UMass Worcester Human Research Protection Program (HRPP) Newsletter

Volume 9 March/April 2019

UMass Worcester
UMass CCTS
Human Research Protection Program
ACC 7th Floor

UMass Medical School awarded AAHRPP Re-Accreditation

On December 17, 2018, the Council on Accreditation of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) awarded UMass Medical School Full Accreditation for a period of five years. This is a continuation of the initial Full Accreditation, first awarded to the Medical School in 2015.

AAHRPP is an independent, non-profit accrediting body headquartered in Washington, DC which promotes high-quality research through accreditation. According to AAHRPP, "As the "gold seal," AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that an HRPP is focused first and foremost on excellence."

For questions and additional information about the HRPP at UMMS, please contact Meg Johnson, JD, CIP, HRPP Compliance Administrator at Meg.Johnson@umassmed.edu

HRPP QUALITY CORNER: Spotlight on...

Clinical Research Professionals Group

The UMMS CRPG holds monthly meetings with topics of interest to the clinical research community, and is open to anyone involved in the conduct and/or support of clinical research at the Medical School. In addition to meetings, the CRPG email distribution list serves as a platform for dissemination of important updates, policies and information related to clinical research.

As part of the ongoing HRPP website enhancements, recordings from the March 2019 CRPG meeting onward will be made available online. As always, live attendance (in person or via Zoom) is always your best option.

To be added to the CRPG distribution list and receive email updates including meeting notices, contact Anne Roussell in the UMass Center for Clinical & Translational Science at Anne.Roussell@umassmed.edu.

HRPP Annual Survey

Thank you to respondents to the recent HRPP Annual Survey. Feedback from the Human Research community at UMMS is critical to the ongoing enhancement and development of programs and resources. Results of the survey will be shared at the April CRPG meeting.

Updated Study Opportunity Listing Website

The study opportunity website has been upgraded and is available at www.conqueringdiseases.org. Please note, studies must be entered and open to enrollment in OnCore to be included on the study opportunity listing website

Contact Us:
IRB@umassmed.edu

HRPeducation@umassmed.edu

Visit us on the web:
http://www.umassmed.edu/ccts/human-research/

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Human Research Protection

Upcoming Events

IRB Drop-in Sessions
2nd and 4th Thursday of each month
12:30-1:30 pm
UMMS Library

Clinical Research Professionals Group April Meeting
April 11, 2019
1:30-2:30 pm
or via Zoom (Login information available from CRPG listserv or by contacting hrpeducation@umassmed.edu)

Intermediate Study Coordinator Course
Wednesday 4/24/19 from 9-2:30 pm
Pre-Registration Required: contact Anne.Roussell@umassmed.edu

Outside UMass:

ACRP
April 12-15, 2019
Nashville, TN
https://2019.acrpnet.org/

MAGI Clinical Research Conference
May 5-8, 2019
Boston, MA
https://www.magiworld.org/forms/EventInfo.aspx?PK=46

SOCRA Clinical Research Nursing Conference
May 2-3, 2019
Philadelphia, PA
https://www.socra.org/conferences-and-education/training-conferences-workshops-courses/clinical-research-nursing/program-information/

Human Subjects Regulations: Set Your Reminders in the Era of the Revised Common Rule

The Revised Common Rule went into effect on January 21, 2019, and the UMMS IRB has started issuing new exemptions and new three-year approval periods for minimal risk non-exempt studies. Because FDA and DOJ have yet to harmonize with the Revised Common Rule, many UMMS studies will continue to receive one-year approvals. **If your study is exempt or has a three-year approval period, be sure to set an annual reminder for yourself to close the study once it's complete.** All Exempt and Non-Exempt studies, all changes to Non-Exempt studies, and select changes to Exempt studies continue to require prior IRB review and approval. For an overview of the Revised Common Rule (originally set to take effect in 2018), visit https://www.umassmed.edu/ccts/irb/what-you-should-know-about-the-2018-regulations/

General Requirements	
Exempt Studies	All Other Studies, Including Those With Three-Year Approvals
Conduct the research in accordance with the Investigator's Manual https://www.umassmed.edu/ccts/irb/	Conduct the research in accordance with the Investigator's Manual https://www.umassmed.edu/ccts/irb/
Obtain prior IRB review and approval for all Modifications that involve HIPAA or that potentially change the risks, exemption category, or scope of the research	**Obtain prior IRB review and approval for all Modifications**
Maintain a current list of CITI-trained Active Study Staff in eIRB	Maintain a current list of CITI-trained Active Study Staff in eIRB
Adhere to Prompt Reporting Requirements	Adhere to Prompt Reporting Requirements
Update conflict of interest declarations	Update conflict of interest declarations
Close the study via **Modification**	Close the study via **Continuing Review**

Community Engagement & Participation

Does your research team want to ensure that recruitment and retention plans are culturally sensitive and aware? Do you have questions about how to make your research more community-informed and/or better serve the needs of underserved populations through research? Do you want to connect with community organizations and leaders?
The consultation service at the Science Participation Research Center (SPRC) helps research teams with recruitment and retention strategies from grant planning phase to when projects are funded and under recruitment. SPRC will consult with study teams on a variety of aspects of the process, including cultural sensitivity in recruitment and retention approaches, to community partner connections for a more successful engagement at the community level. To obtain a SPRC consultation, access the following link: https://ummscwmuhs.quickbase.com/db/bkpmpxm27?a=nwr. More information about SPRC is available at https://www.umassmed.edu/ccts/sprc/

Clinicaltrials.gov

New Standard Operating Procedures and Initial Registration Guide have been approved and will be distributed via email and available on the updated CCTS HRPP website.

For answers to questions about clinicaltrials.gov, contact Meg Johnson, HRPP Compliance Administrator at Meg.Johnson@umassmed.edu or Clinicaltrials.gov@umassmed.edu.

Trial Innovation Resources

Resources are available for study development including **infrastructure to support multi-site clinical trials through the Trial Innovation Network (TIN).** Contact Ann Han, Navigator at Ann.Han@umassmed.edu to learn more.