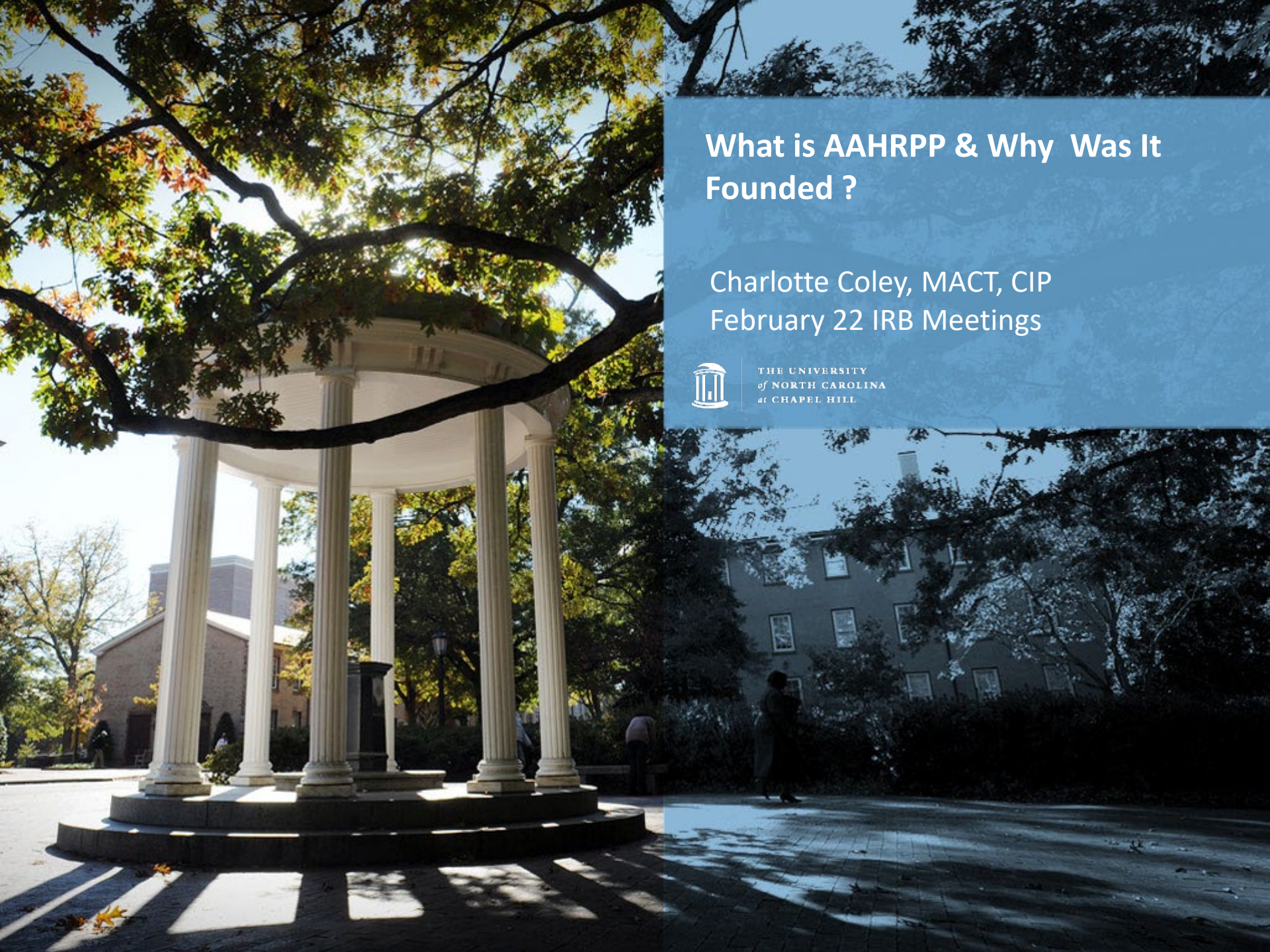


What is AAHRPP & Why Was It Founded ?

Charlotte Coley, MACT, CIP

February 22 IRB Meetings

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

COI Disclosure

AAHRPP consulting:

- serve as a Step 1 Reviewer
- serve as a Site Visitor for initial & re-accrediations

20th Anniversary 2000-2020

https://www.aahrpp.org/

AAHRPP Process

Step 1: submit SOPs. Checklists, templates, etc

Step 2: site visit team visits in person or via zoom for 2+ days of interviews with researchers, IO, leadership, staff, IRB members

Goal: how does the institution protect research subjects, what guidelines are used and do you do what you said you do in your SOPs?

