



Allison Hubel <hubel001@umn.edu>

BioCoR: SUBJECT, position available,

1 message

BioCoR <biocor@me.umn.edu>

Reply-To: biocor@me.umn.edu

To: hubel001@umn.edu

Wed, Oct 20, 2010 at 6:55 PM

**BioCoR Newsletter August 2010****Dear Allison,**

Welcome to the August newsletter of BioCoR. In this newsletter, the mini-tutorial will address basic issues surrounding regulation of cells and tissue for therapeutic applications by Fran Rabe. Fran is an instructor in our preservation short course and we are fortunate to have her extensive expertise in this field. Regulatory issues have been very important in the field of cell therapy for many years and will more than likely become increasingly important in the field of biobanking.

BioCoR and the U of MN Medical Device Center are developing joint programs to accelerate technology development for preservation. We are seeking the input from the community with regard to needs for technology development.

As always, your comments are very important to us. We expect to see you at www.biocor.net.

BioCoR is a national resource focused on advancing the science, technology and practice of biospecimen preservation. We are dedicated to developing biopreservation protocols, improving preservation and storage technologies, establishing standards and guidelines and training individuals and institutions in the science and technology of biopreservation.

More information can be found on the **BioCoR** website: www.biocor.net. Or you may contact us now at biocor@me.umn.edu

Establishing a Biorepository: Promoting the Idea to Institutional Officials

***An Abbreviated Glance at the U.S. Food and Drug Administration Regulation of Tissues and Cells****Fran Rabe, M.S.**Director of Quality Assurance**University of Minnesota Molecular and Cellular Therapeutics Facility*

The Center for Biologics Evaluation and Research (CBER) regulates human cells, tissues, and cellular or tissue-based products, commonly referred to as HCT/Ps under Food and Drug Administration (FDA) 21 CFR Parts 1270 and 1271. Examples of such products are bone, skin, corneas, ligaments, tendons, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of human organs.

Landmark regulation was published without warning on December 14, 1993 with the FDA's unannounced publication of an Interim Rule, which immediately imposed rules on certain aspects of tissue manufacture and distribution. In 1991 the reported disease transmission of Human Immunodeficiency Virus (HIV) Type 1 through a donor with no known risks for HIV resulted in the transmission of the disease in recipients of the donor's organs and tissues². Further investigation of the situation proved to be scientifically interesting in that the transmission of disease was related to the manufacturing method utilized for the different tissues. Simultaneous with this unintended scientific case study of the transmission of disease through transplantation, the Center for Disease Control's (CDC's) concerns over the transmission of Creutzfeldt-Jakob Disease (CJD)³, a fatal neurological condition resulting through the transplantation of dura mater brain tissue, were growing. These demonstrated and theoretical risks of disease transmission provided increased impetus for federal regulation of the tissue and organ industry.

Hallmarks of the Interim Rule were prescribed donor health history screening, infectious disease testing, the requirement to test donor blood using certified labs under the Clinical Laboratories Improvement Amendments and ensuring appropriate donor test-blood sample handling, which consider donor hemodilution factors that may interfere with the accuracy of infectious disease test results. The interim rule was limited in scope in that it did not regulate sperm or ova. Vascularized organs continued to be regulated under the Health Resources and Services Administration (HRSA). Although the regulatory fate of sperm and ova were to change in years to follow, HRSA continues to regulate organ transplantation today. In later years bone marrow transplantation was added to the regulatory auspice of HRSA while other cellular therapies such as umbilical cord blood and peripheral blood were becoming increasingly regulated by the FDA.

While the Interim Rule of 1993 was the birth of the regulation of tissues, much iteration of the regulations has resulted in a comprehensive regulatory tiered risk-based approach by the FDA. In years to follow, the regulations were fine tuned and expanded to also include cells and gene therapy.

While FDA regulation of tissue banks and hematopoietic cell transplantation is relatively new, the tissue and cell therapy industry has been voluntarily self-regulated through standards imposed by professional associations such as, but not limited to, the American Association of Tissue Banks (AATB), the American Red Cross (ARC), AABB (formerly American Association of Blood Banks, Eye Bank Association of America (EBAA) and Foundation for the Accreditation of Cellular Therapy (FACT).

Due to the requirement for a close human leukocyte antigen (HLA) donor/recipient match, the FDA has taken a unique approach to the regulatory framework of cellular therapies. The FDA recognizes cells must be routinely obtained from donors that may present with social or medical history that places the donor at increased risk of infectious disease transmission to the recipient. The regulations describe the exceptions and rules which allow for transplantation under this unique situation. ⁴

While FDA regulation of cells and tissue are in relative infancy as compared to other biologic products, drugs and medical devices, the FDA continues to further control the use of cells through future licensure requirements. In October, 2011 the use of cord blood in the unrelated minimally manipulated transplant setting will be required to be licensed by the FDA.⁵ Based on previous announcements by the FDA⁶, it is anticipated that the manufacture of minimally manipulated unrelated peripheral blood will also require FDA licensure in the near future.

