

Cases/Examples Table: Evaluating Research Involving Human Specimens or Data in Research Project Activities

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The following cases/examples may be helpful in determining whether an application describing research project(s) or activity(ies) involving specimens or data from either one or many sources involves human subjects (HS) research

Provider or Recipient Activity:	Providing Institution/Repository?	Who is the Provider?	Role of Provider(s) in Applicant's Research:	What is being provided? (Individually identifiable?)	Are all specimens or data "existing"?	Is the Provider conducting HS research?	Are specimens or data identifiable to recipient investigators?	Does the Applicant's use of these specimens or data constitute HS research?	Does the Applicant's use of these specimens or data meet the criteria for Exemption 4?	Human Subjects Research?
Project/ Activity 1	Specimen Repository	Specimen or Data Repository	Solely providing specimens or data	Coded or unidentifiable specimens or data without identifiers from repository	No	No	No, the repositories' policies or procedures prevent release of identifiers	No	Not Applicable (ongoing collection)	No
Project/ Activity 2	Department at a Medical School	Faculty Member	Providing specimens or data and collaborating in the applicant's research	Coded, identifiable or unidentifiable specimens or data from an ongoing clinical trial conducted by the provider	No	Yes	No, but the provider meets the definition of an investigator and will have access to identifiers as the PI of the trial	Yes	No, specimens or data are neither existing nor unidentifiable to provider who is collaborating with recipient	Yes
Project/ Activity 3	Pathology Department at a Clinical Hospital	Pathologist	Solely providing specimens or data	Archived, coded, or unidentifiable excess tissue from diagnostic procedures	Yes	No	No, provider and recipient have non-disclosure agreement	No	No, coded specimens or data were not collected for the proposed research and the provider and recipient have a non-disclosure agreement	No

If the research describes the use of all of the above specimens, the PHS398 facepage, Item 4 "Human Subjects Research?" should be checked "Yes".