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Last review date: 08/15/2011

Purpose

To obtain LCBRN subjects’ informed consent while following appropriate regulations and ethical requirements.

Responsibility

Personnel associated with the LCBRN Biospecimen Resource Sites who are responsible for obtaining informed consent under the direction of the Site Principal Investigator.

Applicable Regulations and Guidelines

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| 21 CFR 50.25 | Elements of informed consent |
| 21 CFR 50.27 | Documentation of Informed Consent |
| 21 CFR 56.109 | IRB review of research |
| 21 CFR 56.111 | Criteria for IRB approval of research |
| 21 CFR 312.54 | Emergency research under 50.24 of this chapter |
| 21 CFR 312.60 | General responsibilities of investigators |
| 21 CFR 312.62 | Investigator recordkeeping and record retention |
| 45 CFR 46.116 | General Requirements for Informed Consent |
| 45 CFR 46.117 | Documentation of Informed Consent  FDA Internal Compliance Program Guidance Manual, 1994; 7348.811: Clinical Investigators |
| FDA Information Sheets,  October, 1995  May 9, 1997 | Frequently Asked Questions, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator, The Belmont Report and Declaration of Helsinki  International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline |

Procedure

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1. Ensure that informed consent is obtained from each subject before any research activities begin.
2. Ensure that the written informed consent form, and any other written information provided to a subject (if approved by the IRB) has the written approval of the IRB.
3. Ensure that the most recent version of the IRB approved consent form is used.
4. Ensure that the approved consent contains required HIPAA language or provide a stand-alone HIPAA authorization with the appropriate protocol title and IRB number.
5. Ensure that any information given to the subject is expressed in a language that the subject can comprehend and understand.
6. Allow the subject sufficient time to read the document(s) and ask questions. Encourage input from family members and other care providers as appropriate.
7. Review the informed consent form(s) (including the HIPAA stand-alone authorization if applicable) with the subject by thoroughly discussing all of the elements. Provide a complete description of the research using non-technical language. If possible, conduct this discussion in a location that provides privacy.
8. Ensure that informed consent is obtained from each subject prior to initiating any study required procedures, including any specimen collections.
9. Never influence a subject to participate or to continue to participate in a trial.
10. Ensure that the subject provides written informed consent in manner which complies with all institutional requirements for informed consent.
11. Ensure that the subject initials each page of the informed consent if required by institutional IRB.
12. Sign and date the informed consent form as the member of the research team who obtained informed consent from the subject as required by the institutional IRB.
13. Provide a copy of the fully signed, initialed, and dated informed consent form to the subject.
14. Retain and file the original signed informed consent form. (Note: The original should be in a file maintained by the investigator/coordinator and a copy should be in the subject’s medical record [if appropriate].)
15. The study team shall maintain source documentation regarding the informed consent process for each subject.
16. If there are substantive changes made to an informed consent during the course of the study, re-consent subjects for whom the changes may impact their willingness to continue in the study. Examples: if there is an increase in risk to the subject, if there are changes to the type or frequency of the procedures, or if new information has been obtained.

**Change History**

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| Version # | Significant change(s) | Author | Effective Date |
| 1 |  | Sandra Burks | 09/01/2011 |