Hello Researcher:

Please use the following flowcharts and checklists to help you determine when your research may require a review by the Institutional Review Board (IRB).

Please note that these flowcharts and checklists are from the IRB Researcher Manual.

Other helpful resources may be found on the IRB website- https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb:

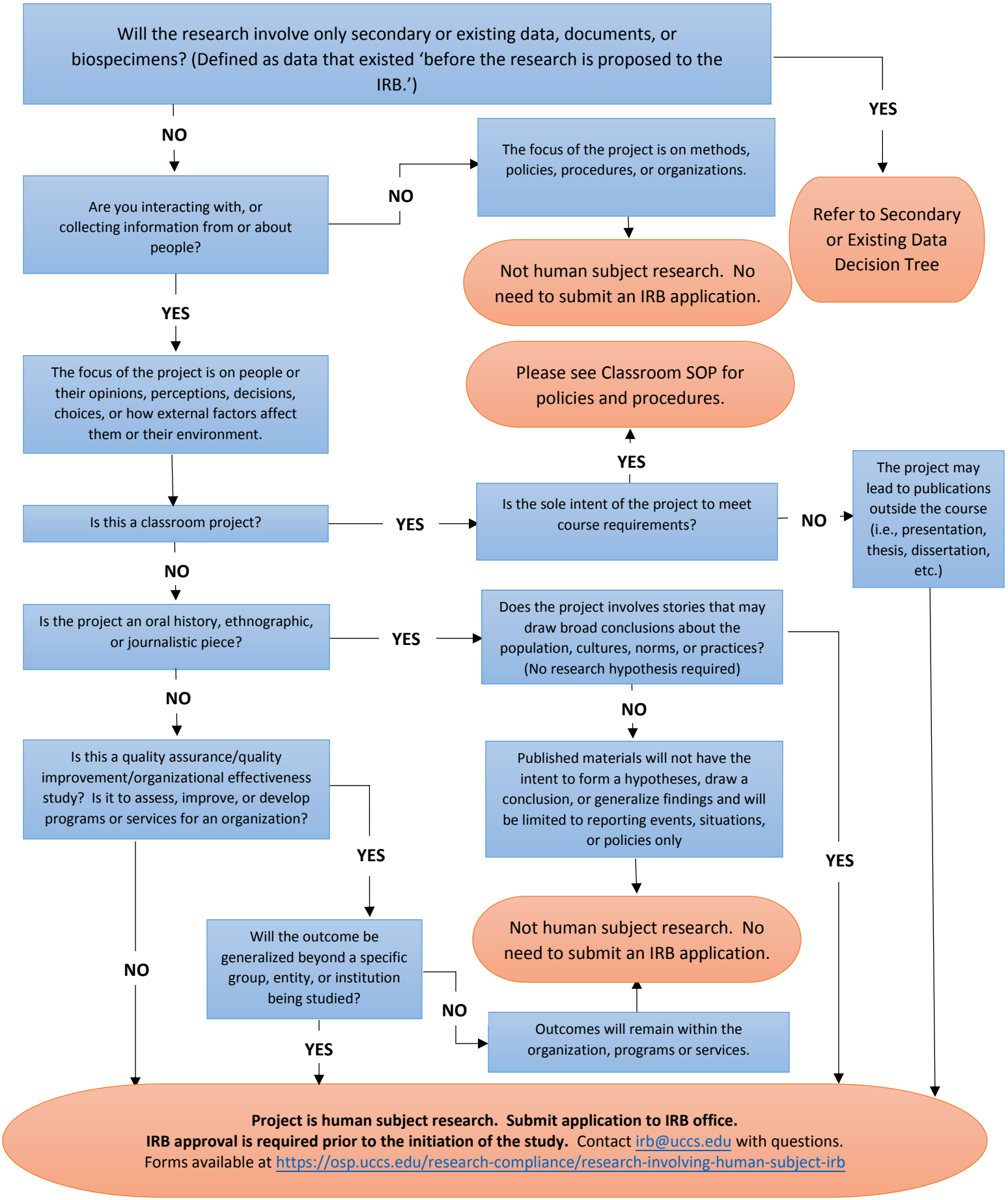
1. IRB Researcher Manual
2. A Dozen Tips for a Successful IRB Application
3. Research with Local School Districts
4. IRB Research Summary Instructions (provides guides for sections of the IRB application)
5. IRB Standard Operating Procedures (SOPs)

If you have questions about your specific research project, please feel free to contact us at IRB@uccs.edu. We would be happy to help.

