Mountain States Health Alliance, an affiliate of Ballad Health:
Research Definition

All East Tennessee State University (ETSU) and Mountain States Health Alliance, an affiliate of Ballad Health (Mountain States), research studies require Mountain States/ Ballad Health administrative and ETSU IRB approvals (or formal reliance).

Only non-Mountain States/non-ETSU research studies require Mountain States administrative approval and general IRB approval. ETSU/VA IRB approval is not required if the activity meets the exception.

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

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

Research at Mountain States includes the following situations:

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

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Reminder: ETSU Research Criteria

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.