may involve comparison of variations in programs. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>QI 5. The project is NOT externally funded. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	
<p>QI 6. NO drugs, biologics and/or devices without FDA approval are being used in the project or being used for a non-FDA approved purpose. <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	



If **YES** to **1 & 2** these activities constitute research. **Go to Section 2.**



If **NO** to **any of the QI/QA or Program Evaluation Questions**, these activities constitute research. **Go to Section 2.**



Otherwise, the criteria for research are not met. **Go to Section 4.**

SECTION 2: DETERMINATION OF "HUMAN SUBJECT"

Human subject - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through *intervention or interaction* with the individual or (2) *identifiable private information*.

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 researcher and subject.

Identifiable includes when it is possible that the identity of the subject is or may be ascertained by the researcher or associated with the information

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 or educational record information). Private information must be *individually identifiable* through use of identifiers (name, dob, SSN) or through use of a code.

Use the definitions above to answer the following questions.

1. Are the human subjects *living individuals*? This also applies to charts reviews and datasets.

YES NO



If **NO** to 1, the criteria for **human subjects** are **not met**. Go to **Section 4**.

2. Do the activities involve CU personnel obtaining information through *intervention* or *interaction* about the individuals (i.e., prospective collection of data/specimens; online interactions or surveys; etc.)?

YES NO



If **YES** to 1 & 2, the activities involve human subjects. Go to **Section 3**.

3. Do the activities involve CU personnel accessing *individually identifiable* (e.g., names, medical record numbers, social security numbers, study ID codes, etc.) **and** *private* information about living individuals? This applies to charts, records, datasets, and specimens. ****Even if you are not recording identifiers, if the source of the data contains identifiers, then mark this question as a "yes."**

YES NO



If **YES** to 1 & 3, the activities involve human subjects. Go to **Section 3**.

4. Do the activities involve CU personnel obtaining or receiving *individually identifiable* (e.g., names, medical record numbers, social security numbers, study ID codes, etc.) and *private* information about living individuals? This applies to charts, records, datasets, and specimens.
 ***If you are receiving a coded dataset, and a key exists somewhere to link the data to the original participant, even if you do not have access to the key, mark this question "Yes".

YES NO



If **Yes to 1 & NO to 4** the criteria for **human subject** are **not met**. **Go to Section 4.**

4a. If **yes to #4**, will your dataset contain direct identifiers such as name, date of birth, social security number or medical record number?

YES NO



If **YES to 1 & 4 & YES to 4a**, the activities involve human subjects. **Go to Section 3.**

4b. If **yes to #4 and No to #4a**, you appear to be using coded data. Is there:

- a written agreement that prohibits the CU researcher and his/her research team from having access to the key linking the study ID number to personal identifiers, OR
- are there legal requirements or written policies in place restricting release of the key until the participant is deceased, OR
- is it extremely unlikely that the CU researcher will ever be able to access the key?

YES NO



If **YES to 1 & 4, NO to 4a and NO to 4b**, the activities involve human subjects. **Go to Section 3.**



If **YES to 1 & 4, NO to 4a and YES to 4b**, the activities **DO NOT** involve human subjects. **Please explain your response to 4b below and then go to Section 4.**

SECTION 3: DETERMINATION OF “ENGAGED”

Engaged: An institution is considered to be engaged in research if certain federal criteria are met and may be subject to IRB review/approval.

CU Auspices: CU personnel (student, faculty, or staff) who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities.

Non-CU researchers wishing to conduct human subjects research using CU personnel as subjects or its facilities are not considered to be engaged. This document is for the determination of CU IRB review only and you are expected to obtain other permission as necessary. For example, the CU IRB does not have authority to grant the release or use of CU listservs, equipment, or facilities.

ENGAGED	NOT ENGAGED
<p>CU is considered to be engaged in human subjects research if CU or CU personnel are involved in any the following activities under CU auspices:</p> <ul style="list-style-type: none"> • direct awardee of a federal grant, award, or contract; • obtaining informed consent; • performing invasive or noninvasive procedures with subjects; • intervening for research purposes with any subjects by manipulating the environment; • interacting for research purposes with any subject; (e.g., conducting research interviews or administering questionnaires); or • obtaining private identifiable information. 	<p>CU is considered to not be engaged in human subjects research if CU or CU personnel are solely involved in the following activities:</p> <ul style="list-style-type: none"> • performing commercial/service where: (a) the services performed do not merit professional recognition or publication privileges; (b) the services performed are typically performed by those institutions for non-research purposes; and (c) the institution’s employees or agents do not administer any study intervention being tested or evaluated under the protocol; • inform (e.g., provide a copy of informed consent document, information about contacting the investigator, seek or obtain the prospective subjects’ permission for investigators to contact them) prospective subjects about the availability of the research but do not obtain subjects’ consent for the research or act as representatives of the investigators; or • releasing identifiable private information/specimens pertaining to the subjects of the research.

Use the information above to answer the following question.

1. Is CU engaged in human subjects research?

YES NO*

*If **YES** or **NO**, please explain why CU **IS** or is **NOT** engaged in human subjects research:
<Type Here>

2. Is any non-CU IRB involved in reviewing this project?

YES* NO

*If **YES**, please explain which IRB(s) and the status of IRB approval(s):
<Type Here>

 If **YES** to **1**, CU is engaged. **Go to Section 4**  Otherwise, CU is not engaged **Go to Sec.4.**

SECTION 4: IS YOUR PROTOCOL HUMAN SUBJECTS RESEARCH, AND CU IS ENGAGED?

If based on your responses in [Section 1](#) the activities constitute research; **and** per your responses in [Section 2](#) the activities involves human subjects; **and** per your responses in [Section 3](#) CU is engaged then IRB review and approval of your study is required before study activities can begin. Please complete and submit the appropriate documents for a New Study Submission and submit them through IRB Chair. All forms will be available on the [IRB website](#) under the [Forms and Templates](#) section. If you have questions, contact the IRB office at irb@clafin.edu. If your responses indicate that CU is **not engaged in human subjects research**, you are **not required** to submit an IRB application. If you would like confirmation and documentation from the IRB staff that your proposed activities do not constitute CU being engaged in human subjects research, or if you are uncertain if your study meets the definition of human subjects research, please complete this form including Sections 5 - 6 below and submit the MS Word document to irb@clafin.edu.

SECTION 5: STUDY INFORMATION

1. Describe the purpose of the proposed activities. State the overall objectives and specific aims. Provide a brief description of the procedures.
<Type Here>
2. Describe the subject population, or the type of data and/or specimens to be studied.
<Type Here>
3. Describe how the data and/or specimens will be obtained.
<Type Here>

SECTION 6: PROJECT TITLE AND RESEARCHER

Project Title:			
Name:		Department/Institution:	
Telephone:		Email:	

IRB DETERMINATION OF CU ENGAGEMENT IN HUMAN SUBJECTS RESEARCH

Researchers do not complete this section. **For IRB staff only**

The activities as described **DO NOT** constitute CU being engaged in Human Subjects Research. Submission of an IRB Application to CU is not required.

The activities as described **DO** constitute CU being engaged in Human Subjects Research. Submission of a CU IRB Application **IS REQUIRED**. IRB Approval must be obtained before the research can begin.

IRB Chair	Date
-----------	------