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Upcoming Events:

October 5th —

Human Participant Research @ UMB 101: "What You Need To Know To Get Started"

October 9th —

Columbus Day

October 11th —

Research Grand Rounds - "Crossing the Bridge, UMB and VA Research Compliance"

December 7th—

Making it Public! Privacy and Confidentiality in Human Participant Research

For More Details visit the HRPO Website.

Special Announcement

Bruce Jarrell, M.D., Vice Dean for Research and Academic Affairs, has been appointed as the Institutional Official.

NEWS OF THE MONTH:

University of Maryland, Baltimore Institutional Biosafety Committee (IBC)

An IBC is required for institutions receiving support from the National Institutes of Health (NIH) for recombinant DNA research. The roles and responsibilities of the IBC and Principal Investigators (PIs) are spelled out in detail in the "[NIH Guidelines For Research Involving Recombinant DNA Molecules](#) (NIH Guidelines)".

Human Gene Therapy Trials

The deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants is defined by NIH as human gene transfer. PIs at UMB must submit such work to the NIH Recombinant DNA Advisory Committee (RAC) for review and to the IBC for review and approval before research participants are enrolled. UMB investigators participating in multi-center clinical trials of human gene transfer must obtain IBC approval before research participants are enrolled even though the project sponsor

has obtained NIH RAC review and approval. The NIH requirements for protocol submission, review, and reporting of human gene transfer research are found in [Appendix M](#) of the NIH Guidelines.

Certain types of human gene transfer experiments, often referred to as vaccine trials, are exempt from the requirements for NIH RAC review and reporting. **However, they are not exempt from IBC review.** Specifically, this exemption applies to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected. When all three criteria are met, investigators need only submit the information requested in Appendix M-II through M-V of the NIH Guidelines to the IBC.

NIH has provided the IBC clarification on the applicability of the NIH Guidelines to vaccine trials, as follows:

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Mission:

The University of Maryland School of Medicine HRPO's mission is to cultivate a culture of conscience in the University of Maryland, Baltimore's research community to ensure the highest levels of human participants' advocacy and protections.

The UMB IRB uses a web-based system to manage all human research protocol submissions, called the Biomedical Research and Assurance Network (BRAAN). To access the BRAAN system go to - <http://medschool.umaryland.edu/orags/hrpo/>

Contact Information:

The HRPO hours of operation are Monday - Friday 8:30 am - 4:30pm
[University of Maryland School of Medicine](http://medschool.umaryland.edu/)
<http://medschool.umaryland.edu/>
Human Research Protections Office
Health Science Facility I (HSF I)
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Exempt from the NIH Guidelines: IBC registration and review <u>not required</u>	IBC review and approval <u>required</u>
Subunit vaccines (such as the Hepatitis B and the HPV vaccines) where no recombinant DNA molecule is being delivered to a human, even though they were constructed using recombinant DNA technology.	DNA vaccines, sometimes called naked DNA vaccines.
Live attenuated or inactivated vaccines made from recombinant or re-assorted organisms created by natural recombination. Example: flu vaccines constructed by natural re-assortment in eggs.	Live attenuated or inactivated vaccines made from recombinant or re-assorted organisms using recombinant DNA technology. Example: flu vaccine created by “reverse genetics.”

Research Involving Recombinant DNA and Infectious Agents

In addition to human gene transfer protocols, the IBC requires registration and review of all laboratory research with recombinant DNA molecules as [defined by the NIH Guidelines](#). Research conducted with non-recombinant microorganisms that are pathogenic to humans, plants, or animals as well as research using [select agents](#) also requires registration.

For more information on the NIH requirements for human gene transfer work, see the [NIH FAQ web site](#). For more information on the IBC, contact Melissa Morland at 410-706-7845, or

James Jaeger at 410-706-7055. Instructions for submission of research protocols for IBC review are found at:

<http://www.ehs.umaryland.edu/biosafety/rrformdirect.cfm>

- Contributed by: Melissa A. Morland, MS, RBP, CBSP, Assistant Director & Biosafety Officer, Environmental Health and Safety

Important Information:

The staff of the HRPO encourages you to visit our website frequently at <https://medschool.umaryland.edu/hrpo/> for updated information and breaking news in the research community.

On our website you will find the most recent editions of the *Policies and Procedures Manual* in Word, PDF, and HTML formats. Please discard all manuals and versions prior to the posted dates.

Did You Know That:

CITI Human Protections Training is offered in 5 Languages?

If you are conducting human participant research internationally and need your international investigators and/or research staff to complete a human protections training, CITI offers their human research protections training in the following languages: **Spanish, French, Portuguese, Chinese, and English**. You can access this training at: <http://irbtraining.org/>

If you have any questions please contact Khristy Bozylinski, MS, CCRC, HRPO Program Manager for Education at 410-706-4514

or kbozylinski@som.umaryland.edu

New Electronic Protocol Management System Announced

The Human Research Protections Office is pleased to announce that the Dean's office has provided funding for a **new electronic protocol management system** and that a contract has been secured with **Click Commerce**. Click Commerce is a publicly traded company (NASDAQ symbol CKCM). Their product is currently installed and operating in six of the top ten NIH-funded research institutions in the country, with over thirty clients that use them in the IRB Operations venue...

(Read the rest of the press release on the HRPO Website)