

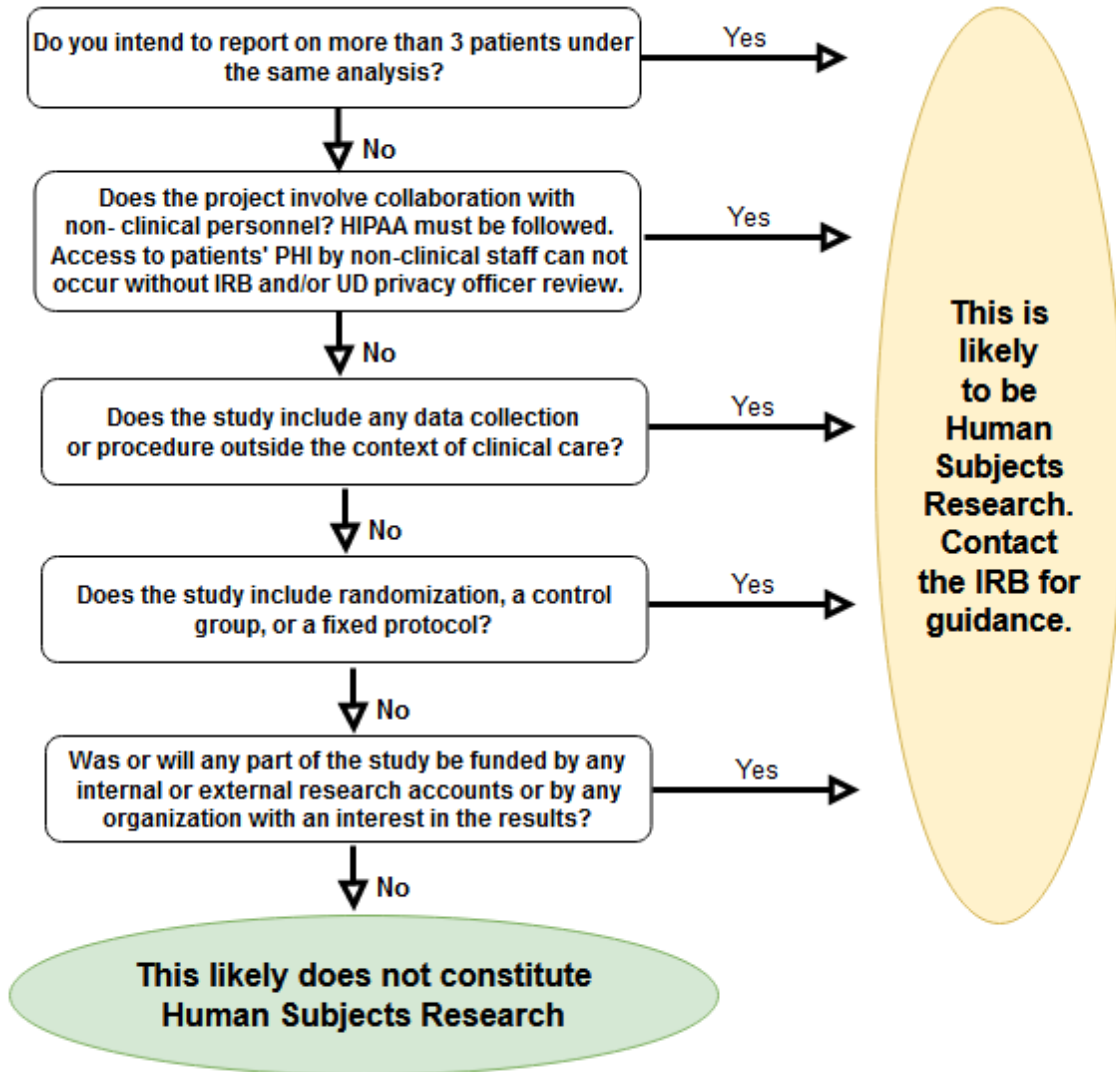


## Case Study vs. Research UD Guidance

### Does a Case Report or Case Series Require an IRB Submission?

- Review of medical records can constitute human subjects research (HSR) requiring Institutional Review Board (IRB) review and approval. The following is guidance offered in determining when a project involving study of records may be considered HSR by the University of Delaware IRB.
- IRB review and approval is needed when the proposed effort meets the definition of HSR by answering yes to the following questions:
- **Is it research? Research** means a systematic investigation, including research development, testing, and evaluation, *designed to develop or contribute to generalizable<sup>5</sup> knowledge*.  
<sup>5</sup>**Generalizable** does not mean “publishable”, but rather, research *where findings/ information collected or generated can be applied to a larger population than one the studied*. Results are intended to develop, test, or support theories, principles, and statements of relationships.
- **Does it involve Human Subjects?** A **human subject** means a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- Most clinical case reports are a description of a unique condition, presentation, treatment, or outcome observed in an individual. Single patient case reports are normally anecdotal evidence and do not meet the HSR definition, nor do they require IRB review and approval. The provider should not have any research intent at the time of the clinical intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treatment].
- Case series include multiple cases and may be considered research. If more than three patients’ cases are to be included in the same report the project would need review by the IRB. Secondary analysis of private identifiable information or identifiable biospecimens is normally deemed research exempt from the regulations. Exempt research determinations require submission to the IRB.
- Even if IRB approval is not required to present a case study/series it may be requested by some scientific journals prior to publication.
- Medical records and protected health information (PHI) are protected under the HIPAA Privacy Rule. Access and reporting from those records must be done in compliance with the Rule. Access to records must be done only when allowed by the scope of treatment. A case report/series must be completely de-identified prior to presentation.
- **Below is a decision tool you may find useful in determining whether your project constitutes HSR. Please note that this is a guideline, not an absolute. When in doubt, consult with the IRB.**

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For questions to the UD IRB please contact [hsrb-research@udel.edu](mailto:hsrb-research@udel.edu)



Detailed information about IRB requirements and submission procedures can be found at <https://research.udel.edu/regulatory-affairs/human-subjects/>