

# OHRPP updates

**FDA Inspections**



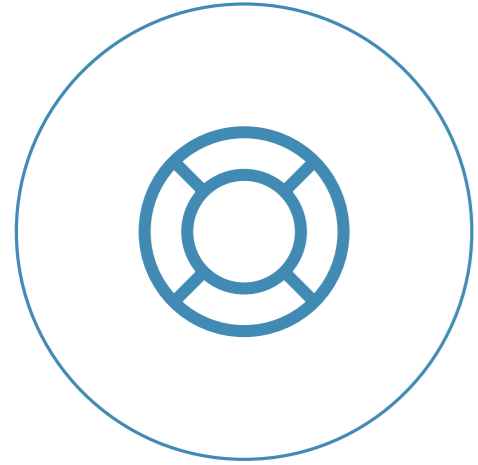
**Training Opportunities**



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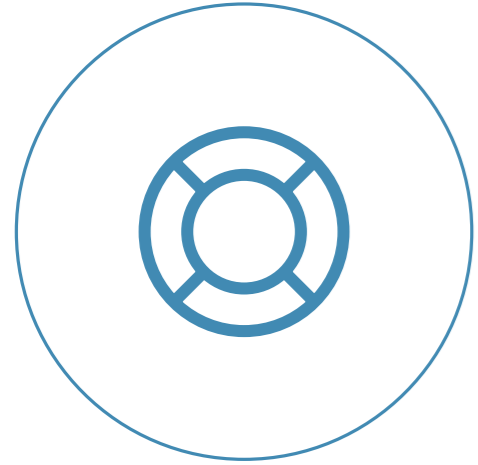
# FDA inspections



## The FDA inspects IRBs

- IRBs are inspected much less frequently than investigators
- The UCLA MIRB1 received a not-for-cause inspection during the week of June 24, 2019
  - The UCLA IRBs were last inspected in 2012
  - The current inspection lasted 3 days
  - Not-for-cause inspections of IRBs can happen as frequently as every 2 years

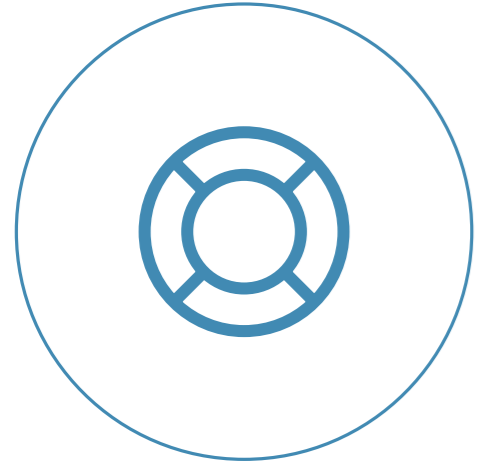
# FDA inspections



## The FDA inspects IRBs

- The outcome of the recent inspection of the UCLA MIRB1 one minor finding (“voluntary action indicated”) not related to patient safety
- FDA inspections of IRBs can possibly trigger for-cause inspections of investigators
  - For example, if there is a glaring omission of reportable events (such as no serious adverse event PARs submitted for a high-risk trial – where other participating sites have submit a large volume of SAE reports)
  - If the IRB is made aware of a pending investigator inspection, we will notify the investigator

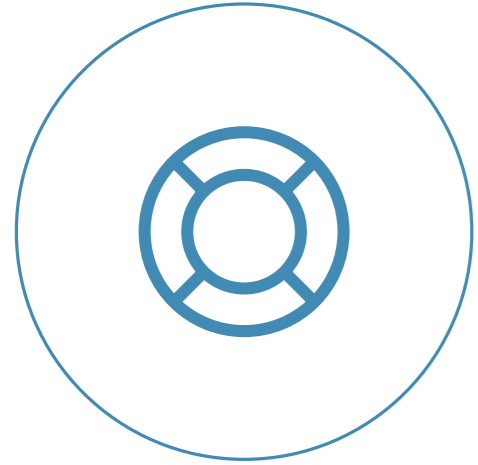
# FDA inspections



## The FDA inspects Investigators

- The FDA identifies clinical investigators for not-for-cause inspections by abstracting names from FDA forms [1571](#) (IND holders) and [1572](#) (clinical investigators)
- FDA inspections of Investigators can possibly trigger inspections of IRBs, so ***please notify the IRB*** if you will be inspected by the FDA
- Also, contact [Marlene Berro](#), UCLA Director of FDA Affairs for assistance with your FDA inspection
  - For more information on FDA Inspections of investigators, please visit the CTSI “[Research Go](#)” page

# FDA inspections



## The FDA inspects to the regulations

- For both IRBs and Investigators, the FDA Inspector may provide verbal comments about their ideas of best practices, but the written findings from their inspections should only reflect regulatory requirements.
- Nevertheless, it is in the best interest of Investigators and IRBs to follow written FDA guidance (as best practice)

# OHRPP Training Opportunities - Reminder



OHRPP Quality Improvement Unit ***will come to your division/department for IRB-related training, customized to your needs.***

*Recent examples include:*

- IRB Submission Basics
- Revised Common Rule

➤ *To request a training, please contact: OHRPP Assistant Director, Education & Quality Improvement Moore Rhys (310) 794-6339*

# OHRPP “Human Research News” - Reminder



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