Guidance on Definitions and Approval of Medical and Investigational Devices

- Device use is common in research, but many devices do not meet the Food and Drug Administration (FDA) definition of a medical device and are therefore exempt. For example, a marketed device that is used to measure muscle strength, blood pressure, or pulse would generally not be considered a medical device. This is because these devices are not intended (on their own) to diagnose disease or to directly treat a disease. They also do not affect body structure or function.
- In contrast, a device that that is used as part of a research intervention that affects body structure or function would be subject to FDA regulation. In that case the device must be classified as either non-significant risk or significant risk, which will determine what regulations apply.
- Studies using a non-significant risk device – with documentation noting this from the sponsor or FDA – are generally eligible for an Abbreviated Investigational Device Exemption (abbreviated IDE), in which the IRB can concur with the non-significant risk determination and approve the study. Studies using significant risk devices generally require an FDA-approved Investigational Device Exemption.

Helpful Links on Device Use in Research

- **FDA guidance on determining if your device is a medical device**
  https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device#step1

- **Guidance developed by the University of Florida IRB, most of which is generally applicable to other IRBs and to the VA Human Research Protections Program (HRPP)**
  - https://irb.ufl.edu/wp-content/uploads/Guidelines/Guideline-FDA-Test-Articles-and-Research-Devices.pdf
  - https://irb.ufl.edu/wp-content/uploads/Guidelines/Guideline-FDA-Test-Articles-and-Research-Devices.pdf

- **Guidance from the Department of Health and Human Services on significant risk versus non-significant risk devices**
  https://www.fda.gov/media/75459/download