IRB Requirements for Continuing Review
After Enrollment and Data Collection are Completed

Study Status	**Identifiable Private Information**	**Level/Category of Review or other**	**Submission Requirements**
Continuing data analysis under the **original research intent** of the IRB approved protocol.	YES	Expedited under category 8, if no additional risks identified.	Continuing Review Application via iStar
Continuing data analysis under the **original research intent** of the IRB approved protocol.	NO	Expedited under category 8, if no additional risks identified.	Continuing Review Application via iStar
Data analysis (secondary) under **new research intent.**	YES	Expedited Review/Full board depending on type of data being analyzed.	New Protocol Application submitted via iStar
Data analysis (secondary) under **new research intent**.	NO	Exemption under category 4.	New Protocol (Exemption) Application submitted via iStar
Data analysis of "coded data/specimens" **under new research intent**	NO	Determination of Coded Private Information or Biological Specimens	Not Human Subject Research (NHSR) Application via iStar

- **Studies which qualify for expedited review (even if originally submitted for full board review) must be submitted for continuing review annually as long as no additional risks have been identified.**

- **Studies that are determined to be exempt are not subject to 45 CFR 46 and/or IRB continuing review. Exempt research activities are subject to the same subject protections and ethical standards as outlined in The Belmont Report. All research conducted under exempt review is subject to all of the applicable USC Institutional, IRB policies and procedures, appropriate State Laws and possibly HIPAA regulations. The Investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate subject protections (i.e., confidentiality).**

- **In order for research to fall under the Coded Private Information or Biological Specimens guidance the following is required: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf**

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1) **The data is "coded"**
2) **The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals and**
3) **The Investigator cannot readily ascertain the identity of the individual(s) to who the coded private information or specimens pertain because:**
    a. **the key to decipher the code is destroyed before the research beings**
    b. **the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased**
    c. **there are IRB -approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances until the individuals are deceased**
    d. **there are legal requirements prohibiting the release of the key to investigators until the individuals are deceased**

DEFINITIONS

Identifiable Private Information: Information contains one or more data elements that can be combined with other reasonable available information to identify the individual. (e.g. social security #)

Coded: (1)Identifiable information (such as name and/or address) that is replaced with a number, letter, symbol, or combination thereof, that would enable the investigator to readily ascertain the identify of the individual and (2) Key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Secondary Data Analysis: The analysis of data collected by someone else, perhaps for some purpose other than that of subsequent analyses

Exemption: Research with human subjects that is "exempt" from the provisions stated in the Code of Federal Regulations (45 CFR 46).

Exemption Category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Expedited Review Category 8: Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.