

# Good Clinical Practice

Sarah Temkin, MD

# What is Good Clinical Practice?

- Good Clinical Practice (GCP) is an international ethical and scientific standard for conducting biomedical and behavioral research involving human participants.
  - The objective of this guideline is to provide a unified standard across the European Union (EU), Japan, the United States, Canada, and Switzerland to facilitate the mutual acceptance of data from clinical trials by Regulatory Authorities.
- The current system of Good Clinical Practice has evolved, in part, in response to revelations of past episodes in which research participants were grossly abused.
- Outlines the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data) of clinical trials.

# Why is GCP training necessary?

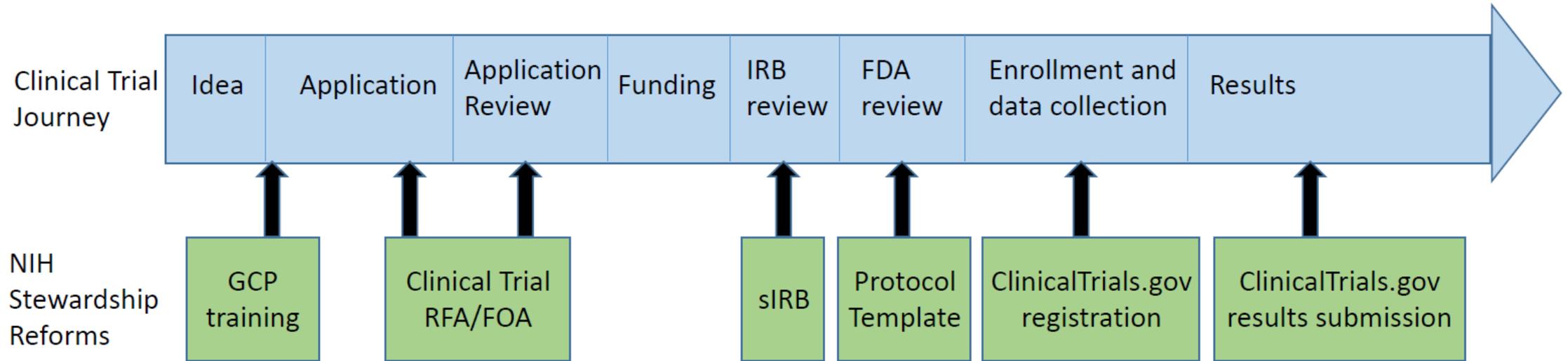
- This training is important for all staff involved in Clinical Research and ensures an understanding of the principles adopted in research.
- GCP is widely accepted and expected in all research involving human participants.
- GCP is not specific to a protocol, but rather is general and applicable to all protocols.

# International Conference on Harmonization: GCP Principles

- Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
- Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial participant and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
- The rights, safety, and well-being of trial participants are the most important considerations and should prevail over the interests of science and society.
- The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
- Clinical trials should be scientifically sound and described in a clear, detailed protocol.
- A trial should be conducted in compliance with a protocol that has received prior institutional review board (IRB) approval.
- The medical care given to, and medical decisions made on behalf of, participants should always be the responsibility of a qualified physician or, when appropriate, a qualified dentist.
- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
- Freely given informed consent should be obtained from every participant prior to clinical trial participation.
- All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.
- The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
- Systems with procedures that assure the quality of every aspect of the trial should be implemented.

# Improving Clinical Trials: “Toward a New Era of Trust and Transparency in Clinical Trials”

Kathy L. Hudson, PhD; Michael S. Lauer, MD; Francis S. Collins, MD, PhD



**eFigure. Improving Clinical Trials.** The new, multifaceted effort shown above will enhance the quality and efficiency of NIH-supported clinical trials by focusing on a variety of key points along the “lifespan” of a clinical trial.

# GCP requirement is the first step in improving clinical trials (NIH)

- NIH requires Good Clinical Practice (GCP) training for investigators and NIH staff responsible for conducting or overseeing clinical trials.
- The aim is to help ensure that all involved in the clinical trial enterprise have the appropriate knowledge about the design, conduct, monitoring, recording, analysis, and reporting of clinical trials.
- While GCP training on its own may not be sufficient, it provides a consistent and high-quality standard.

Notice Number: NOT-OD-16-148

Key Dates

**Policy effective Date:** January 1, 2017

- Purpose
- **Policy Statement**
- This policy establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonization (ICH) E6
- The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data)

# Background

- GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials.
  - The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States.
  - The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.
- GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials.
  - Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.
- GCP training complements other required training on protections for human research participants.
  - Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of a research involving human subjects.

# Scope and Applicability

- This Policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials.
- GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization.
  - Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants.
  - GCP training should be refreshed at least every three years
  - Recipients of GCP training are expected to retain documentation of their training.
- *Investigator*: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- *Clinical trial staff*: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

# Resources

- Biomedical Research:

**CITI:** [citi.psu.edu](http://citi.psu.edu)

**NIAID:** <http://gcplearningcenter.niaid.nih.gov/>

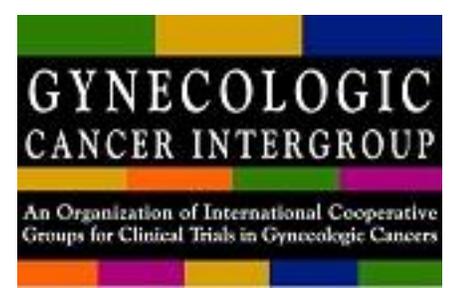
**Clinical Trial Network:** <https://gcp.nihtraining.com/>

GCP Training taken through CITI will be automatically recorded in CATS IRB. Completion reports from any other GCP training should be sent to [IRB-ORP@psu.edu](mailto:IRB-ORP@psu.edu).

