OHRP RESEARCH COMPLIANCE UPDATE: 2022

Laura Odwazny, J.D., M.A.
Office of the General Counsel
U.S. Department of Health and Human Services

1

Disclaimer

- *This presentation does not constitute legal advice. The views expressed are the presenter's own, and do not bind the U.S. Department of Health and Human Services or its components.*

2

2

THE COMMON RULE AND OHRP JURISDICTION

3

Federal Protection of Human Subjects regulations

- U.S. Federal Policy for the Protection of Human Subjects – "Common Rule" (1991)
  - Applies to 20 Federal Departments and Agencies
- Research initiated after January 21,2019 must follow the revised Common Rule (older research grandfathered under prior version of the Common Rule)
- Some Common Rule agencies have adopted additional regulatory protections and requirements
  - E.g., HHS human subjects regulations include Subparts B (pregnant women, fetuses and neonates), C (prisoners), D (children), E (IRB registration)

4

Regulatory Protections

Three basic protections for human subjects:

- **Institutional Assurances**
  - Each institution engaged in human subject research must provide an assurance to the appropriate Dept/Agency that it will comply with the regulations
  - OHRP currently only issues the Federalwide Assurance (FWA), although other Common Rule agencies may issue their own assurances
- **Institutional Review Board (IRB) approval** necessary prior to beginning non-exempt human subjects research
- **Informed consent** of human subjects prior to research involvement
  - May be waived in certain circumstances

5

Determining Applicability of Common Rule

- **Research involving human subjects conducted or supported by Common Rule department or agency**

- **Non-exempt human subject research covered by a Federalwide Assurance (FWA):**
  - Currently, if research institution voluntarily extends FWA to all research regardless of funding source, OHRP can extend jurisdiction to privately funded research
  - Revised Common Rule preamble states plan to eliminate voluntary extension of FWA, although hasn't happened yet

6

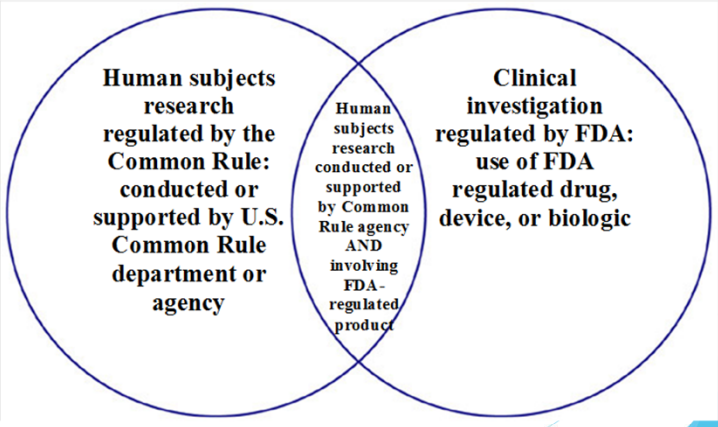
Common Rule vs. FDA Regulations: 45 CFR part 46 vs. 21 CFR parts 50 and 56

- Basic requirements for IRBs and for informed consent are congruent
  - 21st Century Cures now allows FDA to implement waiver of informed consent
- Differences in applicability
  - Common Rule based on U.S. Federal Common Rule agency conducting or supporting human subjects research
  - FDA regulations based on use of FDA regulated product: drugs, devices, or biologics

7

Jurisdiction: Common Rule vs. FDA

- An activity may be regulated under both the Common Rule and FDA informed consent and IRB regulations: e.g., a clinical trial conducted at the NIH Clinical Center that is comparing two FDA-regulated drugs



