

• GU • HU • MHRI • ORNL • WDCVAMC •



GHUCCTS

**Georgetown-Howard Universities
Center for Clinical and Translational Science**

Georgetown University | Howard University
MedStar Health Research Institute | Oak Ridge National Laboratory | Washington DC Veterans Affairs Medical Center

Workshop Organizers/Planners

- Jane Otado, PhD. Director, REKS
- Priscilla Adler, MBA ICR/DC VAMC REKS member
- Claudia Gunawan, MS ICR/DC VAMC REKS member
- Mary Anne Hinkson, MBA, Vice President for Research Administration – MedStar Health Research Institute
- Shaunagh Browning, DNP, RN, CRN-BC Senior Director for Office of Human Subjects Protection, Georgetown University

Introduction to GHUCCTS



Georgetown-Howard Universities Center for Clinical and Translational Science

Partnership of five institutions with the mission of improving the infrastructure that supports high quality multidisciplinary clinical and translational research.



Georgetown
University



HOWARD
UNIVERSITY



MedStar Health
Research Institute



WASHINGTON DC
VETERANS AFFAIRS MEDICAL CENTER
CAPITOL ★ EXCELLENCE



Georgetown University | Howard University | Oak Ridge National Laboratory
MedStar Health Research Institute | Washington DC Veterans Affairs Medical Center



GHUCCTS Mission

Improving the infrastructure that supports research

**To effectively translate new scientific discoveries into
improvements in health care**

Cultivate collaboration
through Team Science



Reduce barriers to the
research process



Foster inclusion of
underserved populations



Georgetown University | Howard University | Oak Ridge National Laboratory
MedStar Health Research Institute | Washington DC Veterans Affairs Medical Center



Who Can Use GHUCCTS Services?

Team members conducting or planning to conduct IRB approved research at any of the GHUCCTS' institutions



Investigators



Research
Nurses



Study
Coordinators



Trainees

Georgetown University | Howard University | Oak Ridge National Laboratory
MedStar Health Research Institute | Washington DC Veterans Affairs Medical Center



GHUCCTS Services



Consultation
Services and
Recruitment
Support

- Biostats & Bioinformatics
- Community & Participant Engagement
- Inclusion of Diverse Populations
- Recruitment
- Outreach events



Trial Innovation
Network



Training and
Workshops



Pilot Funding



Mentored Career
Development



Research
Resources

- Clinical Research Unit (CRU)
- Regulatory Services
 - IRB
 - SEPCOM

Georgetown University | Howard University | Oak Ridge National Laboratory
MedStar Health Research Institute | Washington DC Veterans Affairs Medical Center



Regulatory, Ethics & Knowledge Support (REKS)

Provides ethical consultation to GHUCCTS investigators in the design and implementation of clinical and translational research

**Expert guidance
and assistance**



Promotion of safety and protection of
research participants

Development innovative training and
educational resources for investigators

Facilitation of the regulatory management of
intra- & inter-institutional CTSA research

Georgetown University | Howard University | Oak Ridge National Laboratory
MedStar Health Research Institute | Washington DC Veterans Affairs Medical Center

Human Subject Protection Regulations – Where do I find them?

[45 CFR 46 | HHS.gov](#)

[Part 11, Electronic Records; Electronic Signatures - Scope and Application | FDA](#)

[eCFR :: Title 21 of the CFR -- Food and Drugs](#)

45 CFR 46 – DHHS Protection of Human Subjects



- Subpart A – Basic policy includes IRB functions and membership; criteria for IRB approval; informed consent documentation
- Subpart B – Additional protections for pregnant women, human fetuses & neonates in research
- Subpart C – Additional protections for research involving prisoners as subjects
- Subpart D – Additional protections for children
- Subpart E – Registration of IRBs

Human Subject Protection Regulations – Where do I find them?

European Union (EU): The European Medicines Agency (EMA) plays an important role in the **harmonization and co-ordination** of GCP-related activity at an EU level.

For more information on clinical trial authorization, safety monitoring, GCP inspections, and GCP and GMP requirements for clinical trials in the European Union see [volume 10: clinical-trial guidelines](#) of the rules governing medicinal products in the EU.

Regulatory Updates – Recent Revisions of ICH/GCP and Declaration of Helsinki



- Participants (not subjects)
- Zero tolerance for research misconduct.
- Focuses on inclusion, respect and fair treatment.
- Emphasises equitable treatment and fair distribution of research benefits, risks and burdens

Informed Consent Updates

Priscilla Adler, MBA

Institute for Clinical Research, Inc.

Washington DC VA Medical Center



WHY CHANGES ARE IMPORTANT

- Informed consent is moving from just a document to a continuous ethical process
- Regulatory bodies (FDA, ICH) have updated requirements to improve participant comprehension, transparency and protection.
- Clinical Research staff play central role in implementing these updates.

