



UMass Medical School
 UMass CCTS
 Human Research Protection Program
 ACC 7th Floor

UMass Medical School Human Research Protection Program (HRPP) Newsletter

Volume 7

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Status of New Human Subject Regulations

Updates to federal Human Subject Research regulation, better known as the “Common Rule,” were slated to take effect on January 19, 2018 and are now scheduled to take effect July 19, 2018. However, there is a strong possibility that the effective date will be further delayed to January 21, 2019.

The UMass Medical School IRB is ready—and has been working hard to ensure the research community is ready as well.

The IRB has already started to implement the updated regulations for new non-federally funded human research where it is possible. Research subject to the federal regulations must wait until the effective date for any application of the updated regulations.

Information and resources are available at:

<https://www.umassmed.edu/ccts/irb/what-you-should-know-about-the-2018-regulations/>

Please monitor the IRB website and notifications for news and updates—stay tuned!

HRPP QUALITY CORNER: Spotlight on...

Re-using old IRB Forms: the good and the not-so-good

Re-using and recycling paper, plastic and glass are all good ideas to help conserve resources. Recycling and re-using forms used on prior IRB submissions: not so much.

Re-use of IRB forms may seem like a time-saver, but the IRB continually updates and improves forms for regulatory or for operational improvement reasons—so always use the latest forms and templates. Otherwise, your application will be returned for revision

A few examples of recent updates: the Investigator Study Plan template was updated on 8/8/17 to provide users a handy checklist to help make sure the necessary supporting documents are submitted to the IRB. The Consent Form template was updated on 12/20/17 to incorporate a “key information” section as well as the HIPAA Authorization for Research—a move which helps streamline the consent and authorization process and reduce paperwork and reading burden for participants.

The most current templates and forms are always available at:

www.umassmed.edu/ccts/irb/forms_templates/



Contact Us:

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HRPeducation@umassmed.edu

Visit us on the web:

<http://www.umassmed.edu/ccts/human-research/>



UMass Medical School
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Human Research Protection

Upcoming Events

Clinical Research Professionals Group April Meeting

Thursday April 19, 2018, 1:30-2:30 pm
Hiatt Amphitheater
S1-608 or via Zoom (Login information available from CRPG listserv or by contacting crpg@umassmed.edu)

HRPP Readiness Bootcamps

Starting mid-July
Stay tuned for details!

Outside UMass:

Research Community Form & Symposium: Informed Consent: Content, Communications and Emerging Technologies.

May 1-2
Harvard Catalyst and Office for Human Research Protection
<https://catalyst.harvard.edu/services/regevents/ohrprcf.html>

Putting Patients at the Center of Research: Opportunities and Challenges for Ethical and Regulatory Oversight

Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics at Harvard
June 29, 2018
Harvard Law School
<http://petrieflom.law.harvard.edu/events/details/putting-patients-at-the-center-of-research>

AAHRPP Re-Accreditation & Changes in the UMass Medical School Human Research Protection Program

UMass Medical School is in the process of securing re-accreditation for its Human Research Protection Program from the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP). UMass Medical School was first awarded AAHRPP Accreditation (full) in December 2015. The re-accreditation process includes document submission followed by a multi-day site visit. An announcement to the research community will be made once we are informed of the site visit dates.

The UMass Medical School Human Research Protection Program has undergone a staff restructuring, with several individuals moving into new roles, including:

- Organizational Official: Katherine Luzuriaga, MD
- Director of Clinical Research Operations (Industry CTAs, Budgets & post award): Danielle Howard
- Education/Quality Improvement & Quality Assurance: Anne Roussel, RN
- Navigation and Support: Ann Han, MS
- ClinicalTrials.gov support and Investigator Training: Meg Johnson, JD, CIP
- IRB Vice Chair: Oren Schafer, MD
- Conflict of Interest: Laurie Richard (Administrator), Stuart Levitz, MD (Chair)

Focus on: ClinicalTrials.gov

If you are a “Responsible Party” for a clinical trial—meaning you initiated a clinical trial and/or hold an IND or IDE application as a Sponsor-Investigator, and the clinical trial is subject to the registration requirements of ICMJE, NIH or FDAAA 801, you are responsible for ensuring your clinical trial is registered on clinicaltrials.gov within a specific timeframe. Furthermore, if you are a “Responsible Party” on a clinical trial subject to NIH or FDAAA 801 requirements you must enter your results.

UMass Medical School is developing resources, policies and procedures to better secure compliance and to streamline operations.

Responsible Parties at UMass Medical School can obtain assistance from The UMass Center for Clinical and Translational Science.

- Meg Johnson is the new UMass Medical School ClinicalTrials.gov PRS administrator and is available for assistance and guidance. New accounts and clinicaltrials.gov assistance can be obtained by emailing clinicaltrials.gov@umassmed.edu and include PI’s last name in the subject line

Translation and Interpreter Services

The UMass Center for Clinical and Translational Science is launching an interpreter services access program to increase the availability of human research opportunities for the Limited English Proficient (LEP) population. Interpretative and translation services can be accessed in differing modalities from a variety of select vendors at competitive prices. Services include:

- Telephonic and Video interpretation
- Coordination of in-person interpretive services, including tablet for video interpretation
- Document translation

To secure services and obtain pricing, fill out the [Interpreter Services Request Form](#) or contact Ann Han at ann.han@umassmed.edu or 508-856-1960 for more information