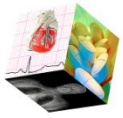


Food and Drug Administration (FDA) Resources

General

- **FDA Select GCP/Clinical Trial Guidance Documents Website** https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm

- **2009 FDA Guidance on Investigator Responsibilities** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-protecting-rights-safety-and-welfare-study-subjects

- **2013 FDA Investigators, and Sponsors IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed** www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf

Glossaries:

- **FDA Drug Terms Glossary** - http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm

- **Drug Development and Review Definitions -** http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm176522.htm

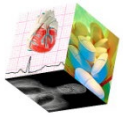
- **FDA Acronyms Glossary -** https://www.fda.gov/AboutFDA/FDAAcronymsAbbreviations/default.htm

- **FDA IDE Definitions and Acronyms -** https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046698.htm

Drug Research

Drug (Food Drug and Cosmetic Act) = "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) may also be considered drugs within the meaning of the FD&C Act. It is important to note that the *drug* definition is not limited to compounds intended for therapeutic purpose but also includes compounds intended to affect structure or function of the body without regard to influence on a disease process. [Source 2010 FDA Investigational New Drug Applications (IND) Guidance]

- **Drug Approvals and Databases** - http://www.fda.gov/Drugs/InformationOnDrugs/default.htm



Food and Drug Administration (FDA) Resources

- **2013 FDA Determining Whether Human Research Studies Can Be Conducted Without an IND**
  http://www.fda.gov/downloads/Drugs/Guidances/UCM229175.pdf
- **University of Kentucky (UK) Summary of FDA Exemption from IND Requirements**
  https://www.research.uky.edu/uploads/ori-d460000-summary-fda-regulations-exemption-ind-requirements-pdf

- **2004 FDA Guidance on IND exemptions for marketed products in cancer treatment**
  http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071717.pdf

- **PRE-IND Consult Program**
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm#preIND

- **FDA Information for Sponsor-Investigator's submitting an IND**
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071098.htm

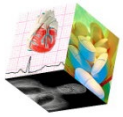
- **FDA IND TABLE of links to information for Investigator-Initiated IND Applications**
  https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm343349.htm

- **IND Applications for Clinical Treatment: Contents and Format**
  https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm363005.htm

- **FDA Investigator's Checklist for IND Application Submission**
  https://fda.report/media/86911/Investigator%27s-Checklist-for-IND-Application.pdf

- **FDA IND website**
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm

- **FDA Best Practices for Communication Between IND Sponsors and FDA During Drug Development**
  http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm475586.pdf



Food and Drug Administration (FDA) Resources

Biologic

- **What is a biologic product?**
  https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers
- **FDA Draft Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat Clostridium difficile Infection Not Responsive to Standard Therapies**
  https://www.federalregister.gov/articles/2016/03/01/2016-04372/enforcement-policy-regarding-investigational-new-drug-requirements-for-use-of-fecal-microbiota-for
- **Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal

Expanded Access Drugs

- **FDA Expanded Access to Investigational Drugs for Treatment Use Questions & Answers**
  https://www.fda.gov/media/162793/download

- **Expanded Access to Investigational Drugs Treatment Use & Charging for Investigational Drugs**
  http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf

- **UK Expanded Access SOP**
  https://www.research.uky.edu/uploads/ori-c30300-expanded-access-sop-pdf

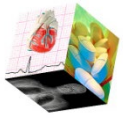
- **FDA Expanded Access Website for all constituents** https://www.fda.gov/news-events/public-health-focus/expanded-access

- **FDA Presentation Expanded Access Training** https://www.fda.gov/media/98959/download

Dietary Supplements, Botanicals, Foods, Cosmetics Complementary Medicine Research

- **FDA 101: Dietary Supplements**
  https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements

- **FDA Q and A on Dietary Supplements**
  https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-



Food and Drug Administration (FDA) Resources

answers-dietary-supplements

- **FDA: Is product a cosmetic, drug, or both, or a soap?** http://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074201.htm

- **FDA Determining Whether Human Research Studies Can Be Conducted Without an IND-Section V.** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf

- **FDA FAQ on Botanical Drug Products** http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090989.htm

- **FDA Complementary and Alternative Medicine Products** http://www.fda.gov/RegulatoryInformation/Guidances/ucm144657.htm
- **New Dietary Ingredients in Dietary Supplements** https://www.fda.gov/food/new-dietary-ingredient-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry

- **Medical Foods FAQ - under MD supervision** (e.g., for inborn error of metabolism – reduced phenylalanine for PKU) https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory-information

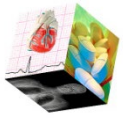
Emergency Use

- **FDA Emergency Use of Investigational Drug or Biologic** http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm

- **UK Emergency Use SOP** https://www.research.uky.edu/uploads/ori-c30250-emergency-use-sop-pdf

Device Research

Device (Food, Drug & Cosmetic Act) - A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, 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 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 …. and which is not dependent upon being metabolized for the achievement of its primary intended purposes.



