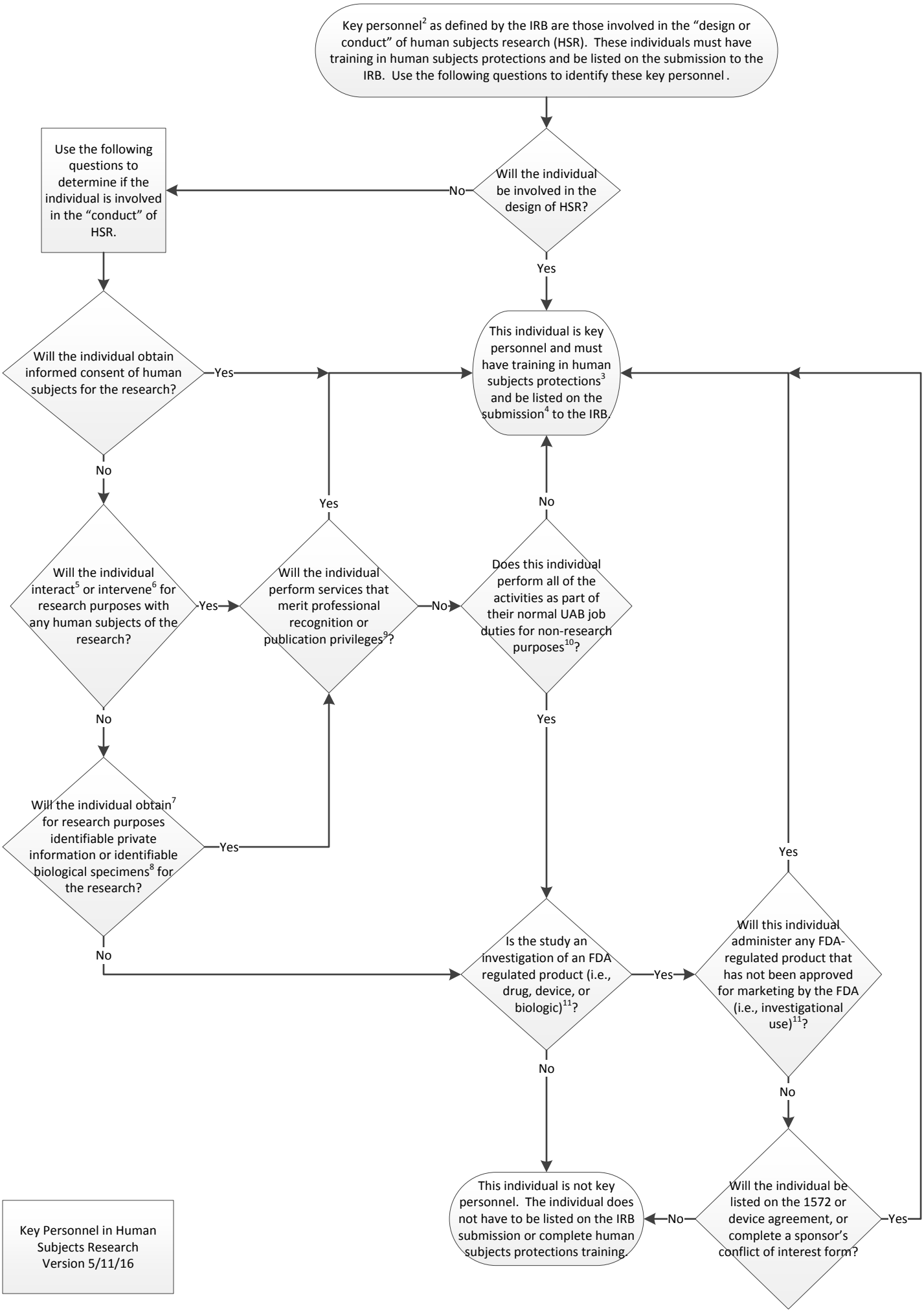
Key personnel[2] as defined by the IRB are those involved in the "design or conduct" of human subjects research (HSR). These individuals must have training in human subjects protections and be listed on the submission to the IRB. Use the following questions to identify these key personnel.
Will the individual be involved in the design of HSR?
No
Use the following questions to determine if the individual is involved in the "conduct" of HSR.
Yes
This individual is key personnel and must have training in human subjects protections[3] and be listed on the submission[4] to the IRB.
Will the individual obtain informed consent of human subjects for the research?
Yes
No
Will the individual interact[5] or intervene[6] for research purposes with any human subjects of the research?
Yes
Will the individual perform services that merit professional recognition or publication privileges[9]?
No
Does this individual perform all of the activities as part of their normal UAB job duties for non-research purposes[10]?
Yes
No
Yes
No
Will the individual obtain[7] for research purposes identifiable private information or identifiable biological specimens[8] for the research?
Yes
No
Is the study an investigation of an FDA regulated product (i.e., drug, device, or biologic)[11]?
Yes
Will this individual administer any FDA-regulated product that has not been approved for marketing by the FDA (i.e., investigational use)[11]?
Yes
No
No
Will the individual be listed on the 1572 or device agreement, or complete a sponsor's conflict of interest form?
Yes
No
This individual is not key personnel. The individual does not have to be listed on the IRB submission or complete human subjects protections training.
Key Personnel in Human Subjects Research
Version 5/11/16

