Investigational Drug Services

Busy Day Tool Kit Preceptor Instructions

Learner level: Identify appropriate audience: IPPE and APPP students.

Estimated time to complete: Completion of this module may take several days/weeks and can be done intermittently while completing other assigned projects.

Preceptor Instructions: Check in with the student periodically to see if there are questions and topics needing clarification. Ask students which modules they thought were most useful/informative.

Student Instructions: Complete the activities as outlined in the module. Provide feedback to your preceptor about one or a two of the topics/activities.

Investigational Drug Services

Background on clinical trials/What are clinical trials?

- Search Tip: www.nhlbi.nih.gov/studies/clinicaltrials
- (Click on the featured video in the middle of the page. Scroll down and click on link for video on Children and clinical trials.)

History of the FDA

- Search Tip: www.**fda**.gov/About**FDA**/WhatWeDo/**History**/
- Also click the link for FDA's Flickr photo-stream at the bottom of the page listed above.

Milestones in Food and Drug Law History

- Search Tip: https://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/EvolvingPowers/ucm2007256.htm
- Significant Dates in U.S. Food and Drug Law History

The Story of the Laws Behind the Labels

- Search Tip: Overviews on FDA History > The Story of the Laws Behind the Labels

Review past defining issues with human subjects research

- Search Tip: "Tuskegee Syphilis Experiment Documentary - You Tube"

Continue to review past defining issues with human subjects research

- Search Tip: – www.cdc.gov>Tuskegee Home

Review the Declaration of Helsinki

- Tip: Search –The world medical association's Declaration of Helsinki historical and contemporary perspectives
  - Review the Belmont Report and understand its significance to human subjects research and human subjects protection.
- Search Tip: Belmont Report Educational Video You – Tube

Continue to review the Belmont Report and understand its significance to human subjects research and human subjects protection.

- Search Tip: The Belmont Report/HHS.gov

Review the phases of drug development

- Search Tips: www.**fda**.gov/downloads/**drugs**/resourcesforyou/consumers/ucm284393.pdf
- Images for phases of drug development

Review the Code of Federal Regulations

- Search Tip: Title 21 of Code of Federal Regulations - You Tube

Review the purpose of an Institutional Review Board (IRB)

- Search Tip: Institutional Review Boards Frequently Asked Questions – Information Sheet

Review the topic of informed consent in human subjects research

- Search Tip –Informed Consent Tips (1993)| HHS.gov
- Search Tip: Informed Consent FAQ's/HHS.gov

Review the topic of receiving a drug through an Expanded Access Program

- Search Tip: Expanded Access - You Tube

Continue to review the obtaining a drug using an Expanded Access (Compassionate Use) Program

- Search Tip: - Expanded Access (Compassionate Use) (FDA website)

Emergency Use of an Investigational Drug

- Search Tip – FDA Guidance Documents> Emergency Use of an Investigational Drug or Biologic Information Sheet

Describe the difference between Expanded Access (or Compassionate Use) drugs and drugs used for Emergency Use

Review the rules for charging subjects for Investigational Drugs

- Search Tip - Charging for investigational drugs under an investigational new drug application
- Search Tip –Charging for Investigational Products - Information Sheet (FDA)

All those involved in human subjects research should take a Good Clinical Practice (GCP) Training course. Although not recommended here, know there are several training courses available if/when needed by a practitioner.

Review the process/conventions for developing generic drug names

- Search Tip –Procedure for Naming A Generic Drug/USAN/AMA
- Search Tip – Generic Name Stems – Drug Informational Portal – US National Library

Review the process for developing proprietary drug names

- Search Tip: How FDA reviews proposed drug names
- Search Tip: Best Practices in Developing Propriety Names for Drugs – FDA

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Complete the FDA case study on bringing a new drug to market

- Search Tip: "FDA Case Study" (from June 2014)

Activities:

- Prepare a short discussion of one the topics presented that was new or interesting to you.

- Review *ASHP Guidelines for the Management of Investigational Drug Products*