

LIBERTY IRB



When Time and Quality are of the Essence

THE LIBERTY LOG. WINTER 2011. ISSUE 2.

FROM THE DESK OF THE PRESIDENT

Welcome to the winter 2011 edition of the Liberty IRB Newsletter!

It is hard to believe another year has come to a close. It was a year of growth and in the economic situation we all find ourselves in, it makes us feel very fortunate. Most notably Liberty has put into play the formation of a second review board. As the AAHRPP metrics indicate, an IRB that has approximately 400 open studies generally finds the need for a second board. We are at that number and indeed do find that we need another board both to accommodate the additional studies and workload that places on our board members as well as to fill the needs of certain types of studies. We now review numerous oncology studies. The field of oncology is rapidly changing so we feel the need for more representation in this field. We have an agreement with an oncologist and an oncology nurse to serve in this capacity in addition to an oncology consultant.

Our service remains professional, friendly and prompt. We have no intentions of changing that this year!

Our Goal: To protect the rights and welfare of human subjects who enter clinical trials.

We wish you all a wonderful year and look forward to doing business with you throughout 2011.



Regards,
Cheryl
Cheryl Talaber, *President*

The Freedom portal, Liberty IRB's web portal is compliant with Title 21 Part 11 of the Code of Federal Regulations. We know that completing IRB paperwork is an involved process. The Freedom Portal allows investigators, sponsors and CROs to submit documents and keep track of them electronically.

**FREEDOM
PORTAL**



ISM CONFERENCE

Debra Reed, Vice-President of Liberty IRB will attend the Institute for Supply Management's (ISM) 3rd Annual Women Executive Supply management Summit to be held in Boca Raton, Florida February 9-11th.

Founded in 1915, ISM is the largest supply management association in the world as well as one of the most respected. ISM's mission is to lead the supply management profession through its standards of excellence, research and education. ISM is a not-for-profit association that provides opportunities for the promotion of the profession and the expansion of professional skills and knowledge.

For more information and to view the agenda for this event, please visit:

<http://www.ism.ws/education/content.cfm?ItemNumber=20590>

AMGEN AWARDS LIBERTY IRB FOR DIVERSITY COMMITMENT



Liberty IRB recently received recognition from Amgen, the world's largest bio-technology company, headquartered in Thousand Oaks, California. Farryn Melton, CPM, global Chief Procurement Officer presented the Florida based independent IRB with an engraved silver plate for their commitment and support to Diversity Alliance for Science at an executive power luncheon on December 9th at Amgen.

Diversity Alliance for Science (DA4S) is a non-profit organization created to support, mentor and develop minority businesses in the life sciences. Cheryl Talaber, President of Liberty IRB, Inc. serves on the Board of Directors for DA4S.

LIBERTY IRB ANNUAL AAHRPP REPORT

January 12, 2011

AAHRPP www.aahrpp.org congratulated Liberty IRB, Inc. on their continued commitment to the most comprehensive protections for research participants and the highest quality research.

AAHRPP is a non-profit organization created to work with organizations that conduct human research or oversee ethical review of human research. AAHRPP accredits only the highest quality protection programs that promote excellent, ethically sound research, surpassing state and federal regulations. Accreditation is also about peer review, self regulation and establishing the highest standards of ethical conduct. It is about continuous improvement. Liberty IRB has met these high standards.

Cheryl Talaber, President of Liberty comments, "Accreditation validates our commitment to provide a program that fully addresses human subject protection and quality research. We at Liberty embrace higher standards than those required by law and have built extensive safeguards at every level to ensure that protection. We hope that accreditation will lead to an increased level of public trust."

Liberty IRB, Inc. (LIRB) was established in 2003 as an independent institutional review board or IRB. LIRB is a leading provider of IRB services for clients nationwide. Liberty provides ethical review for Phase I-IV research in a variety of therapeutic areas. LIRB is a member of the Consortium of Independent Review Boards (CIRB) and WBENC. For more information visit www.libertyirb.com.

CISCRP, THE FIRST NON-PROFIT OF ITS KIND

The Center for Information and Study of Clinical Research Participation (CISCRP) is a first-of-its-kind non-profit organization dedicated to educating and informing the public, patients, medical/research communities, the media and policy makers about clinical research and their role in the process.

CISCRP provides a wealth of information on how to become an informed research participant. CISCRP strives to help locate ongoing clinical trials by supporting SearchClinicalTrials.org.

Please check out AWARE FOR ALL Clinical Education Days on the CISCRP website at www.ciscrp.org.

Liberty IRB will be co-hosting such an event in our community on July 21st with Compass Research in Orlando, Florida.

REGULATORY CORNER: OHRP ANNOUNCEMENTS

DECEMBER 1, 2010

GUIDANCE ON IRB CONTINUING REVIEW OF RESEARCH

OHRP has posted on its website a finalized guidance document entitled, "Guidance on IRB Continuing Review of Research." The guidance document supersedes OHRP's January 15, 2007 guidance entitled "Guidance on Continuing Review." The guidance document finalizes the draft guidance that was made available for public comment through a notice in the Federal Register on November 6, 2009 (74 FR 57487). The public comments submitted on our draft document were very helpful to us as we finalized this guidance document, and we thank those of you who took the time to provide us with your feedback.

The finalized guidance document is available on the OHRP website at:

<http://www.hhs.gov/ohrp/policy/continuingreview2010.html> or <http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf>.

The Federal Register notice announcing the availability of this new guidance document can be found at:

<http://edocket.access.gpo.gov/2010/2010-30198.htm> or <http://edocket.access.gpo.gov/2010/pdf/2010-30198.pdf>.

DECEMBER 1, 2010

GUIDANCE ON IRB APPROVAL OF RESEARCH WITH CONDITIONS

OHRP has posted on its website a finalized guidance document entitled, "Guidance on IRB Approval of Research with Conditions." The guidance document provides OHRP's first formal guidance on this topic. The guidance document finalizes the draft guidance that was made available for public comment through a notice in the Federal Register on November 6, 2009 (74 FR 57486). The public comments submitted on our draft document were very helpful to us as we finalized this guidance document, and we thank those of you who took the time to provide us with your feedback.

The finalized guidance document is available on the OHRP website at:

<http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html> or URLs <http://www.hhs.gov/ohrp/policy/conditionalapproval2010.pdf>.

The Federal Register notice announcing the availability of this new guidance document can be found at:

<http://edocket.access.gpo.gov/2010/2010-30201.htm> or <http://edocket.access.gpo.gov/2010/pdf/2010-30201.pdf>.

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LIBERTY IRB

Full AAHRPP Accreditation

Weekly IRB Meetings

Two Day Document Turnaround

Project Management Approach

WBENC Certification

CAPA Certification

Member of the Consortium of Independent Review Boards

Translation Services

Cost Effective for Multi-Site Trials

Phase I-IV Studies