Mandatory changes for Consent Forms with combined HIPAA Authorizations that include optional research procedures

According to HIPAA requirements, subjects must be given the opportunity to authorize use of their Protected Health Information (PHI) for any optional research procedures (including sample and data banking) separately from their authorization to use their PHI for the primary study.

Recent changes to the HIPAA rule have allowed this separate authorization to take two different forms. In response to this change, COMIRB has developed two new Consent Form Templates with combined HIPAA Authorization that are each structured differently to allow subjects to authorize use of their PHI for optional research procedures separately.

Any study that utilizes a Consent Form with combined HIPAA Authorization will be required to modify the structure of their Consent Form to match the structure of one of our new templates by their next Continuing Review.

The two new Consent Form templates with combined HIPAA Authorization are available on COMIRB’s form page: http://www.ucdenver.edu/academics/research/AboutUs/comirb/forms/Pages/default.aspx (cut/paste the url into your browser address window)

OFFICE OF RESEARCH DEVELOPMENT AND EDUCATION (ORDE)

The New Investigator Research Funding Opportunities e-Book has been completely updated by the Office of Research Development and Education and is now available for download to your mobile devices and/or computers. The 2013-14 edition features information on more than 300 grant competitions specifically targeting early career researchers in the natural and biomedical sciences, social and behavioral sciences and arts and humanities. Both federal and private sponsors are listed. Descriptions, eligibility criteria, deadlines and links to sponsor websites are provided for each opportunity. Go to the ORDE website at http://www.ucdenver.edu/academics/research/AboutUs/ORDE/funding/Pages/NewInvestigatorsFundingOpps.aspx to download your copy (cut/paste the url into your browser address window).

One drug to shrink all tumors….

Researchers have found that a single drug can shrink or cure human breast, ovary, colon, bladder, brain, liver and prostate tumors that have been transplanted into mice. The treatment, an antibody that blocks a “do not eat” signal normally displayed on tumor cells coaxes the immune system to destroy the cancer cells. More than decade ago, Irving Weissman from Stanford discovered that leukemia cells produce higher levels of a protein called CD47 than do healthy cells. He and other investigators found that CD47 is also displayed on healthy blood cells. It is a marker that blocks the immune system from destroying them as they circulate. Cancers take advantage of this flag to trick the immune system into ignoring them. In the last several years, Weissman’s laboratory showed that blocking CD47 with an antibody cured some cases of lymphomas and leukemias in mice by stimulating the immune system to recognize the cancer cells as invaders. He has also shown that the CD47 blocking antibody may have a far wider impact than just blood cancers. What Weissman showed is that CD47 is not just important on leukemias and lymphomas; it is on every single human primary tumor that they have tested. The cancer cells always had higher levels of CD47 than did healthy cells and that how much CD47 a tumor made could predict the survival odds of a patient. To determine whether blocking CD47 was beneficial, they exposed tumors to macrophages, a type of immune cell and anti-CD47 molecules in vitro. Without the drug, the macrophages ignored the cancer cells, but when the CD47 was present, the macrophages engulfed and destroyed the cancer cells. The investigators then transplanted human tumors into the feet of mice where tumors can easily be monitored. When they treated the mice with anti-CD47, the tumors shrank and did not spread to the rest of the body. In mice given human bladder cancer tumors, 10 of 10 untreated mice had cancer that spread to their lymph nodes. Only 1 of 10 mice treated with anti-CD47 had a lymph node with signs of cancer. In addition, the implanted tumor often got smaller after treatment - colon cancers transplanted into the mice shrank to less than 1/3 of their original size, and in 5 mice with breast cancer tumors, anti-CD47 eliminated all signs of the cancer cells and the animals remained cancer free 4 months after the treatment stopped. Weissman’s group also showed that even after the tumor has taken hold, the antibody can either cure the tumor or slow its growth and prevent metastasis. A report of this work appeared recently in the Proceedings of the National Academy of Sciences. Although, much work needs to be completed, Weissman’s team of investigators would like to move this information into a Phase I human trial.

THE COLORADO CLINICAL AND TRANSLATIONAL SCIENCES INSTITUTE (CCTSI)

Biostatistical Services for CCTSI Investigators

Effective August 1, 2013, new policies for biostatistics consultation and collaboration provided by the CCTSI Biostatistics, Epidemiology and Research Design (BERD) Core have been implemented. For specifics on the new Program Income System and BERD Seeds program please visit: http://cctsi.ucdenver.edu/Research-Resources/Pages/Biostatistics-Epi-Research-Design.aspx (cut/paste the url into your browser address window).
Philip S. Strain, PhD is Professor of Educational Psychology and Psychiatry at the University of Colorado Denver. He received his master’s and doctoral degrees in special education from Peabody College. He is the author of over 250 papers, chapters and books and has served on the editorial boards of 20 professional journals. His research interests are two-fold. First, he has been conducting intervention studies for the last 35 years focused on the efficacy of discrete intervention procedures (e.g., parent skill training, typically developing peers as social skill intervention agents, function-based treatments for severe problem behavior) as well as a comprehensive intervention model (LEAP Preschool) for young children with autism. In this work he has focused on producing immediate behavior change, behavior change that extends across diverse contexts (using words at home, preschool, in the community) and the social validity of outcomes. In this treatment context social validity refers to the extent to which significant adults in the child’s life view the changes in behavior as valuable and the intervention procedures to be doable in real world contexts. Together, these several dozen intervention studies have shown that the developmental trajectory of young children with autism can be greatly enhanced and sustained over time.

Secondly, Phil is interested in reducing the discrepancy between what is possible with high quality early autism services and what most children and families receive. This “transfer of technology” issue is complicated by restrictive public policies, funding challenges and provider training issues. In an effort to bridge this gap he has established long-term mentoring and research relationships with school districts in seven states that have made a major commitment to installing, scaling-up and maintaining quality services.

Free UCD Clinical Research Support Center Launching in October

In October, the UCD Office of Regulatory Compliance will launch its first-ever Clinical Research Support Center. The virtual center, which is a free, centralized source of guidance for investigators and professional research assistants, will offer one-on-one assistance with budgeting, IRB review, FDA submission, subject recruitment, ongoing compliance and more.

“The Support Center was developed in response to a need that has been expressed again and again in the research community over the years,” says Dr. Alison Lakin, Assistant Vice Chancellor for Regulatory Compliance. “Being educated about the requirements and how to satisfy them will help research professionals get their trials open as quickly and efficiently as possible. This guidance through the regulatory maze will make their lives easier,” she states, “allowing them to focus on finding the answers that will positively impact millions of lives.”

The Support Center will celebrate its grand opening with six lunchtime meet-and-greet events from 12 pm to 1 pm at the locations listed below. Those interested can drop by to pick up a snack and flier, meet the team, and learn more about the free assistance they can receive through the Support Center. For more information, go to www.UCDenver.edu/ClinicalResearchSupportCenter. The Support Center can be reached by phone at 303-724-1111.

Clinical Research Support Center - meet-and-greet event schedule: 10/8: Building 500 cafeteria; 10/9: Research 1 South Tower; 10/16: Quad outside Fulginiti Pavilion; 10/17: Research 2 lobby; 10/23: Health Sciences Library coffee shop; 10/24: AO1 lobby