

# **Data Gathering Activities That Do Not Constitute Human Subjects Research**

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- The OHR-34 form was created to assist Jefferson personnel in determining whether an IRB submission is necessary for the intended project.

- Category 1
- Quality assurance or quality improvement projects in which the data collected will be used only to verify, alter or improve quality of care or efficiency within the Jefferson entity. (If external publication or public presentation of data is intended, project will require IRB review.)

- Category 2
- Information-gathering interviews, questionnaires & surveys where questions focus on factual information such as processes, services, or policies, and do not gather personal information about living individuals, or; research gathering factual information from source texts.

- Category 3
- Research involving cadavers, autopsy materials or bio-specimens from deceased individuals. (Note: HIPAA does not exempt decedent research, and so this research requires review by the Privacy Officer. Please complete form OHR-17 and submit to Office of University Counsel.)

- Category 4
- Coded private information or biological specimens that were not collected for the currently proposed research and for which the investigator cannot link the coded data/specimens back to individual subjects. (Note: This research requires that you submit OHR-19 form to the Office of Human Research.)

- Category 5
- Research where Jefferson is not engaged in the research. Examples of this include: when Jefferson's employees or agents 1) act as consultants or provide paid service for research but at no time obtain, receive, or possess identifiable private information, or 2) inform prospective subjects about the availability of research. (Note: this is not a complete list of examples.)

- Category 6
- Case reports of one or two cases. (Three or more case reports in one series require IRB review). While one or two case reports do not require IRB review, they do require review by the University or Hospital Privacy Officer, depending on which entity owns the charts to be reviewed.



- The OHR-34 does not need to be submitted to the IRB. It is provided so that the personnel can document the non-research category of their project and provide as necessary to inquiry.

- If none of the categories on the OHR-34 apply to the project, the personnel should contact OHR to discuss and determine whether an IRB submission is required.

- Thanks