Pre-2000

- Most IRB Offices very small part-time staff
- Often SOPs existed in the head of the IRB Chair
- No written guidelines
- Everything done on paper and in multiple copies
- Only primary reviewer got a paper copy of the protocol, other upon request

Research Design World Shift

Then--1974

45CFR46

Revised Common Rule

Now

History that prompted the need for accreditation

- Series of Inspector General Reports in late 1990s
- Serious Adverse Events/non-compliance
- NIH Office of Protection from Research Risks (OPRR) shutdowns of several prominent programs 1999-2000

The Washington Post

WEDNESDAY, MAY 12, 1999

U.S. Halts Research On Humans at Duke

University Can't Ensure Safety, Probers Find

By RICK WEISS
Washington Post Staff Writer

The U.S. government has temporarily shut down federally funded research on humans at Duke University Medical Center, one of the nation's largest and most prestigious medical research facilities, after federal investigators determined that the university could not ensure the safety of participants.

Among the problems cited by the government in its May 10 suspension letter to Duke were an oversight committee's failure to keep track of human studies after they began—the only way to make sure people are not being unexpectedly harmed by research—and a failure to document that special, federally mandated protections for children were in place.

Jesse Gelsinger (1999)

18-year-old with mild OTC deficiency

Conflicts of Interest

- Genovo owned patent on the adenovirus vector
- Genovo provided 20% of the annual research budget for Institute for Human Gene Therapy (IHGT) of University of Pennsylvania
- James Wilson (the PI on the OTC trial) was founder and 30% shareholder in Genovo
- Genovo had exclusive rights to develop Wilson's research into commercial products
- University of Pennsylvania held 5% equity in Genovo

Ellen Roche
(2001)

Healthy Subject on an Asthma Study

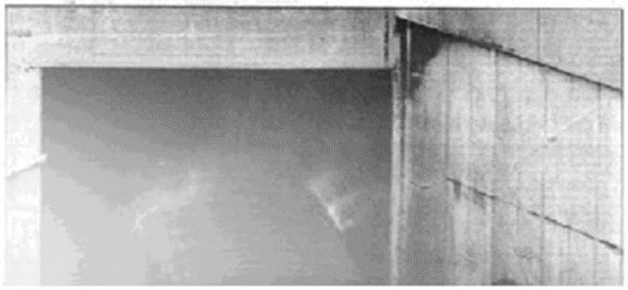
THE SUN

Friday, July 20, 2001 HOWARD COUNTY Baltimore, Maryland : 50 cents

U.S. halts Hopkins research

CHEMICAL TRAIN FIRE

Burning cars in rail tunnel resist control



Most experiments on human subjects ordered suspended

Federal funding withheld

Oversight agency decries safety lapses in volunteer's death

By Jonathan Bor and Tom Pelton
SUN STAFF

Seven weeks after the death of a young woman in an asthma study, the federal government suspended hu-

The response

Excerpts from the Johns Hopkins University's response to the federal Office of Human Research Protection:

"This action was taken in utter disregard of patients' health and potentially of life. ... [The suspension] seems to us to be an extreme example of regulatory excess."

Full text [Page 14a]

More inside

Impact: When regulators shut down research on human subjects, "It's devastating," one university official

FDA Audit Findings @ Hopkins

"… an investigation into the death of a healthy volunteer…"

- "You failed to submit an IND…"
- "You did not supply adequate animal toxicity data"
- "You failed to submit a summary of previous human studies"
- "…you failed to promptly report unanticipated problems…"


APRIL 22, 2002
Powell's Mission Impossible
TIME
HOW MEDICAL TESTING HAS TURNED MILLIONS OF US INTO ...
HUMAN GUINEA PIGS
www.time.com AOL Keyword: TIME

Most Common Investigator Violations

- Failed to retain records
- Failed to notify the IRB of AEs
- Failed to report AEs to the sponsor
- Inadequate informed consent form

