Presentation Title	Dates
FDA Site Inspection Guide: Your Best Tool for Preparing The Food and Drug Administration (FDA) conducts site inspections of clinical investigators involved in FDA-regulated clinical trials to determine compliance with applicable regulations. The HSO's FDA Site Inspection Guide provides practical advice for Principal Investigators (PI) and research staff undergoing an FDA inspection. The Guide outlines step-by-step pre-inspection preparations, recommended study team conduct during the inspection, potential post-inspection outcomes, and directions for post-inspection activities. This presentation will illustrate where to find the Guide, provide a high-level review of its contents, and how to use it to prepare for an FDA Site Inspection.	**Wednesday, February 15, 2023** **12:00 PM-1:00 PM** Zoom
Top 10 Reasons People Come to Office Hours and the Guidance we Give IRB Office hours are a resource for all UI Faculty, staff, investigators, HawkIRB delegates, and research team members involved with Human Subjects research. While each new project is unique, there are some topics and questions that come up regularly during office hours sessions. Join us for a review of commonly queried topics such as consent, human subjects research determinations, expedited/exempt applications, modifications, single IRBs and external IRBs and best practices for first time application submissions.	**Tuesday, February 21, 2023** **12:00 PM-1:00 PM** Zoom
Human Subjects Research Hot Topics & Updates – March 2023 Learn about new initiatives, HawkIRB enhancements (rolled out or in-production) and important information/reminders from the Institutional Review Board (IRB) and the UI Human Research Protection Program (HRPP). To supplement the information provided in the monthly IRB Connection Newsletter, the Human Subjects Office (HSO) offers these presentations at least three times a year to disseminate information in a timely manner and to be transparent about current projects and initiatives. Attendees will gain knowledge and resources necessary to design research projects, prepare thorough HawkIRB applications and effectively oversee the conduct of human subjects research. Target audience: • Principal Investigators (PIs) • Faculty Advisors for student PIs • Study Coordinators • IRB Liaisons • Departmental Research Administrators • Others involved in human subjects research administration or oversight The topics will be announced closer to the date of the presentation.	**Wednesday, March 22, 2023** **11:30 AM-12:30 PM** Zoom

ClinicalTrials.gov Reporting Requirements: Consequences for Noncompliance Simply registering a research study with ClinicalTrials.gov is not enough to comply with federal regulations and NIH policies. Responsible parties (PIs) of "Applicable Clinical Trials" or "NIH-funded clinical trials" are required to report both scientific and administrative information on trial outcomes no later than 1 year from the primary completion date. This presentation will provide an overview of: • ClinicalTrials.gov results reporting requirements • Anticipating a delay in results submission –good cause extension • Consequences for failure to comply with results reporting requirements • How to prevent violations of federal regulations and NIH policies	**Tuesday, April 4, 2023** **10:00 AM-11:00 AM** Zoom
Casting the Net: Research Ethics in the Age of Social Media Social media offer a wealth of data for researchers as well as ethical questions for researchers and IRBs. While federal regulations do not specifically reference social media, human subjects research through social media platforms must still comply with federal and institutional policies. This presentation will help researchers navigate ethical issues that arise during human subjects research using social media data. The following are some of the topics we will address to help researchers navigate IRB review of human subjects research with social media data: • Determining if a study is "human subjects research" • Recruitment on various social media platforms • Terms of Service and permissions to access data • Informed Consent: When is it required? How to obtain it? • Privacy and confidentiality	**Wednesday, April 19, 2023** **11:00 AM – 12:00 PM** Zoom