The purposed of this regulatory guidance document is to provide support to UF Administrators and IRB Board Members in determining whether the Institution (or affiliated site) is engaged in research.

The following criteria must be met:

1. If the following criterion is met, the institution is engaged:

1.1.	The organization receives funding directly from a Federal department or agency (other than DOD) for nonexempt research

2. If the following criteria are met and none of the exceptions in Section 3 are met, the institution is engaged:

2.1.	Employees or agents of the institution will obtain data about subjects through interaction for research purposes
2.2.	Employees or agents of the institution will obtain data about subjects through intervention for research purposes
2.3	Employees or agents of the institution will obtain informed consent of subjects to take part in the research
2.4	Employees or agents of the institution will obtain identifiable private information about subjects for research purposes

3. Exceptions:

3.1.	Employees or agents of the institution will perform commercial or other services for investigators, where all of the following are true: 1. The services performed do not merit professional recognition or publication privileges 2. The services performed are typically performed by those organizations for purposes other than research 3. Employees or agents do not administer any study intervention being tested or evaluated under the protocol
3.2.	The institution was not selected as a research site, but employees or agents of the institution will provide clinical trial-related medical services that are dictated by the protocol and are typically performed as part of routine clinical monitoring or follow-up of subjects enrolled at a study site by clinical trial investigators, where all of the following are true: 1. Employees or agents of the institution do not administer the interventions being tested or evaluated under the protocol 2. The clinical trial-related medical services are typically provided by the organization for clinical purposes 3. The employees or agents of the institution will not enroll subjects or obtain the informed consent of subjects to take part in the research 4. When appropriate, investigators from an engaged institution will retain responsibility for both: a. Overseeing protocol-related activities b. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required by the protocol.
3.3.	The institution was not initially selected as a site, but employees or agents of the institution will administer the interventions being tested or evaluated under the protocol on a one-time or short-term basis, where all of the following are true: 1. An investigator from an engaged institution determines that it will be in the subject's best interest to receive the interventions being tested or evaluated

	2. Employees or agents of the institution will not enroll subjects or obtain their informed consent to take part in the research 3. Investigators from the institution engaged in the research will retain responsibility for all of the following: a. Overseeing protocol-related activities b. Ensuring the interventions are administered in accordance with the protocol c. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required by the protocol 4. The IRB will be informed that interventions being tested or evaluated have been administered at the institution's site
3.4.	The activities of the employees or agents of the institution will be limited to the following: 1. Inform prospective subjects about the availability of the research 2. Provide prospective subjects with information about the research but do not obtain subjects' consent to take part in the research or act as representatives of the investigators 3. Provide prospective subjects with information about contacting investigators for information or enrollment 4. Seek or obtain the prospective subjects' permission for investigators to contact them
3.5.	The institution will permit investigators from another institution to use its facilities for research
3.6.	Employees or agents of the institution will release identifiable private information about subjects to investigators at another institution
3.7.	The organization's employees or agents of the institution will: 1. Obtain coded private information from another institution involved in the research that retains a link to identifiable private information, and 2. Are unable to readily ascertain the identity of the subjects to whom the coded information or specimens
3.8.	The organization's employees or agents of the institution will access or use identifiable private information only while visiting an institution that is engaged in the research, provided their activities are overseen by an IRB of the institution that is engaged in the research
3.9.	Employees or agents of the institution will access or review identifiable private information for auditing purposes
3.10.	Employees or agents of the institution will receive identifiable private information for purposes of satisfying FDA reporting requirements
3.11.	Employees or agents of the institution will author a paper, journal article, or presentation describing a research study

4. Footnotes:

4.1.	OHRP Guidance: Engagement of Institutions in Human Subjects Research (2008)
4.2.	In this worksheet, "research" means research as defined by DHHS involving human subjects as Defined by DHHS and "subject" means human subject as defined by DHHS.
4.3.	Employees or agents refer to individuals who: (1) act on behalf of the organization; (2) exercise organizational authority or responsibility; or (3) perform organizationally designated activities. Legal counsel for the institution being evaluated for engagement should decide which individuals at an institution are employees or agents.