Major Regulatory Sources Updated

- FDA – Harmonization with Common Rule
- ICH GCP E6(R3) – Finalized 2025
- IRB/EC trends – emphasis on comprehension and the continuing process of consent

FDA UPDATES



Harmonization with Common Rule

- FDA now aligns with 45 CFR 46.116(f) for waivers/alterations of consent
 - Waivers allowed only when:
 - Research involves minimal risk
 - Consent is impracticable
 - Rights/welfare of subjects are protected
 - Greater consistency across federally funded and FDA-regulated research

FDA Draft Guidance – Key Information



- Required key information section at the beginning of the consent form
- Must explain
 - Why someone might want to participate
 - Why someone might not want to participate
- Must be concise
- Must be in layman's terms
- Must be participant-centered

FDA: New Basic and Additional Consent Elements



- New Basic Element: Clear reasons to participate or decline
- New Additional Elements
 - Foreseeable risks
 - Costs to participants
 - Consequences of withdrawal
 - Early termination
 - Communication of new findings
 - ClinicalTrials.gov
 - Alignment with Common Rule structure

ICH GCP
E6(R3)
Consent
Key Updates



ICH GCP Updated Consent Framework

- Consent is an ongoing, continuous process
- Strong emphasis on participant's comprehension
- Encourages eConsent and other electronic formats to increase comprehension
- Requires documentation of ongoing consent interactions
- Reinforces prohibition of exculpatory language

Implications for Coordinators

- Use plain language
- Confirm understanding (teach back)
- Re-consent participants when new information emerges
- Document consent conversations throughout the study

Other Considerations

- Post-trial access refers to the continued provision of an investigational drug or device to clinical-trial participants after the study ends, based on ethical principles outlined in frameworks such as the Declaration of Helsinki (2024 revision).
- Post-Trial Access – must be arranged in advance and disclosed in consent
- Ensure consent forms reflect accurately post-trial access plans

Consent as a Continuous Process

- Ensure continuous communication throughout participation
- Ensure voluntariness
- Ensure comprehension
- Ensure ongoing right to withdraw

Special Considerations for E-Consents

- Research staff must ensure adherence to data governance guidelines to safeguard participant privacy and secure data streams.
- Data governance defines **standards, policies, and procedures** for data collection, storage, usage, and protection.

Checklist to Ensure Consents are Updated

- Include Key Information section
- Use plain language and check comprehension via teach-back methods
- Provide e-consent/multimedia learning tools when appropriate
- Document ongoing consent interactions
- Disclose post-trial access plans

Summary

- Focus is now on comprehension, transparency and participant autonomy
- CRCs are essential to implementing these changes in daily practice
- Updated consent processes strengthen participant trust and study integrity



ICH E6 (R3): What's New



Key Takeaways

- Not a minor update but a major philosophical and structural overhaul of GCP
- R3 modernizes GCP to support flexible, risk-proportionate approaches

Timeline for Adoption

- Principles and Annex 1 adopted: 6 January 2025
- Annex 2 adopted: 3 June 2026
- Consolidated guideline published: 16 June 2026
- Annex 2 effective date (EMA): 15 January 2027
- R3 replaces R2 as the unified GCP standard

Structural Changes

- R2: Single document with Sections 1-8
- R3: Layered structure:
 - Principles & Objectives
 - Annex 1: Traditional interventional trials
 - Annex 2: Non-traditional designs (decentralized, pragmatic, real-world data)
- Restructuring supports better clarity, flexibility and modern trial designs

Philosophical Shift from R2 to R3

- R2: prescriptive, uniform procedural rules
- R3: Quality by Design (QbD) and risk-proportionate approaches
- Sponsors must now design quality into the trial
- One size does not fit all

Principles of R3

- Participant rights, safety and well-being
- Scientific soundness and data reliability
- Proportionate approaches based on risk
- Transparency (results reporting)

Annex 1: Interventional Trials

- More flexible monitoring approaches
- Updated expectations for investigator oversight
- Modernized guidance on electronic systems and data governance
- Revised essential document framework.

Annex 2: Non-Traditional Designs

- Decentralized clinical trials
- Pragmatic trials
- Trials using real-world data

Investigator Responsibilities

- Oversight must be *documented and proportionate* to trial complexity.
- Increased expectations for managing digital tools, remote processes, and data integrity.
- More explicit requirements for delegation, training and supervision.
- Widened training scope of R3 requires subinvestigators and any other research staff making medical decisions to be properly qualified by education, training and experience.

Practical Steps for Sites

- Update SOPs to align with risk-based approaches
- Strengthen delegation and training documentation
- Review digital tools for compliance with R3 expectations
- Prepare for hybrid monitoring visits and remote data review
- Ensure consent processes (including eConsent) meet new clarity standards.

ALCOA/ALCOA+/ALCOA++

- The **ALCOA framework** is a set of standards for clinical trial documentation to maintain data integrity and regulatory compliance under ICH GCP guidelines
- Alcoa – Attributable, Legible, Contemporaneous, Original and Accurate
- Alcoa+ - adds Complete, Consistent, Enduring and Available (account for data governance of wearables and electronic data streams)
- Alcoa++ - European Medicine Agency (EMA) adds traceability across digital systems.

Summary



- R3 emphasizes flexibility, critical thinking and proportionate approaches while reinforcing the core values of participant protection and data integrity/reliability

Workshop Evaluation

