21. REGULATORY PROCEDURES

21.1 Confidentiality and HIPAA Considerations

Confidentiality

All CALERIE participants must provide informed consent and signed HIPAA authorization prior to the performance of any screening or main study procedures. Participant confidentiality will be protected throughout the study and no subject-identifying information will be released to anyone outside the project. Confidentiality will be secured through several mechanisms. Each participant will be assigned an anonymous study ID, which will be used on all study forms. Any study forms and paper records that contain personal identifier information (e.g., address lists, phone lists) will be kept secured and locked at each of the clinical sites. No personal identifiers will be placed on biological samples and/or other personal identifying documents forwarded to central labs and reading centers. Only the CALERIE ID number, subject initials and the date of the evaluation will be provided. Access to all participant data and information at the sites, including biological samples, will be restricted to authorized personnel.

Only authorized personnel at the Coordinating Center will have access to study data files. Authorized personnel will be assigned user logon IDs, passwords and appropriate access privileges to CALERIE data. Authorization documentation will be kept per the Coordinating Center's data management's SOPs. Study participants will be identified only by their initials and a CALERIE ID number, and no personal identifiers, such as name, address, social security number, etc., will be entered into the Coordinating Center's database. Any participant-specific data reported to any CALERIE committees will only be identified by a CALERIE ID number.

Participants will not be identified by name in any reports or publications. Nor, will the data be presented in such a way that the identity of individual participants could be inferred. Analysis files created for further study by the scientific community will have no participant identifiers. These data files will be created in accordance with the CALERIE Ancillary Studies and Publication policy.

HIPAA Considerations

The main issues to keep in mind are that you must:

- Have permission to perform the initial screening and main study assessments
- Notify your IRB of your recruitment plans
- Receive acknowledgment from the IRB
- Obtain participant authorization

The elements of authorization include:

- Who may use or disclose the information
- Who may receive the information
- Purpose of the use or disclosure
- Expiration date or event
- Individual's signature and date
- Right to revoke authorization
- Right to refuse to sign authorization

- A statement about the potential for the personal health information (PHI) to be re-disclosed by the recipient

The authorization can be a separate document or can be combined with the informed consent form (ICF).

Authorization can be withdrawn. When a participant withdraws authorization, it must be in writing and, therefore, any information from the time of withdrawal going forward must stay at the site unless related to an adverse event or as otherwise required by law. Note that if a study subject subsequently dies after withdrawal, the site cannot give out information about the death to the sponsor as decedent information is now covered under HIPAA.

HIPAA compliance is the responsibility of the site and cannot be transferred to the sponsor. However, in order to ensure proper access to their participants' study data, sites will be required to provide HIPAA authorization to the Data Coordinating Center and the NIA for review and approval prior to study activation. This authorization may be incorporated into the informed consent form or as a stand-alone document. In addition, as part of the informed consent review performed during on-site monitoring visits, the monitor will ensure that authorization was obtained.

21.2 Approval by Institutional Review Boards

The informed consent and protocol must be approved by each participating site's Institutional Board (IRB) prior to activation. A photocopy of the letter from the IRB approving the protocol and ICF(s) should be submitted to the Data Coordinating Center and the **original** letter kept in the site's file. The IRB letter should:

- Be on IRB or hospital letterhead.
- Be addressed to the PI listed on the grant.
- Identify the protocol by project number and/or full title verbatim.
- Include the protocol date (month, day, and year).
- Include the protocol project number.
- Include the date of IRB approval.
- Include approval of all applicable ICFs, including their specific version dates.
- Be signed by the IRB chairman, co-chairman, or designee.

Any amendments to the protocol, other than simple administrative and typographical changes, will be approved by each IRB before they are implemented. Any ICF revisions, change in Principal Investigator or location, advertisements, recruitment tools, and Serious Adverse Events-external and internal should be reported to the IRB and a copy provided to the Data Coordinating Center. IRB correspondence is to be maintained at the site.

21.3 Annual Renewals

The sites will seek annual renewals of their IRB approvals in accordance with local procedures. The site is to provide a copy of their IRB renewals to the Data Coordinating Center. If it is the policy of the sites IRB to include an ICF with the renewal approval, the site will need to provide a copy of the ICF along with the approved renewal to the Data Coordinating Center.