

HAC Policies and Procedures

Research Using Data, Documents, Records and Biological Specimens

Research that uses data about human subjects obtained under an earlier research protocol or for other reasons (standard of care, quality assurance projects, etc.) may require HAC approval. This type of research involves the secondary use of data that was collected in an earlier approved research project or other approved method. These protocols must be submitted for review prior to initiating the research.

Some research may use data that may appear to be publicly available data for a secondary analysis. These types of data sets are not always truly publicly available and the HAC must make the final decision on if the protocol is exempt from full review.

People who have legitimate access to information that individuals would reasonably expect to remain confidential and not disclosed to others without their consent or permission (e.g., medical records, grades, test results, etc.) may provide “masked” or “blind” data to an investigator only after the HAC approves the research. Legitimate access may be someone such as a person’s primary physician or dentist, other health care workers, employer or school officials. This may require an informed consent waiver or specific de-identification procedures. Masked or blind data means that the investigator cannot link this information back to a specific person.

Secondary use of data that can be linked to an individual will require HAC approval prior to the use of the data. At times, it may be impracticable to obtain informed consent from the individuals and the HAC may approve a waiver of informed consent. All requests for waiver of informed consent require full committee review.