THE OHIO STATE UNIVERSITY

Office of Research

Office of Responsible Research Practices

Research Administration Building
1960 Kenny Road
Columbus, OH 43210

614-688-8457 Phone
800-678-6251 Phone

orrp.osu.edu

Additional Resources

Recording info – FDA-Regulated Research – Myth vs. Reality: Medical Devices – Part 1

Video URL: https://mediasite.osu.edu/Mediasite/Play/87d4fdb9bb4442faa5bdfdf856c906e71d

Timestamps:

- Welcome and introduction 00:00
- Step 1: What is a medical device? 7:36
- Step 2: Is the study a clinical investigation? 26:02
- Step 3: Which IDE requirements apply? 35:50
- How and when to contact the FDA 1:25:42

Special appearance by ORRP honorary staff member Maxi the Cat: 16:03 – 19:00

General Resources for Clinical Investigations Involving Medical Devices

- From ORRP:
  - Investigator Guidance: https://orrp.osu.edu/irb/investigator-guidance/
  - HRPP Policy: Research Involving Medical Devices: http://orrp.osu.edu/files/2012/02/Research-Involving-Medical-Devices.pdf
  - Past ORRP Educational Sessions: http://orrp.osu.edu/irb/workshopsseminars/orrpeducation/, including *FDA-regulated Research: Myth vs. Reality – Drugs* (Sept. 2020)
- From FDA:
  - Clinical Trials & Human Subject Protection: https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection
  - Clinical Trials Guidance Documents: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents
  - Medical Device Guidance Documents: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
  - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency
- Others:
  - ReGARDD: Regulatory Guidance for Academic Research of Drugs and Devices: http://www.regardd.org

Summary Tables: FDA Medical Device Regulations – Device Class/Marketing & IDEs

Device classes & marketing pathways

Device class	Device risk*	Examples	Marketing pathway	Controls	FDA Database	Regulatory docs to submit to IRB (if device is already marketed)
Class I	Low risk	Dental floss Scalpel Arm sling	**Most:** exempt from premarket notification requirements (i.e., 510(k) exempt) *Some Class I devices require 510(k) premarket notification*	General controls	Types of Class I and Class II devices exempt from premarket notification	PDF of device regulation (example; select "Print" icon and print to PDF) *If device requires 510(k), provide 510(k) Summary (see below)*
Class II	Moderate risk	Powered wheel chair MRI Clinical mercury thermometer	**Most:** 510(k) premarket notification *Some Class II devices are exempt from premarket notification requirements (i.e., 510(k) exempt)*	General & Special controls	510(k) Premarket Notification Database	510(k) Summary (PDF) *If device is 510(k) exempt, provide PDF of device regulation (see above)*
Class III or unclassified (novel device)	High risk	External defibrillator Replacement heart valves	Premarket Approval (PMA)	General controls & PMA	PMA Database	PMA Approval Order & labeling (PDFs)
Class I / II with no legally marketed predicate	Low or Moderate risk	Game-based digital health device for ADHD	De Novo request	General & Special controls (if Class II)	De Novo database	De Novo Reclassification Order (PDF)
*The **Humanitarian Device Exemption (HDE)** offers a marketing pathway for **Humanitarian Use Devices (HUDs)**, devices intended to benefit patients in the treatment or diagnosis of disease in a disease or condition that affects fewer than 8,000 individuals in the US per year. HUD "studies" at Ohio State are typically initiated for treatment purposes only. Contact ORRP with questions about HUDs.*						

** "Device risk" in this context is different than Significant/Nonsignificant risk device studies and the IRB's minimal/greater than minimal risk determination.*

IDE requirements

Type of device study	Type of device	Use in study	IRB verifies…	Subject to IDE regs (21 CFR 812)?
IDE-exempt study (two most common types)	Legally marketed device (PMA, 510(k), 510(k) exempt, de novo)	"On label": Consistent with approved/cleared indications for use	Use is consistent with approved/cleared indications	No
	Diagnostic device (marketed or not marketed)	Meets certain criteria (see item 2 here)	Diagnostic device exemption criteria are met	
Nonsignificant risk (NSR) device study	Legally marketed device (PMA, 510(k), 510(k) exempt, de novo)	"Off label": Not consistent with approved/cleared indications and use in study is NSR	Use in study is NSR	Yes, abbreviated requirements
	Device is not legally marketed	Use in study is NSR		
Significant Risk (SR) device study	Legally marketed device (PMA, 510(k), 510(k) exempt, de novo)	"Off label": Not consistent with approved/cleared indications and use in study is SR	FDA has approved an IDE for the study	Yes, full requirements
	Device is not legally marketed	Use in study is SR		

Medical Device Information: Product labeling & classification

- Medical Device Databases (all):
    - Devices@FDA (basic search of devices marketed under PMAs & 510(k)s): https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm
    - Product Classifications: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm
    - Premarket Approvals (PMAs): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
    - 510(k) Premarket Notifications: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Product Jurisdiction – for biologics & combination products that may be regulated as medical devices
    - Biologics Product Jurisdiction: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-product-jurisdiction
    - Combination Products: https://www.fda.gov/combination-products
    - Draft guidance: Requesting FDA Feedback on Combination Products: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice
    - Guidance: Classification of Products as Drugs and Devices & Additional Product Classification Issues: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/replies-inquiries-fda-good-clinical-practice

Investigational Device Exemption Applications (IDEs) & IDE Exemptions

- From FDA:
    - General IDE page: https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide
    - IDE Responsibilities: https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-responsibilities
    - FDA Guidance: Medical Devices, Frequently Asked Questions – Information Sheet: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-about-medical-devices
    - FDA Guidance: Significant Risk and Nonsignificant Risk Medical Device Studies – Information Sheet: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/significant-risk-and-nonsignificant-risk-medical-device-studies
    - FDA Guidance: “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices
- Ohio State Resources
    - Center for Clinical and Translational Science (CCTS) IND/IDE support: https://ccts.osu.edu/content/indide-support
- Other Resources
    - ReGARDD’s Initial IDE Submission information (templates, info, and video walk-through): http://regardd.org/devices/initial-ide-submission
    - UNC/ReGARDD IND Workshop (3 hours): https://panopto-web.med.unc.edu/Panopto/Pages/Viewer.aspx?id=821faaa1-8b84-42fb-a339-daff026f9808

FDA Divisions Relevant to Device Research & Contact Information

- Device Advice - Center for Devices & Radiological Health (CDRH), Division of Industry & Consumer Education (DICE): https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance
- Digital Health Center of Excellence: https://www.fda.gov/medical-devices/digital-health-center-excellence
- Center for Biologics Evaluation and Research (CBER): https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber
- IND/IDE Contacts (general): https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/indide-contacts