

IRB APPLICATION FOR CONTINUATION

When conducting continuing review, the IRB starts with the working presumption that the research, as previously approved, does satisfy all of the Health and Human Services (HHS) regulations set forth for the approval of research (45 CFR 46.111, 46.204-207, 46.305, and 46.404-409) (45 CFR 46.109(a)).

The Baldwin Wallace University IRB will focus on whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects. In addition, the IRB will also assess whether there is any new information that would necessitate revision of the protocol and/or the informed consent document.

PLEASE NOTE: The IRB has the authority to disapprove or require modifications in (to secure re-approval of) a research activity that does not meet the above criteria (45 CFR 46.109(a)). If the research does not satisfy all of the above criteria, the IRB **must** require changes that would result in the research satisfying these criteria, defer taking action, or disapprove the research.

1. PROJECT TITLE

Title of
Project:

2. ORIGINAL IRB ARCHIVAL CODE (E.G. FA12-9999)

Project Code:

3. PRIMARY AND/OR CO- INVESTIGATOR AMENDMENTS:

Indicate whether there are any amendments to the original list of primary or co-investigators. If none, enter NA.

a. All primary investigators must complete CITI Training.

I certify that all investigators have completed the necessary CITI Training Modules.

Yes

No

4. AMENDED PROTOCOL:

Indicate whether there are/were any necessary or proposed amendments to the methodological protocol originally or subsequently approved (including the mitigation of any unanticipated problems). Provide justification for these amendments. If none, enter NA.

5. RESEARCH PROGRESS: Describe the progress made on your previously approved project. Provide justification for the continuation/renewal of the project approval.

6. PROJECT DATES

a. Anticipated starting and completion dates for continuation: _____ to _____

NOTE: Project may not continue beyond original completion date without approval from the IRB.

b. This project may be conducted on an annual basis: Yes

7. CERTIFICATION STATEMENT

In making this application, I certify that I have read and understood Baldwin Wallace University's policies and procedures governing research with human participants (specifically, those as described in Baldwin Wallace University's Institutional Review Board Policy). I shall comply with the letter and spirit of those policies and will not undertake the research without IRB approval. Furthermore, I am aware that certain departments may have their own standards for conducting research, and it is up to me to familiarize myself with them. I further acknowledge my obligation to: (1) obtain written approval of significant deviations from the originally approved protocol BEFORE making those deviations; (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and the Chairperson or Supervisor of my Department; (3) to retain the original signed consent forms for 3 years after completion of the study; and (4) ensure that all approved informed consent forms given to subjects have the IRB archival code (see below) and expiration date on the first page of the form.

(an electronic signature is acceptable here)

Principal Investigator signature

Date

CO-INVESTIGATORS:

a. Name: _____

Title: _____

Affiliation: _____

b. Name: _____

Title: _____

Affiliation: _____

APPROVAL: (TO BE COMPLETED BY IRB CHAIRPERSON)

The Institutional Review Board has reviewed the proposed use of human subjects in the project identified above and has determined that:

The rights and welfare of the subjects are adequately protected;

Yes No

The risks to human subjects are outweighed by potential benefits;

Yes No

The informed consent of human subjects will be obtained by methods that are adequate and appropriate.

Yes No

(an electronic signature is acceptable here)

IRB Chairperson Signature

Date

IRB CONTINUATION ARCHIVAL CODE:

Archival Code: _____