Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

GUIDANCE - CASE STUDIES

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. [45CFR46.102]

- For single case studies, these are considered not human subjects research (NHSR) and must be submitted to the IRB for this determination to be made.
- Any activity that includes information about more than 3 "cases" is considered research. Federal Regulation is not specific; however, Prisma Health policy requires more than 3 cases on a single condition/topic is considered research and must be submitted for IRB review.
- **A complete IRB submission in IRBNet is required for review and determination. A complete submission includes: Protocol, CITI trainings linked for each study team member, assurance forms complete for each investigator/CRC, signatures of PI and each sub-investigator/CRC, completion of the Prisma Health IRB Application, and AVC signature.**
- Subject consent and HIPAA authorization for publication of case studies is *required* when there is the potential of identifiability (some elements presented in the case study document may allow for the identity of the individual to be determined) or if **any** HIPAA identifiers (including unique patient characteristics) will be used (*Please see Template_ Authorization For Use of HIPAA Identifiers in a Case Report in IRBNet forms and templates*).
- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.
- DO NOT upload signed HIPAA Authorization/consent forms to your submission to the IRB. These must be uploaded in the subject's EPIC record. The NHSR submission application is not HIPAA compliant. Just indicate in your submission that written consent has been obtained or submit a redacted version of the consent document used.
- Determine the requirements of the "publisher" prior to submission. Most publishers will require a letter of NHSR determination from the local IRB.
- In the case of any NHSR the IRB will issue a determination not an approval.
- While Human Subject Research regulations apply only to living individuals, HIPAA also applies to decedents.
- For questions, please contact the IRB office at IRB@prismahealth.org.