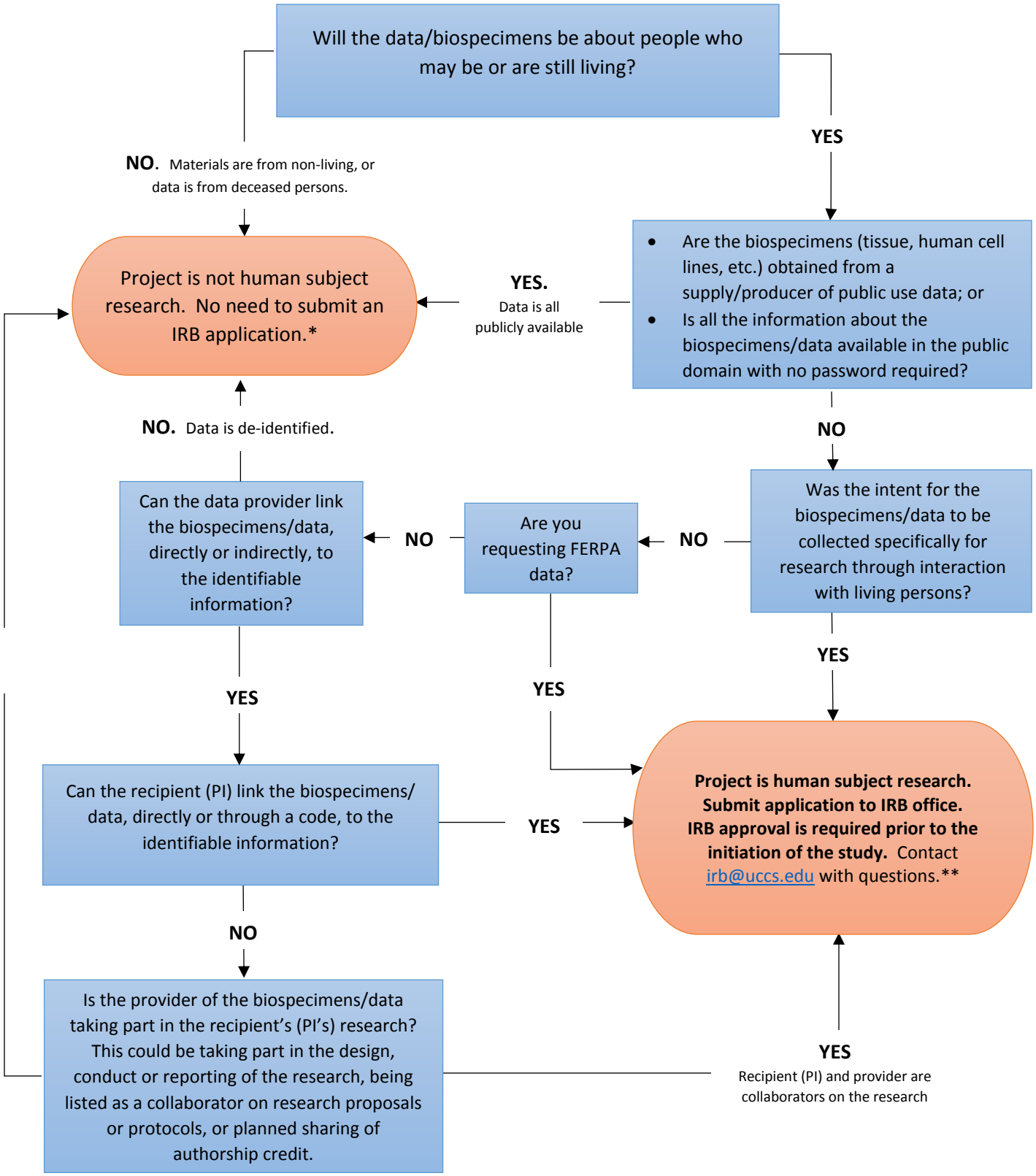
Sincerely,

The Staff of the Office of Sponsored Programs and Research Integrity
(719) 255-3903 (voice) (719) 255-3706 (fax) irb@uccs.edu