1. Definitions for human subjects research – see http://www.uab.edu/research/administration/offices/IRB/guidebook/Pages/01-Introduction.aspx.

2. Key personnel as used by the IRB is a broad term and includes all of the following individuals defined by NIH, OHRP, and FDA:

NIH

NIH Office of Extramural Programs (OEP)

Who needs to receive required education on the protection of human subjects? (https://humansubjects.nih.gov/requirement-education#resource16)
"Individuals who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the education requirement. These individuals are considered to be "Key Personnel" on NIH awards and contracts that include research involving human subjects, this includes the Principal Investigator(s), all individuals responsible for the design or conduct of the study, and those individuals identified as key personnel of consortium participants or alternate performance sites."

NIH Office of Extramural Research

The Glossary of NIH Terms (http://grants.nih.gov/grants/glossary.htm) uses other terms that may be confused with "key personnel" noted above. Unless there are extenuating circumstances to the contrary, "Senior/Key Personnel" and "Other Significant Contributors (OSCs)" of the human subjects research portions of a project are always considered key personnel for purposes of the IRB. Others not fitting these definitions may also be considered key personnel with the IRB (e.g., individuals obtaining informed consent, data entry personnel, data analysis).

OHRP

Who are "investigators"? (http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/who-are-investigators.html)
The HHS regulations at 45 CFR part 46 use the term "investigator" to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies. Such involvement would include:

- obtaining information about living individuals by intervening or interacting with them for research purposes;
- obtaining identifiable private information about living individuals for research purposes;
- obtaining the voluntary informed consent of individuals to be subjects in research; and
- studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

FDA

FDA defines investigator (21 CFR 50.3(d)) as "an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."

While there is not a separate definition in these regulations for subinvestigator, the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) provides a definition for both investigator and subinvestigator as follows:

1.34 Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. See also Subinvestigator.

1.56 Subinvestigator: Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also Investigator.

All investigators and subinvestigators as defined above are considered key personnel for purposes of the IRB.

3. Training - see http://www.uab.edu/irb/training for information on completion of training in the protection of human subjects.

4. Submissions to the IRB include the Human Subjects Protocol (HSP) for projects requiring expedited or full board review, the IRB Exemption Review Application, and the Application for Designation of Not Human Subjects Research (NHSR). Projects designated NHSR do not require human subjects protections training.

5. Interacting includes engaging in protocol dictated communication or interpersonal contact. Examples include asking someone to provide a specimen by voiding or spitting into a specimen container, conducting research interviews, or administering questionnaires.

Note that individuals whose activities are limited to the following are not considered key personnel:

- Individuals who inform prospective subjects about the availability of the research;
- Individuals who provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
- Individuals who provide prospective subjects with information about contacting investigators for information or enrollment; and/or
- Individuals who seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

6. Intervening includes the following:

- performing invasive or noninvasive procedures such as drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.
- manipulating the environment such as controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

7. Obtain - See http://www.hhs.gov/ohrp/policy/cdebiol.html. Under the definition of human subject at 45 CFR 46.102(f), obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research. Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

- using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and
- using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of the investigator.

8. Identifiable – The UAB IRB uses the 18 elements of PHI from HIPAA as the standard for determining identifiability. If one or more of these 18 identifiers is included in the dataset, the UAB IRB would consider the data identifiable for purposes of defining human subjects research and identifying key personnel. For the full list of identifiers, see page 4 of the HIPAA Handbook for Researchers at UAB (http://www.uab.edu/research/administration/offices/IRB/Documents/302%20-%20hipaa-handbook.pdf).

9. Professional recognition or publication privileges – will the individual's contributions be attributed in publications or presentations that result from the research?

10. FOR NON-RESEARCH PURPOSES – for example, an MRI technician who performs MRIs for both regular patient care and research participants. Other examples include the following:

- Phlebotomists
- Receptionist who welcomes department visitors

11. For more information on FDA regulated products, see http://www.uab.edu/research/administration/offices/IRB/guidebook/Pages/16-FDA-Regulated-Research.aspx.