Food and Drug Administration (FDA) Resources

- **Is product a medical device?**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm

- **2006 FDA Frequently Asked Questions about Medical Devices**
  http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

- **2006 Significant Risk and Nonsignificant Risk Medical Device Studies**
  http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

- **UK Summary of FDA Exemption from IDE Requirements**
  https://www.research.uky.edu/uploads/ori-d970000-summaryoffdaregulationson-exemptionfromiderequirements-pdf

- **FDA PRE-IDE Submission Guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

- **FDA IDE Submission Guidance**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm

- **FDA IDA Approval Process**
  https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process

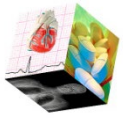
- **In Vitro Diagnostic (IVD) Device Studies – FAQ**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf

- **UK IRB Review of Device Studies**
  https://www.research.uky.edu/uploads/ori-d1100000-irb-review-medical-device-research-pdf

- **2013 FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (Approval with conditions)**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf

- **UK Medical Device SOP (includes investigations, compassionate and treatment use)**
  https://www.research.uky.edu/uploads/ori-c30150-medical-devices-sop-pdf

- **2013 IDE Exemptions for Early Feasibility Studies including certain First in Human (FIH) Studies**
  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocum



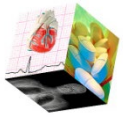
Food and Drug Administration (FDA) Resources

ents/ucm279103.pdf

- **Device Databases including the 510K database , Pre-Market Approval (PMA) database and Humanitarian Use Device (HUD) database** https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

Software, Mobile Applications, & Digital Health Content

- **Digital Health Policy Navigator Tool** https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator
- **FDA Digital Health Center of Excellence** https://www.fda.gov/medical-devices/digital-health-center-excellence
- **Guidance with Digital Health Content – links to multiple guidance on software as medical device** https://www.fda.gov/medical-devices/digital-health/guidances-digital-health-content
- **Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act
- **Examples of Software Functions for Which the FDA Will Exercise Enforcement Discretion** https://www.fda.gov/medical-devices/device-software-functions-including-mobile-medical-applications/examples-software-functions-which-fda-will-exercise-enforcement-discretion
- **2022 Clinical Decision Support Software -** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
- **2019 General Wellness: Policy for Low Risk Devices** – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices
- **2022 Policy for Device Software Functions and Mobile Medical Applications –** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
- **2019 Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices** – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices
- **2019 Off-The-Shelf Software Use in Medical Devices –**https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices



Food and Drug Administration (FDA) Resources

- **FDA Mobile App Website**
  http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm
- **Artificial Intelligence and Machine Learning in Software as a Medical Device**
  https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation
- **Developing a Mobile App? (What rules apply)**
  www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

Expanded Access Devices

- **FDA Early & Expanded Access Investigational Devices- Compassionate, Treatment, & Continued Access**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm

Humanitarian Use Device (HUD) Resources

- **2019 FDA HUD Guidance** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-use-device-hud-designations

- **UK Summary Guidance for HUDs**
  https://www.research.uky.edu/uploads/ori-d540000-irb-summary-medical-devices-humanitarian-use-devices-pdf

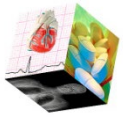
- **UK HUD SOP**
  https://www.research.uky.edu/uploads/ori-c30200-hud-sop-pdf

FDA Presentations

- **Device CDRH Learn Education Resources and Video Presentations**
  http://www.fda.gov/Training/ForHealthProfessionals/

- **Drug CDER Presentation Library**
  http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm074833.htm

- **Regulatory requirements for medical devices – William Sutton** https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medical-devices-transcript



Food and Drug Administration (FDA) Resources

- **IDE Basics – Soma Kalb Ph.D**
  http://fda.yorkcast.com/webcast/Play/696d857b34334d5389364ed8c2db3ded1d

- **Emergency and Compassionate Use of Unapproved Devices**
  http://www.fda.gov/downloads/training/cdrhlearn/ucm180888.pdf

- **IRB & Humanitarian Use Training -Fabienne Santel, MD**
  http://www.fda.gov/downloads/training/cdrhlearn/ucm180884.pdf

Combination Drug and Device Research

- **FDA FAQ for Combination Products**
  http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm

- **FDA Office of Combination Products**
  http://www.fda.gov/CombinationProducts/default.htm

IND and IDE Responsibilities for sponsor-investigators

- **IND Application Procedures: Investigator's Responsibilities**
  https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-investigators-responsibilities