Does Your Project Require a UCCS New IRB Application?



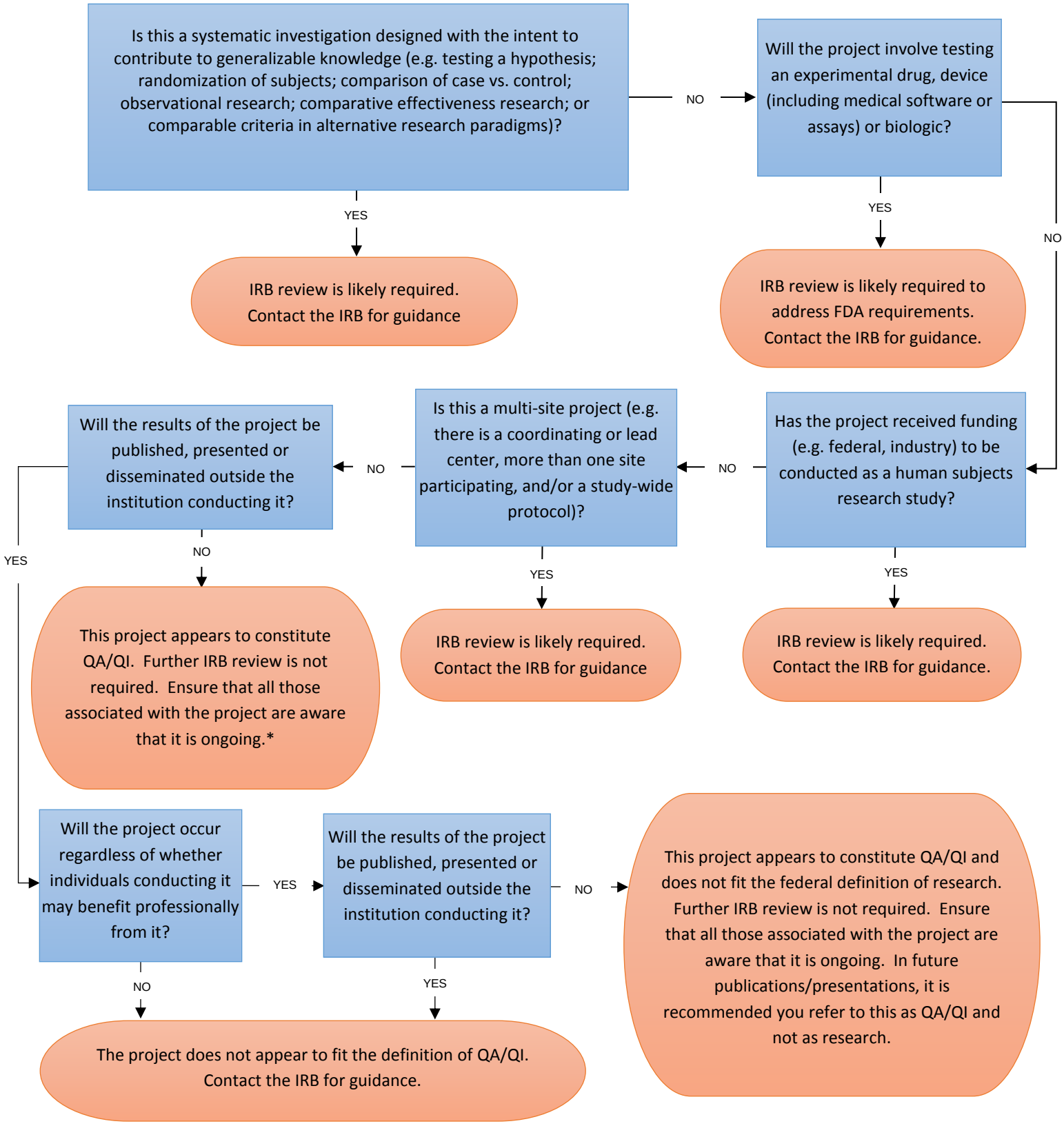
Does Your Research Involving Secondary or Existing Data or Biological Specimens Require Review by UCCS IRB?*