8

Jurisdiction: Institutions and IRBs

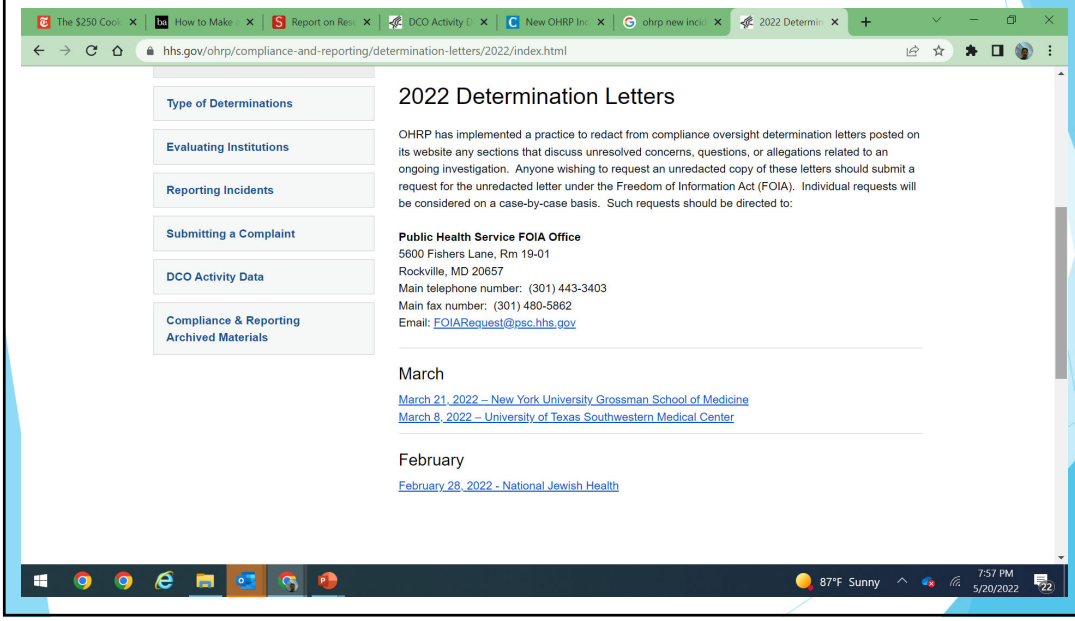
- OHRP exerts jurisdiction over institutions, not directly over investigators
- Revised Common Rule codified OHRP's jurisdiction over independent IRBs

9

OHRP COMPLIANCE ACTIVITIES--2022

10

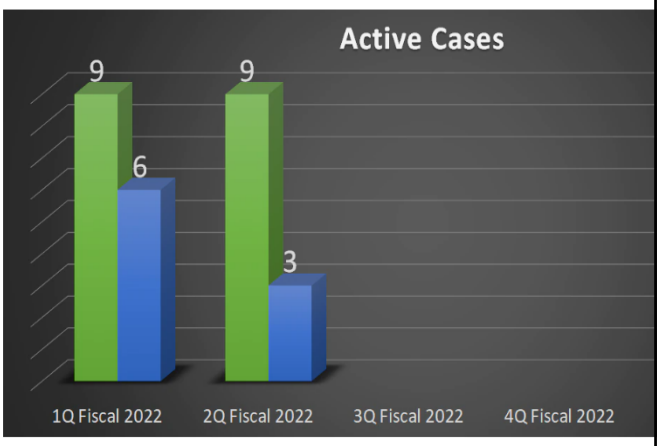
New OHRP Determination Letters



11

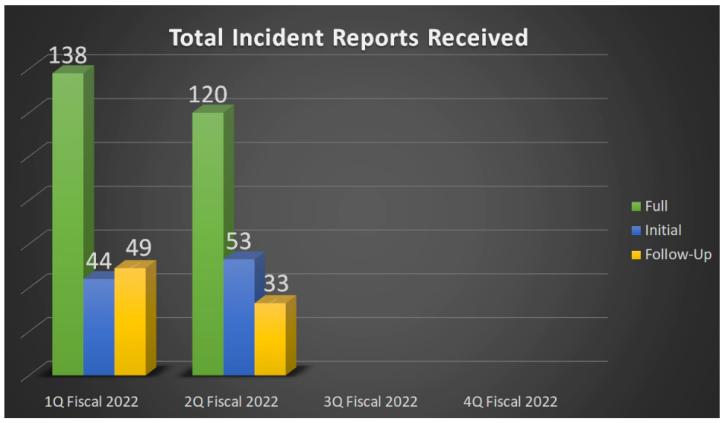
OHRP Division of Compliance Oversight (DCO) Activity Logs FY 2022 - Cases

- For cause: written substantive allegations or indications of noncompliance
- Not for cause: no specific allegations
  - Geographic location
  - Large volume of HHS research
  - Not submitting incident reports
  - Accreditation status
  - Audits of other regulatory agencies
  - Need to evaluate implementation of corrective actions from prior OHRP compliance action



