**FDA Regulated Studies**

The FDA has the final authority on this issue. In the absences of any FDA opinion on a study, IRB staff may determine if a test article is considered to be drug and if the study is exempt from an IND/IDE. The full board must decide if the study requires and IND or determine if a non-exempt device is Significant or Non- Significant risk.

**The study is FDA Regulated if any of the following items apply and are checked on the Regulatory Page of IRB Online**

* Approved Drug, Device or Biologic (*research on*)
* IND Exempt (Drug, Biologic)
* Investigational Device Evaluation
* Investigational Device: Exempt
* Investigational Device: NSR
* Investigational Device: SR
* Investigational Drug, Biologic
* Device: Unapproved USE only, NO evaluations
* Data to FDA

**Research Activities that are not Subject to FDA Regulations**

1. Any study expedited under Expedited Category # 4. *(NOTE: a study expedited under Expedited Category # 1 would be subject to FDA)*
2. Medical records review (retrospective or prospective), ONLY IF the data is NOT submitted to the FDA.
3. Screening tests and procedures when not performed solely for determining study eligibility.
4. Interviews and questionnaires administered to subjects unless they involve the use of the test article, a human subject, and the data will be submitted to (or held for inspection by) the FDA.
5. Study is IND exempt because it is determined the product being evaluated is not considered a drug because the intent of the study is only to evaluate the products effect on the structure or function of the body and is not intended to evaluate the products ability to diagnose, cure, mitigate, treat or prevent a disease. In addition data from this study will not be submitted, or held for inspection, by the FDA. [IND Exempt (Non- Drug/Biologic) is checked on Regulatory Page]
6. Use of a drug or medical device when the purpose is to obtain basic physiological information rather than gathering data for submission to (or inspection by) the FDA. Examples:

* Participants will be given a FDA-approved statin drug after consuming citrus juice, and blood samples will be collected during the next 12 hours to examine the effect on statin metabolism. The use of the statin does not make the study subject to FDA regulations.
* A study is designed to look at the relationship between body temperature and self-reported hot flashes. Body temperature will be measured by having the participants swallow a capsule designed by the PI’s lab that measures core temperature during the 10-20 hours that it takes the capsule to pass through the digestive system. The use of the capsule does not make the study subject to FDA regulations.

1. Use of a drug or device in a study, but the drug or device is not the focus of the study (and data about the item are not being gathered for submission to (or inspection by) the FDA). Example:
   * A study of biomarkers for Alzheimer’s disease will collect cerebrospinal fluid samples from participants. Participants will be provided with aspirin or acetaminophen if they develop a headache due to the spinal tap. The use of the aspirin or acetaminophen does not make the study subject to FDA regulations.
2. Studies of surgical techniques that are evaluating only a new technique and not the safety or efficacy of FDA-regulated devices that are used during the surgery.
3. Use of a custom device, if it is not intended to gather data about the device that will be submitted to (or held for) the FDA.
4. The activity(s) of UVA researchers on a non-UVA researcher’s FDA-regulated study is limited to:
   * Data analysis (whether or not the data are identifiable)
   * Discussing a study with potential subjects (but not obtaining consent)
   * Pre-screening of records for eligibility determination
   * Procedures that will be performed as part of clinical practice and which would be performed exactly the same way regardless of whether the subject is in the study

*IRB Staff: See Examples in Admin FAQ/ FDA/ FDA Regulated Studies: Examples*