

LIBERTY IRB



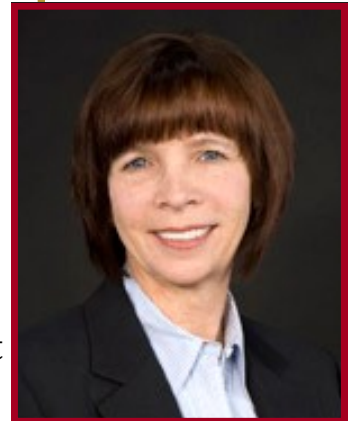
When Time and Quality are of the Essence

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MEET THE NEW PRESIDENT OF LIBERTY

Cheryl Talaber has been named the new President of Liberty IRB, Inc. She is stepping up from Vice-President of the Central IRB located in DeLand, Florida.

Liberty IRB is a 100% female-owned and operated company, certified by WBENC and AAHRPP. Mrs. Talaber is responsible for the strategy and performance of the company, with a sharp focus on customer service. Cheryl serves on the executive board of CIRB, the Consortium of Independent Review Boards, a non-profit organization whose central mission is to protect the rights and welfare of human research participants while promoting an understanding among independent IRBs on ways to support this goal. Cheryl is a graduate of Emory University in Atlanta, Georgia where she received her Bachelors and Masters degrees.



Liberty IRB is proud to announce the implementation of its CAPA program. CAPA stands for Corrective Action Preventative Action. CAPA programs were developed to provide a method of evaluating past episodes of noncompliance, evaluate the root cause of the noncompliance, and develop a preventative action plan to prevent recurrence of the noncompliance. According to Anna Rita Razzetti, Director of Quality Assurance, "Liberty IRB strives to continually find ways to improve processes to maintain the quality of our Human Research Subject Protection Programs." The new CAPA program will focus on systematic investigation of discrepancies. Once a discrepancy is identified, Liberty team members will launch into a root cause analysis. This investigation will identify trends and contributing factors which may have lead to the discrepancy. Finally, team members will develop plans to prevent further deviations and evaluations of these processes.

LIBERTY LAUNCHES CAPA

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OHRP REPORT ON IRBS

A report put out by OHRP titled "Recent Compliance Oversight Determinations" provides details of IRB "errors" from Initial and Continuing Review to IRB Documentation. It outlines a guide of what not to do if you are an independent or institutional review board.

The information comes from determination letters sent out over the past few years. To learn more regarding this report, visit: <http://www.hhs.gov/ohrp/compliance/findings.html>

LIBERTY IRB REGISTERS WITH FDA

As an amendment to current regulations (21 CFR.56.106) every IRB that reviews FDA studies is required to register with the Department of Health and Human Services (DHHS).

Liberty IRB has registered to conduct FDA and OHRP studies. Our registration number is IRB 0003411 and expires August 8, 2012.

To view our registration please visit: <http://ohrp.cit.nih.gov/search>

TRAINING FOR INVESTIGATORS AND RESEARCH STAFF

Training and education is essential in protecting the rights and welfare of research participants. The Liberty Board expects the research staff and investigators to comply with national, state and local laws. Liberty requires all key study personnel be trained in Good Clinical Practice (GCP), Human Research Subject Protection (HRSP) and Code of Federal Regulations (CFR).

There are many ways this can be accomplished:

- National Institute of Health (NIH) Clinical Center (an online program)
- Seminars and live lectures that provide CEU and CME credit relating to human research protection.
- Online training specific to human research protection.
- CITI Program: Online Course in the Protection of Human Research Participants. It has many training modules.

The Collaborative Institutional Training Institute (CITI) training is now available through Liberty IRB for principal investigators, study coordinators and staff at no charge when we are reviewing your study. Please contact us at 386.740.9278 to find out how to log on to this website for training.

REGULATORY CORNER: FOCUS ON REPORTABLE EVENTS

According to the U.S. Food and Drug Administration; Investigators are required to report promptly “to the IRB... all *unanticipated problems* involving risks to human subjects or others,” including adverse events that should be considered unanticipated problems (§§ 56.108(b)(1), 312.53(c)(1)(vii), and 312.66).

Reportable events are separated into two categories; unanticipated events that are adverse events and unanticipated events that are not adverse events.

Specific reporting requirements for Adverse Events can be found in the FDA Guidance entitled; “**Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs — Improving Human Subject Protection.**” As stated in the FDA Guidance document, Investigators are required to report promptly any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately. In general, an AE observed during the conduct of a study should be considered an unanticipated problem involving risk to human subjects, and reported to the IRB, **only** if it were unexpected, serious, and would have implications for the conduct of the study (e.g., requiring a significant, and usually safety-related, change in the protocol such as revising inclusion/exclusion criteria or including a new monitoring requirement, informed consent, or investigator’s brochure). An individual AE occurrence **ordinarily** does not meet these criteria because, as an isolated event, its implications for the study cannot be understood. For device studies, the guidance document states; “For device studies, investigators are required to submit a report of a UADE (Unanticipated Adverse Device Effect) to the sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the event (§ 812.150(a)(1)).” UADE’s are defined as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.”

Reportable unanticipated events include, events found to be unexpected, related or possibly related to participation in the research, or events that places research subjects or others at a greater risk of harm (physical or psychological). Examples of reportable unanticipated events include serious protocol deviations involving informed consent or study related procedures or any event, in the opinion of the investigator, sponsor or study monitor that requires IRB reporting.

Reporting of unanticipated events can be confusing. If you have questions concerning whether or not an event should be reported, contact your Liberty IRB Project Manager at 386-740-9278.

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