

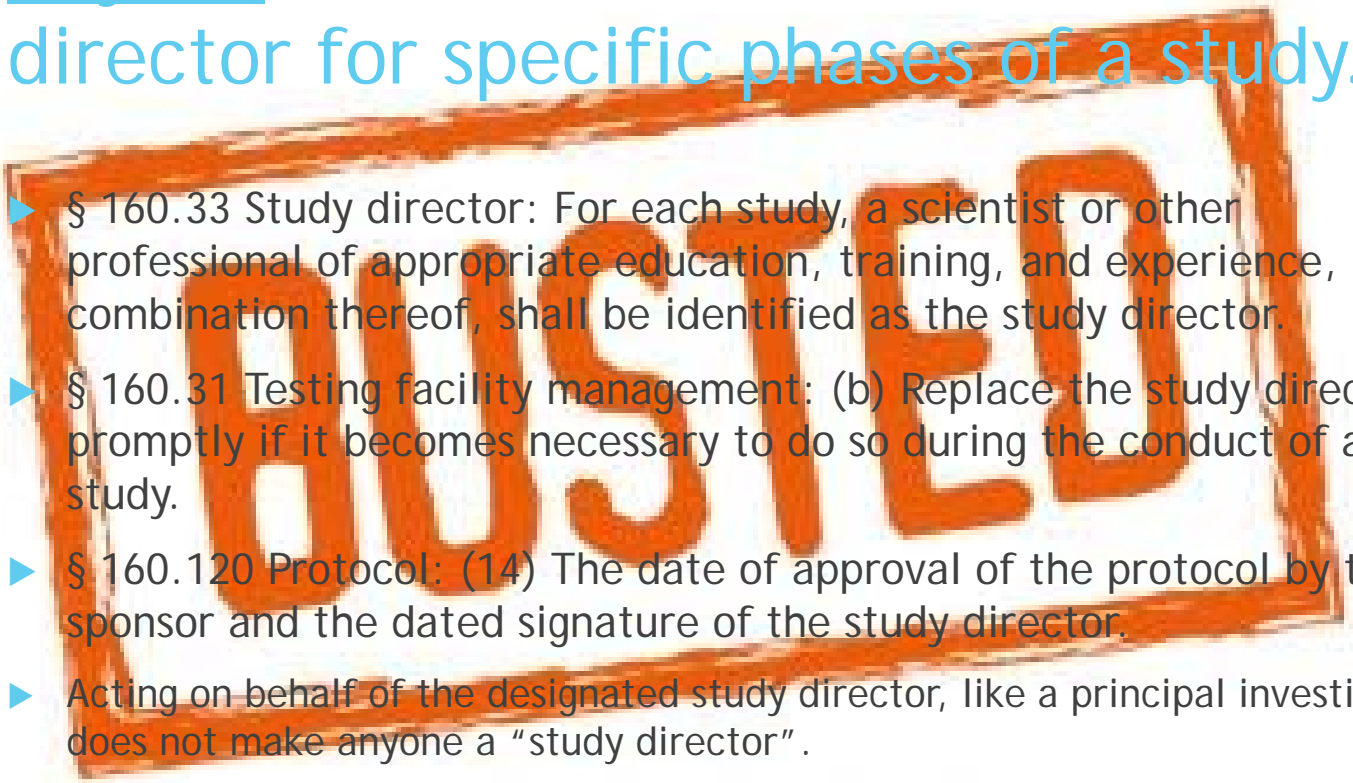


Randy Fuller/IntegriQual, LLC  
NAICC 2018 Annual Meeting

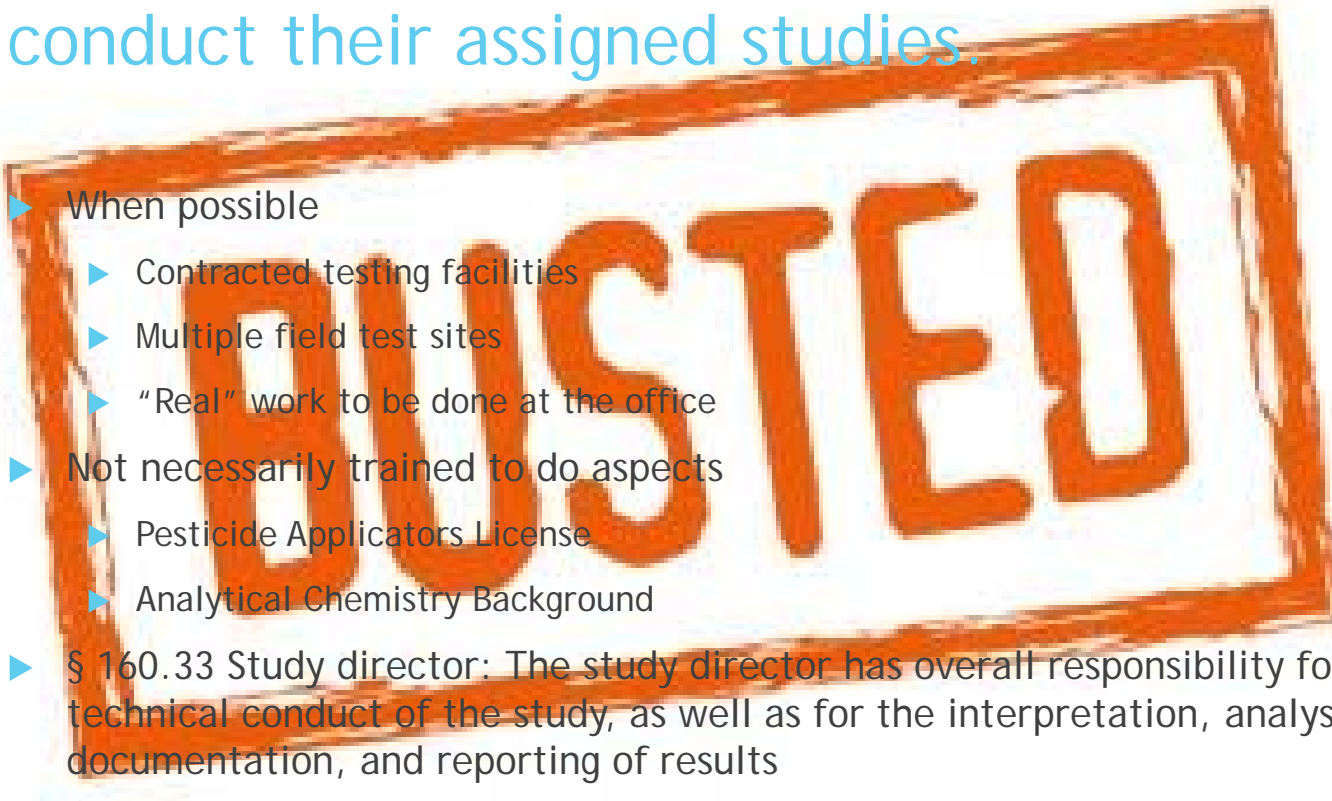
## According to GLP, a Study Director is anyone who has control of a study.

- ▶ § 160.3 Definitions: Study director means the individual responsible for the overall conduct of a study.
- ▶ § 160.31 Testing facility management: Designate a study director as described in § 160.33 before the study is initiated.
- ▶ § 160.33 Study director: For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.
- ▶ § 160.120 Protocol: ...the dated signature of the study director.