For questions related to this new NIH-imposed training requirement or about which GCP training is most appropriate for you, please contact your IRB Analyst or the IRB Program at [IRB-ORP@psu.edu](mailto:IRB-ORP@psu.edu).

- Questions?

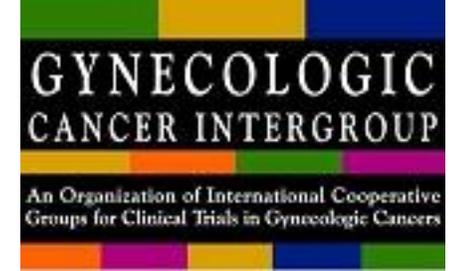
# QA working group Bryce/Brand/Farrelly



## Topics:

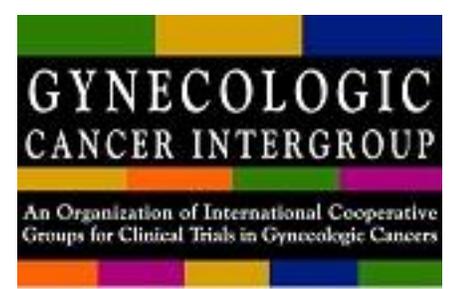
- Important changes to GCP
- Current projects taken on by QA to respond to GCP addendum and strategic planning objectives
- Brainstorming day proposal

# ICH-E6(R2) Summary of changes



- Investigator oversight of their site
- Source documents
  - ALCOA - Attributable Legible, Contemporaneous, Original and Accurate
  - ALCOAC - + Complete
- Recording of location of documents by sites
- Sponsor oversight of vendors
- Quality management – risk based
- Risk based monitoring
- Serious breaches to the protocol or GCP
- TMF may contain more than ICH E6 s 8
- Monitoring plan and monitoring report
- Electronic systems and data handling

# QA working group

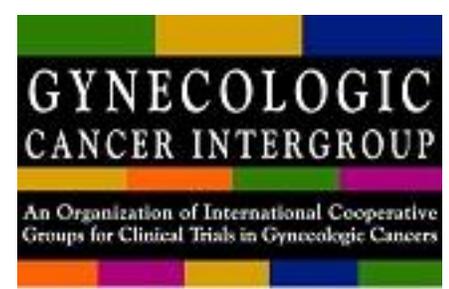


## ONGOING PROJECTS / OBJECTIVES

- Consensus on min evidence of GCP compliance
- Vendor assessment
- Site qualification by groups
- Minimum elements in a trial QA plan
- Standards for assessing trial risk and centralized monitoring.

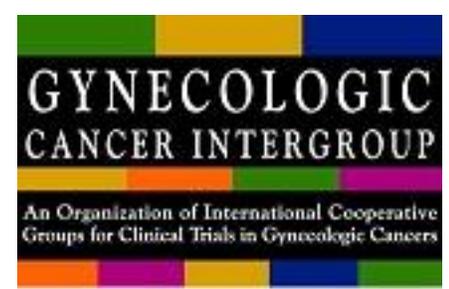
# QA brainstorming day 3

## Breakouts



- A. Evidence of GCP Compliance (QA documentation Standards for GCIG)
- B. Trial QA plan - Standards for assessing risk and centralized monitoring
- C. Vendor/partner assessment (includes site evaluation)

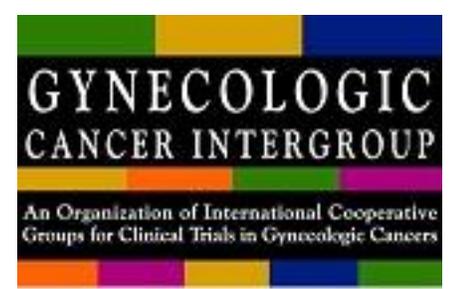
# QA working group



## Vendor assessments

- GCIIG Template vendor assessment for collaborative groups
- Laboratory vendor assessment

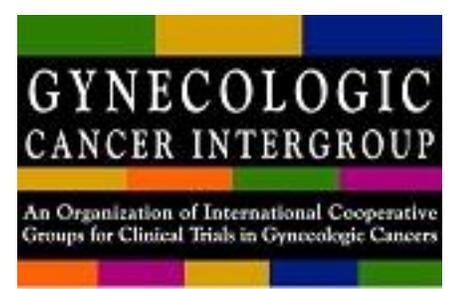
# QA working group



## Trial QA plan

- Standards for assessing risk and centralized monitoring

# QA working group



## Site evaluations

- Site selection checklist
- Site qualification review



Gynecologic Cancer Intergroup

draft v1

**QUALITY ASSURANCE      BRAINSTORMING**

November 2, 2017, 8:00am – 2:00pm, XXXXXXXXXXXXXXXX, Vienna

Chair: Jane Bryce

Co-Chairs: Alison Brand and Laura Farrelly

**PROGRAM**

Please sign in on attendance sheets

- 8:00am      Welcome and Introductions
  - 8:15am      A. Evidence of GCP Compliance (QA documentation Standards for GCI)
  - 8:45am      B. Standards for assessing risk and centralized monitoring (is trial QA plan)
  - 9:15am      C. Vendor/partner assessment (includes site evaluation)
  - 9:45am      Panel – Q's & A's --- general Discussion
  - 10:15 am      Beverage Break
  - 10:45am      BreakOut Groups A B C
  - 12:30pm      Lunch
  - 1:30pm      BreakOut Groups Reports
    - 1:30pm      A. Report (10 min) & Discussion (20 min)
    - 2:00pm      B. Report (10 min) & Discussion (20 min)
    - 2:30pm      C. Report (10 min) & Discussion (20 min)
  - 3:00pm      Conclusions & Future Directions
- ADJOURN

# Link to GCP

[http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_Step\\_4.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4.pdf)