While the scope and complexity of regulation of cell and tissue products increases, the research and utilization of these products is not expected to slow.

References

1 Food and Drug Administration Interim Rule for Human Tissue Intended for Transplantation; December 14, 1993, Federal Register, Vol 58, No. 238, p 65514.

2 Simonds RJ, Holmberg SD, Hurwitz RL, et al. Transmission of human immunodeficiency virus type 1 from a seronegative organ and tissue donor. *N Engl J Med* 1992;326:726-732.

3 Center for Disease Control and Prevention (CDC). *MMWR Morbidity and Mortality Weekly* 1993/42(28);560-563.

4 Food and Drug Code of Federal Regulation Part 1271 Subpart C - Donor Eligibility

5 U.S. Federal Register Vol. 74, No. 201, October 20, 2009

6 U.S. Food and Drug Administration. Proposed approach to regulation of cellular and tissue-based products. Docket 97N-0068, 1997.

There must be a better way of doing this!

Processing samples for preservation can be very time consuming, labor intensive and more importantly post thaw quality may vary with skill/experience of the operator. Having processed samples for decades and observed operations in other organization, we have on more than one occasion said, "*There must be a better way of doing this!*"

What we want: BioCoR is soliciting your suggestions for problems or challenges that you are having with preservation processing of biological specimens.

What we are going to do: BioCoR and other resources within the Institute for Engineering in Medicine (specifically the Medical Device Center (MDC) at the U of MN) will be working to accelerate technology development for preservation needs.

Sample projects: Individuals who have already contacted BioCoR for assistance have given us ideas for devices or technology.

Example #1: Some tissue biospecimens may be quite small (needle biopsies, etc). Existing methods of handling and processing specimens result in poor recovery. New devices and methods are needed to facilitate collection, processing and retrieval of small tissue samples.

Example #2: Biofluid biospecimens typically contain both cells and macromolecules. An easy, quick method of separating cells from fluid is needed-one that would not require a centrifuge.

Just contact us on the website (Contact BioCoR) or send us an email at biocor@me.umn.edu if there are biospecimens that are in particular labor intensive/time consuming or whose quality can vary greatly. You may also contact us with your suggestions on new technologies that may improve preservation.

Position Available

Postdoctoral Position at University of Minnesota on Biostabilization of Biospecimens

A post-doctoral position is available in Biopreservation Core Resource (BioCoR) at the Department of Mechanical Engineering in University of Minnesota. The position is available immediately. The position will focus on understanding the effects of frozen state storage on the stability of macromolecular biomarkers in biofluid biospecimens. The research will extend to the development of strategies to minimize low temperature storage damage and evaluation of alternative stabilization technologies. This project provides ample opportunities to collaborate with the medical and clinical researchers at the Medical School at U of MN.

The candidate must have a Ph.D. in Mechanical, Biomedical or Chemical Engineering or Biochemistry, with specific emphasis on experimental quantification of macromolecular, cellular phenomena and biopreservation. The candidate must have excellent experimentation skills: No candidate without experimental experience in his/her Ph.D. studies will be considered for this position. Experience with cell and tissue culture, spectroscopic and microscopic characterization techniques, SEM, TEM, as well as ELISA, and MS are highly desired.

Interested candidates should contact BioCoR by e-mail (biocor@me.umn.edu). In your message, please include a detailed resume, electronic reprints of recent publications, and the names, and contact information for at least three references.

More information on BioCoR can be found at www.biocor.net

Sign up for BAL Newsletter

As you may be aware, BioCoR is currently working on an improved method of preserving both the cells and the fluid component of bronchoalveolar lavage (BAL). We have been contacted by individuals banking BAL and looking to start collecting and banking BAL. As a result, we are starting a working group in that area and will be sending literature reviews, research updates, and other information on BAL banking. If you are interested in joining this working group, please send an email to BioCoR (biocor@me.umn.edu) or on the website ([BioCoR contact](#)) to sign up for the group (indicate that you want to join the BAL group). We will be adding other specialty newsletters and working groups as BioCoR expands the biospecimens that we study. Stay tuned.

[Forward email](#)

✉ [SafeUnsubscribe®](#)

This email was sent to hubel001@umn.edu by biocor@me.umn.edu.
[Update Profile/Email Address](#) | Instant removal with [SafeUnsubscribe™](#) | [Privacy Policy](#).

Email Marketing by



BioCoR | University of Minnesota | 111 Church St. SE | Minneapolis | MN | 55455
