# UMMS Human Research Protection Program (HRPP) Newsletter

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### Contact Us


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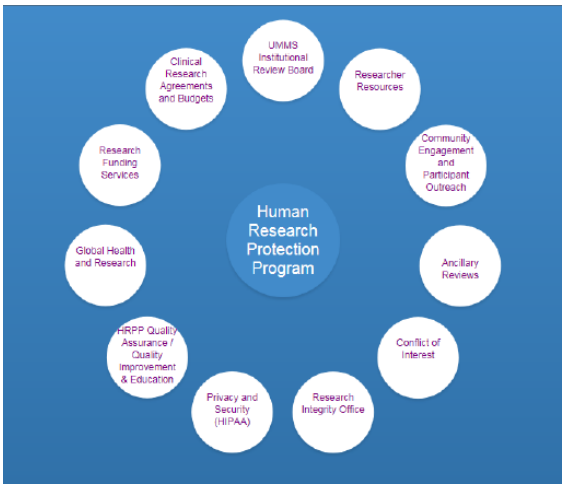
## Welcome

Welcome to the first edition of the UMass Medical School Human Research Protection Program (HRPP) Newsletter. This quarterly newsletter will provide updates, tips and other helpful information to members of the research community at UMMS. Please bookmark the UMMS HRPP website to access the most up to date information.

## What is the HRPP?




The UMMS HRPP describes a comprehensive system put into place to support the protection of the rights and welfare of subjects in Human Research at our institution. The components of this system include the IRB, Research Integrity and Conflict of Interest programs, the Office of Clinical Research, the Office of Global Health, Participant and Community Engagement, Investigational Drug Service, Research Funding Services, UMMS senior leadership, Radiation Safety and Biosafety committees, Emergency Medicine and Cancer Protocol Review Committees and UMMMC device management. For more information about the HRPP at UMMS, please visit: http://www.umassmed.edu/ccts/human-research/

## UMMS AAHRPP Accreditation Effort

UMMS is seeking HRPP accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). AAHRPP accreditation is considered to be an indicator of a high-quality HRPP.

Key components of this effort include the IRB transformation initiative and implementation of the electronic IRB system (eIRB) completed in October 2012. The paper application process is ongoing. An accreditation site visit is anticipated in September 2015. To learn more about AAHRPP, AAHRPP accreditation or to view a list of accredited institutions, visit: http://www.aahrpp.org/

## HRPP Quality Corner

The Quality Assurance/Quality Improvement (QA/QI) Program, led by Terry Sousa, RN, MSN, CCRC, CIP, is a critical component of the UMMS HRPP. By reviewing research studies, issues with study conduct are identified, and adherence to regulations and Good Clinical Practices (GCPs) is monitored. Feedback is provided to investigators and study teams to improve the quality of research. The HRPP Quality Improvement Program website is home to helpful information including HRP-142, the HRPP QA/QI SOP and self-review tools.

***Quality Spotlight: Printing stamped consents from eIRB***

A recent QA/QI trend is that IRB-stamped versions of consent or assent forms are not always being used. When printing from eIRB, select the stamped version of the document from the right hand column. Double check the printed document to make sure the stamp is present. See the *Helpful Hints from the IRB section*, below.

## Helpful hints from the IRB

**eIRB Job Aids Available**

Having trouble navigating eIRB? The IRB has a host of *Job Aids* available to help. These step-by-step instructions aid eIRB users as they walk through specific actions. Many of the Job Aids also have demonstration videos.

If you're having trouble with a specific action, the IRB is always available to help. First, please visit the Job Aids page to see if there is a Job Aid or video to assist you. ***New!*** Check out the Job Aid to assist users to print IRB-stamped consents.

**Policies/SOPs & Checklists/Worksheets…what's what?**

- *Standard Operating Procedures (SOPs)* describe operations or processes related to the Human Research Protection Program.
- *Investigator Guidance* informs investigators of their human research protection obligations in greater detail.
- The *Investigator Manual* guides investigators through requirements specific to conducting human research at UMMS.
- *Checklists and Worksheets* are used by IRB members in determining whether study requirements are met, and can be used by investigators as a resource to guide the preparation of an IRB submission to address these requirements.

## Other important HRPP updates

**New on the Web**

Guidance for studies involving **Investigational Devices**

- HRP-913 Standard Operating Procedure for Investigational Devices
- HRP-914 2014 Medical Device Management Plan
- CE001, Medical Device Electrical Inspection Procedure 2011

## Upcoming Educational Offerings

- **CRPG meetings**:
  - Mon 6/8/15 3-4 PM Lazare S1-607, Wed 7/15/2015 12-1 PM, Hiatt S1-608
- **Basic Clinical Research Coordinator Course** (5/21/15-*Enrollment full!*)
- **IRB Fundamental and Lab training sessions**
  - Visit http://www.umassmed.edu/ccts/irb/education-and-training/education/