* ***If an approval is required to publish, it is a requirement to submit an IRB application. No retroactive approvals will be provided.*** If a PI is needing a signed agreement in order to obtain data, please contact the Office of Sponsored Programs and Research Integrity (OSPRI) at osp@uccs.edu. OSPRI will negotiate the terms of the agreement on behalf of UCCS.

** Forms available at https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb

Is your project Research or Quality Assessment/Quality Improvement?*



Adopted with permission from the University of Wisconsin Health Sciences IRB.

* ***If an approval is required to publish, it is a requirement to submit an IRB application prior to initiation of the project. No retroactive approvals will be provided.***

** Forms available at https://osp.uccs.edu/research-compliance/research-involving-human-subject-irb

Human Subject Worksheet

The University of Colorado Colorado Springs (UCCS) requires that all research involving human subjects conducted by faculty, staff, or students affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, an expedited, or a full review project. The purpose of this worksheet is to provide support for individual in determine whether an activity is Human Subject Research or how it is regulated. This worksheet is to be used and does not need to be completed, submitted, or retained.

1	**Research as Defined by DHHS Regulations** (Check if **"Yes"**.)
☐	Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)
☐	Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)
☐	Is the systematic investigation designed to develop or contribute to knowledge? (Designed: Observable behaviors used to develop or contribute to knowledge. Develop: To form the basis for a future contribution. Contribute: To result in. Knowledge: Truths, fact, information.)
☐	Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.
2	**Human Subject under DHHS Regulations** (Check if **"Yes"**.)
☐	Is the investigator conducting the Research gathering data about *living* individuals, including biospecimens.
3	**Human Subject Under DHHS Regulations** (Check if **"Yes"**.)
☐	Will the investigator gather that data through either of the following mechanisms (Specify which mechanism(s) apply): ☐ Physical procedures or manipulations of those individuals or their environment for research purposes, including biospecimens ("intervention"). ☐ Communication or interpersonal contact with the individuals. ("interaction").
4	**Human Subject Under DHHS Regulations** (Check if **"Yes"**).
☐	Will the investigator gather data that is either? (Specify which category(s) apply): ☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information"). ☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. "Private information").
☐	Can the individuals' identifies be readily ascertained or associated with the information by the investigator (i.e. "identifiable information")?
If any items are checked under 1,2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations	
5	**Human Research Under FDA Regulations** (Check if **"Yes"**.)
☐	Does the activity involve any of the following? (Check all that apply) ☐ In the United States: The use of a drug[i] in one or more persons other than use of an approved drug in the course of medical practice. ☐ In the United States: the use of a device[ii] in one or more persons that evaluates the safety or effectiveness of that device. ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iii]. ☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[iv].
If "Yes", the activity is Human Research under FDA regulations	
If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under UCCS policy.	