12

OHRP Division of Compliance Oversight (DCO) Activity Logs FY 2022 -IRPTs



Full reports are complete reports

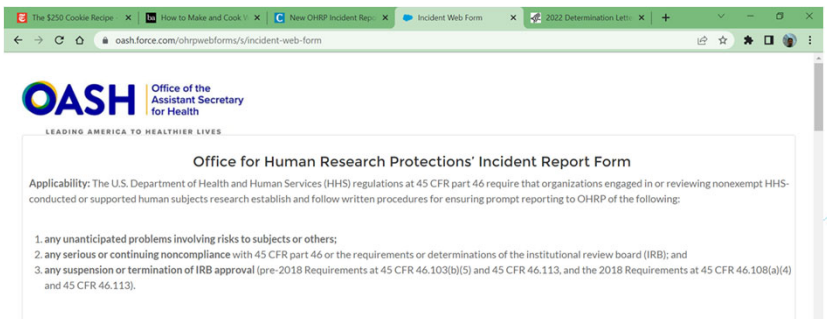
Initial reports require a follow-up report: the institution has not implemented a corrective action plan or has not completed gathering all information

Unanticipated problems involving risks to subjects or others;
serious or continuing noncompliance;
suspensions or terminations of IRB approval.

13

New OHRP Online Incident Reporting Form

- Online form **must** be used unless institution does not have capacity
- Instructions: https://www.hhs.gov/sites/default/files/irpt-pra-instructions.pdf



14

NEW OHRP GUIDANCE

15

Instructions for posting clinical trials informed consent forms (March 29, 2022)

- What clinical trials must meet this requirement
- Where to post
- When to post
- What version to post
- Transitioned research
- Cooperative research
- Posting requirement is not applied to “check the box” research

- https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/informed-consent-posting-guidance/index.html

16

REGULATORY FLEXIBILITIES: RESEARCH CONDUCTED DURING COVID-19 PANDEMIC

17

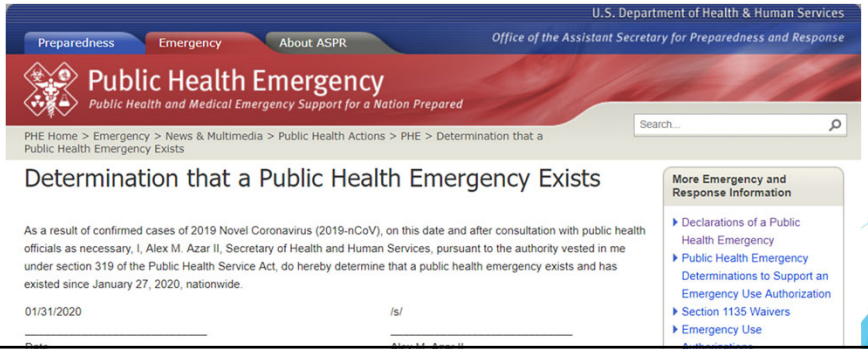
HHS COVID-19 Public Health Emergency Declaration

Public Health Emergency (PHE) is declared by the Secretary of HHS. When declared, the Secretary may:

- Take such action as may be appropriate to respond to the PHE including making grants; entering into contracts; and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder.
- Detail employees of the Department to awardee to aid in carrying out the award.
- Use funds appropriated to the Public Health Emergency Fund to immediately respond to the PHE by facilitating coordination among Federal, State, local, Tribal and territorial entities and public and private health care entities; supporting advanced research and development and biosurveillance; "and other actions determined appropriate and applicable by the Secretary."
- Grant extensions or waive sanctions relating to submission of data or reports required under HHS laws, when the Secretary determines that as a result of the PHE, individuals or public or private entities are unable to comply with deadlines for such data or reports.

18

- Secretary Azar, Determination that a Public Health Emergency Exists. (1/31/20, latest renewal 4/16/2022 by Secretary Becerra), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx
- Letter to Governors 1/22/2021: HHS will provide states with 60 days notice prior to the termination of the public health emergency declaration for COVID-19



19

- FDA's "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency"(issued on March 18, 2020 and subsequently updated)
  - "FDA is issuing this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity for the duration of the COVID-19 public health emergency."
- OHRP's guidance: "OHRP Guidance on COVID-19" (April 2020)
  - Statement that FDA's COVID-19 guidance (version issued on March 18, 2020 and as updated on April 2, 2020) is consistent with the Common Rule
- OHRP sIRB exception –COVID-19 (October 2020)
  - Cooperative research conducted or supported by HHS that is ongoing or initially reviewed by the IRB during COVID-19 public health emergency, as declared by the Secretary of HHS
  - Applies for the duration of the research

20

Thank you for your interest in protecting human subjects!

Questions?

21