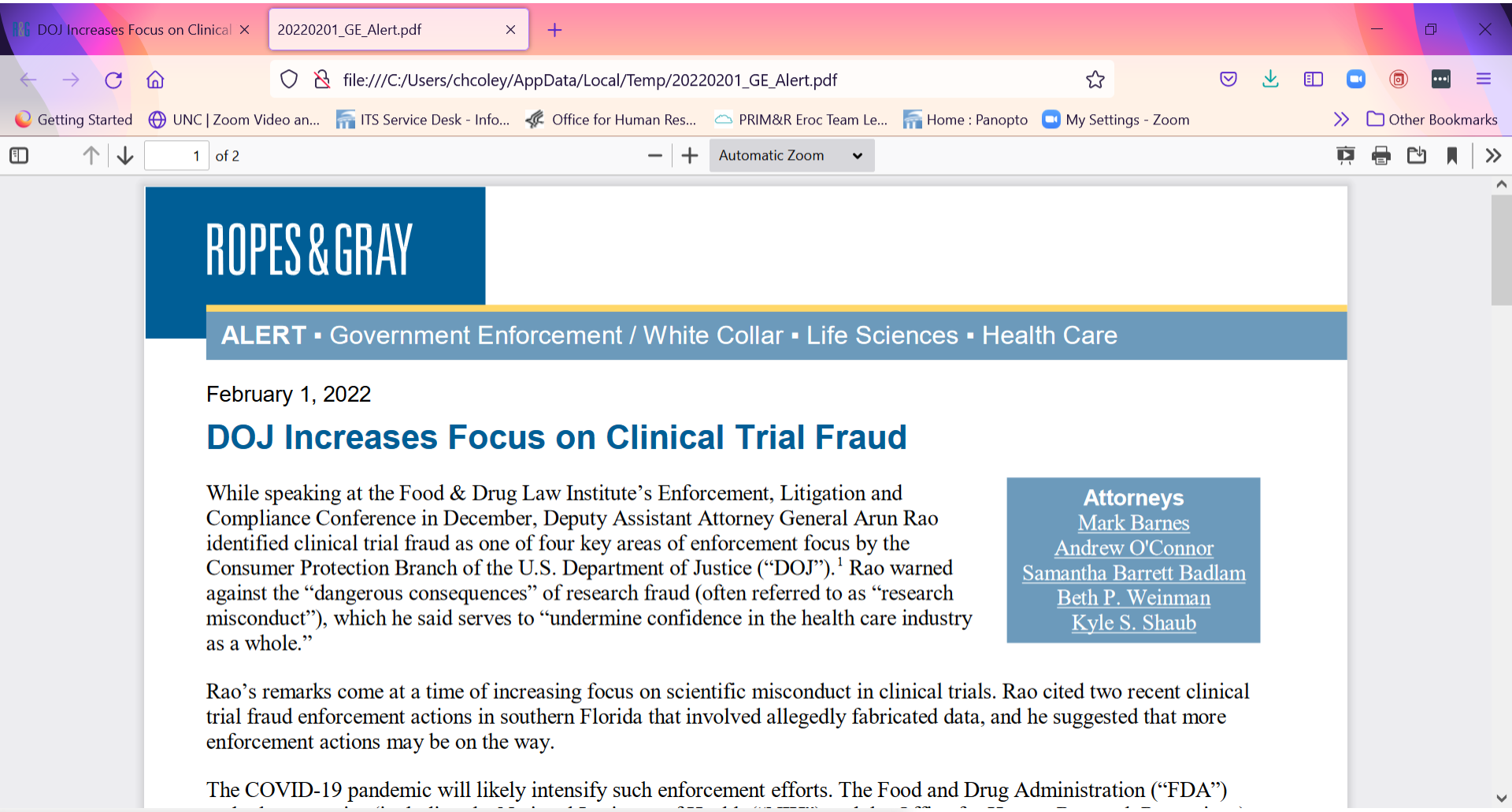
DHHS OIG report: FDA Oversight of Clinical Investigators (June 2000)

Most Serious Investigator Violations

- Enrollment exceeded protocol or IRB limit
- Did not conduct required evaluations related to safety assessments
- Violated clinical hold
- Submitted false information to the sponsor
- Used unapproved product without IND

DHHS OIG report: FDA Oversight of Clinical Investigators (June 2000)

Research Integrity Remains a priority



DOJ Increases Focus on Clinical | 20220201_GE_Alert.pdf

file:///C:/Users/chcoley/AppData/Local/Temp/20220201_GE_Alert.pdf

Getting Started | UNC | Zoom Video an... | ITS Service Desk - Info... | Office for Human Res... | PRIM&R Eroc Team Le... | Home : Panopto | My Settings - Zoom | Other Bookmarks

1 of 2 | Automatic Zoom

ROPES & GRAY

ALERT ▪ Government Enforcement / White Collar ▪ Life Sciences ▪ Health Care

February 1, 2022

DOJ Increases Focus on Clinical Trial Fraud

Attorneys
Mark Barnes
Andrew O'Connor
Samantha Barrett Badlam
Beth P. Weinman
Kyle S. Shaub

While speaking at the Food & Drug Law Institute's Enforcement, Litigation and Compliance Conference in December, Deputy Assistant Attorney General Arun Rao identified clinical trial fraud as one of four key areas of enforcement focus by the Consumer Protection Branch of the U.S. Department of Justice ("DOJ").[1] Rao warned against the "dangerous consequences" of research fraud (often referred to as "research misconduct"), which he said serves to "undermine confidence in the health care industry as a whole."