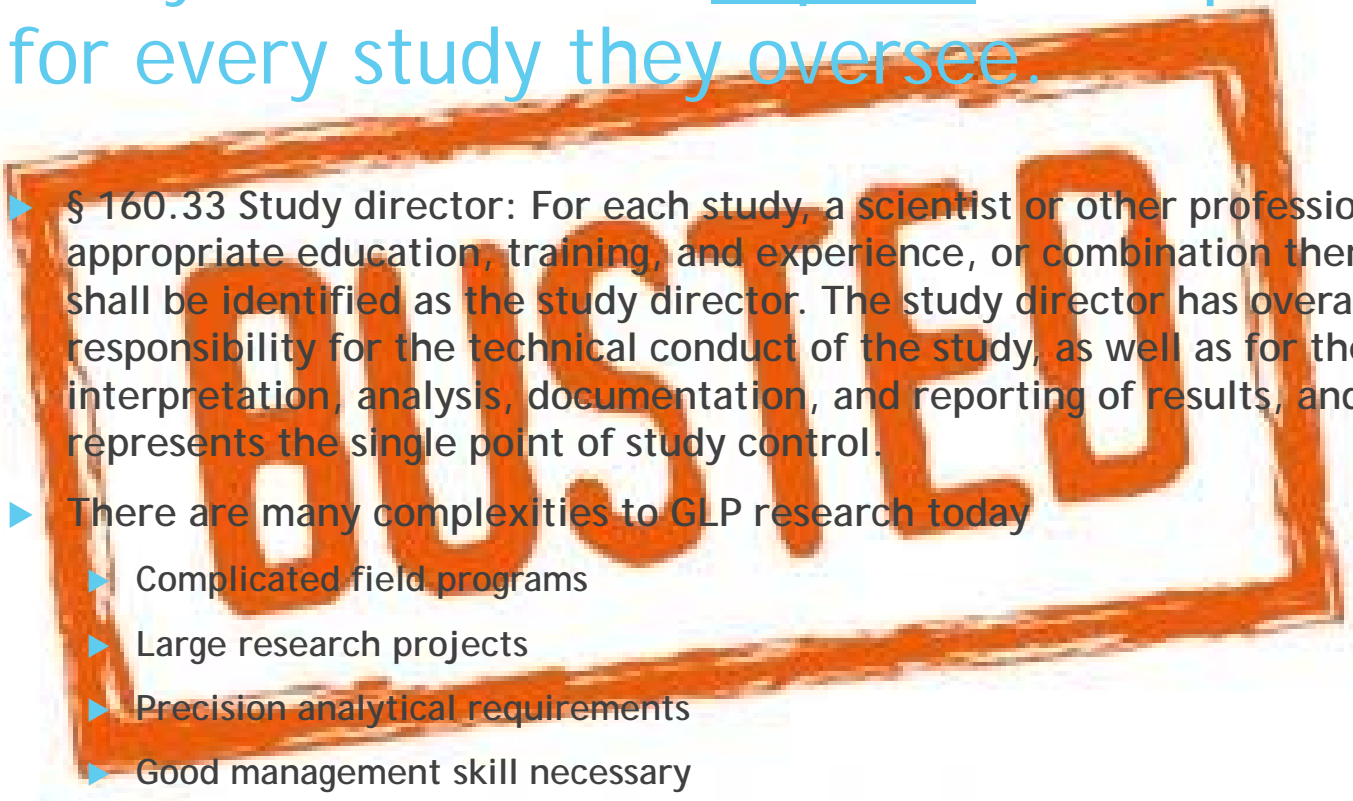
## Anyone can assume the role of the study director for specific phases of a study.

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- ▶ § 160.33 Study director: For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director.
  - ▶ § 160.31 Testing facility management: (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.
  - ▶ § 160.120 Protocol: (14) The date of approval of the protocol by the sponsor and the dated signature of the study director.
  - ▶ Acting on behalf of the designated study director, like a principal investigator, does not make anyone a “study director” .

Study Directors are always in the field/lab to conduct their assigned studies.

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- ▶ When possible
    - ▶ Contracted testing facilities
    - ▶ Multiple field test sites
    - ▶ “Real” work to be done at the office
  - ▶ Not necessarily trained to do aspects
    - ▶ Pesticide Applicators License
    - ▶ Analytical Chemistry Background
  - ▶ § 160.33 Study director: The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results

# Study Directors are experts in all phases for every study they oversee.

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- ▶ § 160.33 Study director: For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control.
  - ▶ There are many complexities to GLP research today
    - ▶ Complicated field programs
    - ▶ Large research projects
    - ▶ Precision analytical requirements
    - ▶ Good management skill necessary

Study Directors monitor too many studies at one time.

- ▶ Subjective Statistic
  - ▶ Study Type
  - ▶ Number of Samples/Data Volume
  - ▶ Duration of Study
  - ▶ Job duties
  - ▶ Personality type
  - ▶ Is study integrity compromised?

**IMPAUSIBLE**

# Study Directors can delegate their responsibilities to other professionals.

- ▶ Often a necessity
  - ▶ Specific Phases or Aspects
    - ▶ Principal Investigators
    - ▶ Study Monitors
  - ▶ Expertise Needed for Specific Aspects
    - ▶ Analytical Chemist
    - ▶ Pathologist
- ▶ Does not absolve SDs from GLP requirements



CONFIRMED

Study Directors miss addressing errors and deviations in their studies.

- ▶ Nobody's Perfect
- ▶ Impact on study integrity
- ▶ Quality Assurance Unit
- ▶ Lost in the Noise

**CONFIRMED**





Study Directors are concerned with the conduct, compliance and integrity of their studies.

- ▶ They should be!
- ▶ Responsive to OAU reports
- ▶ Open Communications between PIs, Mgt
- ▶ Assure Compliance with GLPs
- ▶ Take Responsibility!