Ballad Health Research Definition

Research at Ballad Health includes the following situations:

- The use of Ballad Health facilities (hospitals) while conducting research study*
- The research is conducted by, or under the direction of, any employee of Ballad Health in connection with her/his organizational responsibilities
- A request for access to Ballad Health medical records or other non-public information maintained by Ballad Health for the collection of data and/or identification of potential participants **


This guidance should only be applied to activities that have been determined to be research involving human subjects that are not exempt under HHS regulations at 45 CFR 46.101(b). Completion of the Form 129 via ETSU IRB may help to determine the nature of the study. (Version 3, 09242015)

Exception:
*If the Ballad Health facility provides a standard commercial service that typically is performed for non-research purposes and does not merit professional recognition or publication privileges (no investigational product or device used during procedure).

Note: For collection of additional research samples for studies conducted outside of Ballad Health in limited quantity (ex: extra blood tube/no other activities), a signed Informed consent form for IRB approved study must be present.

**To access medical records based on presence of signed Authorization for release of medical record form for study conducted outside of Ballad Health

IRB approval for any research is required. In addition, Ballad Health administrative approval (via the completion of the Ballad Health Research Proposal Request Form) for any research conducted at Ballad Health facilities or using Ballad Health patients, time or equipment is mandatory.

Based on the design of each study, appropriate legal documentation must be completed.

All East Tennessee State University (ETSU) and Ballad Health research studies require Ballad Health administrative and ETSU IRB approvals (or formal reliance).

Only non-Ballad Health /non-ETSU research studies require Ballad Health administrative approval and general IRB approval. ETSU/VA IRB approval is not required if the activity meets the exception.
Reminder: ETSU Research Criteria (as academic partner)

Any of the following criteria make a study subject to ETSU/VA IRB jurisdiction:

- The research is sponsored by ETSU.
- The research is conducted by, or under the direction of, any employee, faculty, staff, student or agent of ETSU in connection with his or her institutional responsibilities.
- The research is conducted by, or under the direction of, any employee or agent of ETSU using any of ETSU’s property or facilities.
- The research involves the use of non-public information maintained by ETSU to identify or contact prospective participants or participants.
- ETSU is the recipient of a direct federal award to conduct human subject research, even where all activities involving humans are carried out by a subcontractor or collaborator.
- ETSU or ETSU/VA IRB is the IRB of record by contract or MOU.