University of Kentucky
Limited Review Form

The revised federal regulations regarding human subjects research (45 CFR 46) require Limited IRB Review for protocols which meet exempt categories 2iii & 3c. Limited Review is intended to protect the privacy[1] of subjects and maintain the confidentiality[2] of information. “Identifiable information”[3] includes both privacy and confidentiality concerns.

1. Include a detailed list of the identifiable information to be collected and a list of the source(s) of the information.

2. If the use or disclosure of the identifiable information involves no more than a minimal risk to the privacy of individuals and/or the confidentiality of the data. Explain why.

3. Describe the plan to protect the identifiable information.

4. Indicate where the identifiable information will be stored.

5. Who will have access to the identifiable information? (Note: researchers must list all of the entities that have access (Office of Research Integrity/Institutional Review Board, UK/Hospital representatives, sponsors, FDA, data safety monitoring boards and any others given authority by law).

6. All identifiable information collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (explain below). Alternatively, identifiable information collected during the study will not be destroyed because: (explain below).

7. Please describe the procedure used to destroy the identifiable information collected during the study (electronically, paper, audio/video, photography, other).

8. The research could not practicably be conducted without access to and/or use of the identifiable information (explain below).

9. The HHS Revised Common Rule Limited Review provision requires reasonable efforts to limit identifiable information to the minimum necessary to accomplish the intended purpose of the use,
disclosure or request. Explain why the identifiable information obtained for this study is/are the minimum information needed to meet the research objectives.

10. What is the potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

11. If there are privacy guidelines developed by relevant professional associations and scholarly disciplines (e.g., anthropology, psychology, oral history) please explain below.

[1]Privacy

Privacy refers to a person's desire to control the access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. The research proposal should outline strategies to protect privacy including how the investigator will access information from or about participants.

[2]Confidentiality

Confidentiality refers to the researcher's agreement with the participant about how the participant's identifiable private information will be handled, managed, and disseminated. The research proposal should outline strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing of data.

[3]Identifiable Information

Identifiers include but are not limited to: Names (individual, relatives, etc.); Address (street, city, county, zip code); Telephone/Fax Numbers; Social Security Numbers; Dates (except for year) - Birth Date; E-mail addresses/URLs (Web Universal Resource Locators)/IP (Internet Protocol) addresses; Medical Record Number; Account Numbers; Certificate/License Numbers; Biometric Identifiers (e.g. finger or voice prints or full face photographic images).