Rao's remarks come at a time of increasing focus on scientific misconduct in clinical trials. Rao cited two recent clinical trial fraud enforcement actions in southern Florida that involved allegedly fabricated data, and he suggested that more enforcement actions may be on the way.

The COVID-19 pandemic will likely intensify such enforcement efforts. The Food and Drug Administration ("FDA")

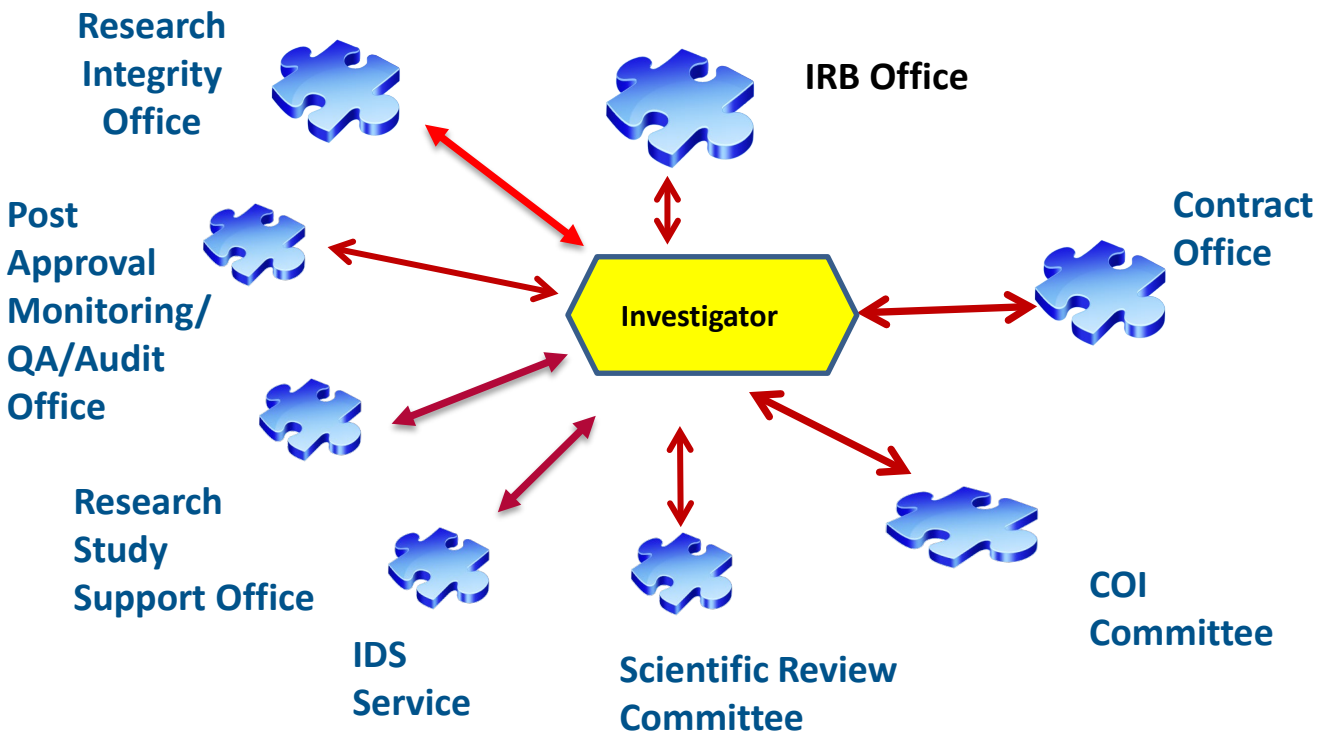
Our Mission, Vision, and Values

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP***) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs).***

An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence—through policies, procedures, and practices—of their commitment to scientifically and ethically sound research and to continuous improvement.

As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence.

The HRPP Puzzle



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