 <b>LEHIGH</b> UNIVERSITY	<b>Institutional Review Board (IRB)</b>		
	Guidance: Human Subjects Research Engagement		
	<b>DATE</b>	<b>AUTHOR</b>	<b>PAGE</b>
7-Dec-2018	N. Coll	1 of 2	

## Background

For many research studies, the role of some members of the investigative team might not meet the definition of human subjects research (HSR). For example, if a laboratory technician receives a blood specimen that is coded and they have no way to re-identify the individual from whom the specimen was obtained, the technician is not engaged in HSR.

If there is uncertainty about whether or not Lehigh University or an investigator at Lehigh University is engaged in the research, the federal Office of Human Research Protections (OHRP) provides [Guidance on Engagement of Institutions in Human Subjects Research](#). The following offers a summary of OHRP's guidance.

For purposes of this guidance, an institution's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees" and "agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.


### Institutions are engaged in HSR if their agents or employees:

1. Receive an award through a grant, contract, or cooperative agreement directly from HHS.
2. Intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures (see the three conditions for limited exceptions in item 1 in the next section below).
3. Intervene by manipulating the environment.
4. Interact with subjects for research purposes.
5. Obtain consent of subjects.
6. Obtain for research purposes identifiable private information or identifiable biological specimens from any source.

*It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution's employees or agents do not directly interact or intervene with human subjects.*

### Institutions are not engaged in HSR if their agents or employees:

1. Perform commercial or other services for investigators (somewhere else) provided that all of the following are also met:
  1. the services performed do not merit professional recognition or publication privileges;
  2. the services performed are typically performed by those institutions for non-research purposes; and
  3. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.
2. Provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators.
3. Administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis.
4. Provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to the investigators.
5. Access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.
6. Conduct non-exempt human subjects research while enrolled as student at another at an institution which is engaged in the research, provided that the individual is not simultaneously

 <b>LEHIGH</b> UNIVERSITY	<b>Institutional Review Board (IRB)</b>	
	Guidance: Human Subjects Research Engagement	
	<b>DATE</b>	<b>AUTHOR</b>
7-Dec-2018	N. Coll	<b>PAGE</b> 2 of 2

operating in their role as an agent or employee of the University and the research activities have received final approval from the IRB of the institution engaged in the research.

*NOTE: the researcher is responsible for confirming exempt vs. non-exempt research status with the engaged institution, as well as providing, upon request, copies of submitted IRB applications, study materials / consent documents, or final IRB approval. [Contact the Research Integrity office](#) if you are unsure whether your research meets the criteria for engagement at Lehigh.*

7. Release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research. NOTE: the subjects would need to provide informed consent at the institution to which the data will be released.