- **Sponsor and Investigator IDE Responsibilities for SR and NSR Device Studies**
  https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-responsibilities

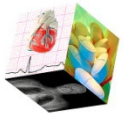
- **UK Sponsor-Investigator training on CITI- description and instructions**
  https://www.research.uky.edu/office-research-integrity/sponsor-investigator-citi-training-faqs

- **UK Summary of FDA Requirements For Investigators Who Are Also Considered Sponsors of New Drug**
  https://www.research.uky.edu/uploads/ori-d440000-summary-fda-requirements-investigators-who-are-also-considered-sponsors-new

FDA Inspections

- **FDA Bioresearch Monitoring (BIMO) program** https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-program-manual/bioresearch-monitoring-program-bimo-compliance-programs

- **2010 FDA Guidance for IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators**
  http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf



Food and Drug Administration (FDA) Resources

- **FDA Warning Letters https://www.fda.gov/ICECI/enforcementactions/warningletters/default.htmPreparing for a FDA Medical Device Clinical Investigator Inspection – Allen Lou** http://www.fda.gov/downloads/Training/CDRHLearn/UCM180892.pdf

Corrective and Preventive Action Plans (CAPA)

- **GxP Perspectives** https://carl1anderson.wordpress.com/?s=capa+plans+for+clinical+trials

- **Northwest University IRB** http://irb.northwestern.edu/policies/compliance/corrective-action-plan

Clinicaltrials.gov

- **Guidance regarding which trials must be registered by study sponsor (or sponsor-investigator)** http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered

- **How to register**? http://clinicaltrials.gov/ct2/manage-recs/how-register

- **Information on access to UK 's account on Clinicaltrials.gov** https://www.ccts.uky.edu/participate-research

- **FDA's Role: Clinicaltrials.gov Information** http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/FDAsRoleClinicalTrials.govInformation/default.htm

- **NIH Guidance on compliance with the FDA clinicaltrials.gov registration requirements** http://grants.nih.gov/ClinicalTrials_fdaaa/steps.htm

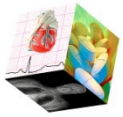
- **NIH Flowchart: Identifying an "Applicable Clinical Trial"** http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm

- **NIH Flowchart: Identifying the "Responsible Party"** http://grants.nih.gov/clinicaltrials_fdaaa/Responsible_Party.htm

- **Proposed Rule for US Clinical Trial Registration and Results Submission, Includes ten common misconceptions about the FDAAA– NEJM 2015; 372:174-180 UK access -** http://www.nejm.org/doi/full/10.1056/NEJMsr1414226#t=article

FDA Safety Reporting

- **FDA Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices**



Food and Drug Administration (FDA) Resources

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices

- **FDA's Final Rule on IND Safety Reporting Requirements**
  http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm

Informed Consent Guidance

- **IRB Waiver or Alteration of Informed Consent**
  https://www.fda.gov/media/106587/download

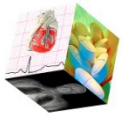
- **Exception from Informed Consent Requirements for Emergency Research**
  https://www.fda.gov/media/80554/download

- **Informed Consent for In Vitro Diagnostic Device Studies**
  https://www.fda.gov/media/122648/download

Real World Data

- **FDA Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices

- **FDA Use of Real-World Data and Real-World Evidence to Support Regulatory Decision Making for Drugs and Biological Products**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-real-world-data-and-real-world-evidence-support-regulatory-decision-making-drug



Food and Drug Administration (FDA) Resources

FDA Contacts

Drugs - Center for Drug Evaluation & Research (CDER)
- 855-543-3784 or 301-796-3400
- druginfo@fda.hhs.gov

Biologics - Center for Biologics Evaluation & Research (CBER)
- 800-835-4709 or 240-402-8010
- ocod@fda.hhs.gov

Device – Center for Devices & Radiological Health (CDRH)
- 301-796-7100 or 800-638-2041
- DICE@fda.hhs.gov
- DigitalHealth@fda.hhs.gov

Sample IND/IDE Number Format
G012345 – Device

12345 – Biologic

123456 – Drug

Foods - Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food And Drug Administration
- 888-723-3366
- https://cfsan.secure.force.com/Inquirypage

Dietary Supplements - Division of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food And Drug Administration
- 888-723-3366 or 240-402-2375
  INDsFoodsDietarySuppCosmetics@fda.hhs.gov

Cosmetics - Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition
- 888-723-3366
- https://cfsan.secure.force.com/Inquirypage

Office of Clinical Policy (Good Clinical Practice)
- 301-796-8340
- gcp.questions@fda.hhs.gov

Division of Small Manufacturers, International and Consumer Assistance
- 800-638-2041 or 301-796-7100
- dsmica@fda.hhs.gov