



Expedited Approval Notification

To:
From: Andrea Lambert South, Ph.D, IRB Chair
IRB #:
Title
Date:

The protocol [], has been approved by the NKU IRB as Expedited according to 45 CFR 46.110: (7) Research on individual or group characteristics or behavior, on **08/28/2017**.

The approval of your study is valid through **08/13/2018**, by which time you must submit either a termination of the protocol or a continuing review to continue the study for an additional year.

Your termination/continuing review must be submitted by **07/16/2018** to allow time for IRB processing and review.

The following documents have been reviewed and approved:

Consent Form
Recruitment Materials
Data Collection Tools
Letter of Support
CITI training documentation
Approved Consent Form

Continuing Review: Pls must reapply for IRB approval each year through the process of a continuing review until the study is terminated. Continuing reviews must be submitted in Mentor IRB.

Amendments: Amendments are required for any proposed changes to studies approved as Expedited. Examples of changes include:

- Changes in study design

- Alteration of study procedures
- Changes in recruiting announcements or strategies

Proposed changes cannot begin until the IRB has reviewed and approved the amendment.

Document and Data Retention: Investigators are required to retain all study related documents (signed informed consents, data collection sheets, etc.) for six years after the end of the study per State of Kentucky record retention policy (U1802). Per State of Kentucky record retention policy (U0120), data from all research studies must be retained for five years after the submission or publication of the final project report for which the data were collected.

Audit or Inspection Reports: Investigators are required to provide to the IRB a copy of any audit or inspection reports or findings issued to them by regulatory agencies, cooperative research groups, contract research organizations, the sponsor, or the funding agency.

Study Termination: The Principal Investigator must terminate the study in the Mentor IRB system upon study completion. The study may be closed out if all data collection is complete AND the data has been deidentified (i.e. contains no identifiable information).

Thank You,

Andrea Lambert South, Ph.D.

IRB Chair

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Federal Wide Assurance #FWA00009011