

Notification of Approval

Date: July 19, 2018

Principal Investigator: David Lounsbury, PhD

Study Title: Survey on Current Policies and Practices around Communicating Bad News to Patients and Families in African Oncology Settings

IRB #: 2018-9222

Reference #: 042041

Type of Submission: Submission Response for Initial Review Submission form

Approval Date: 07/18/2018

Expiration Date: 07/17/2019

The above titled submission was reviewed and approved by expedited review under 45 CFR 46.110 and 21 CFR 56.110 as the research fits into the following category OR categories:

- Category 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.

This submission was approved with the following stipulations:

- Written approval from collaborating research site(s) must be obtained and forwarded to the Einstein IRB prior to beginning the research at those sites.
- Use only IRB stamped copies of the consent form(s) in your research. Do not use expired consent forms.
- The waiver of signed documentation of informed consent was approved.

All changes to a study must receive IRB approval before they are implemented. The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(b)(4), 21 CFR 56.108(a)). In such cases, report the actions taken as a reportable event.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Expiration Notice: IRB approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report by 06/17/2019. To facilitate this, iRIS will send an email reminder 60 days prior to the due date. When this project is completed, submit a final Progress Report to close the file.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.