[i] The term "drug" means:
- (A) Articles recognized in the official United States Pharmacopoeia, Official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) Articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
- (D) Articles intended for use as a component of any article specified in clause (A), (B), or (C)

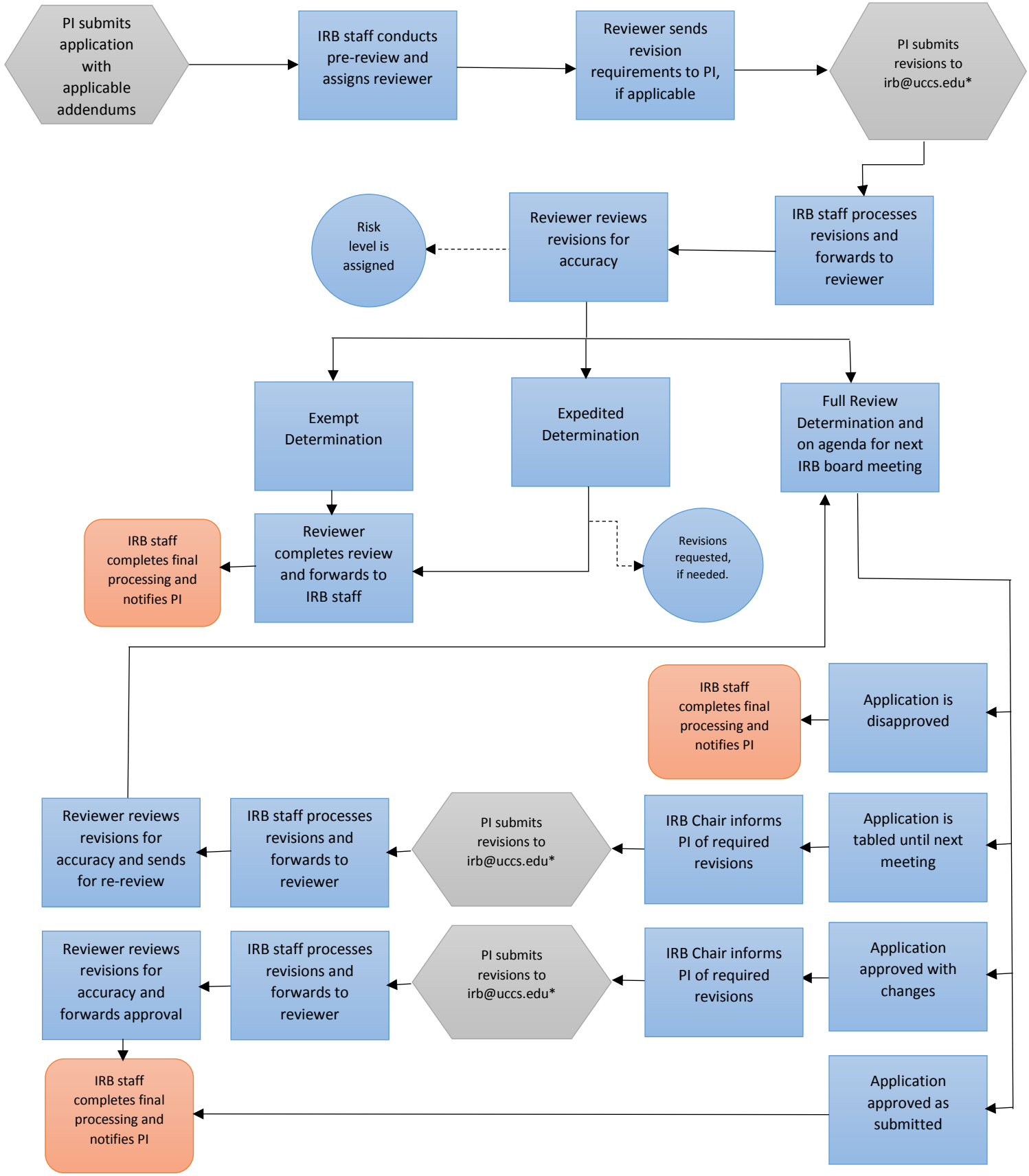
[ii] The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or relate article, including any component, part or accessory, which is:
- (1) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[iii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

***** Review of FDA covered research may need to occur by an outside IRB. Contact us with questions irb@uccs.edu

New IRB Application Review Process



** If the PI is a student, the application must be submitted via the faculty advisor's email address.*