UNIVERSITY of MARYLAND BALTIMORE

SMART IRB & Reliance Processes

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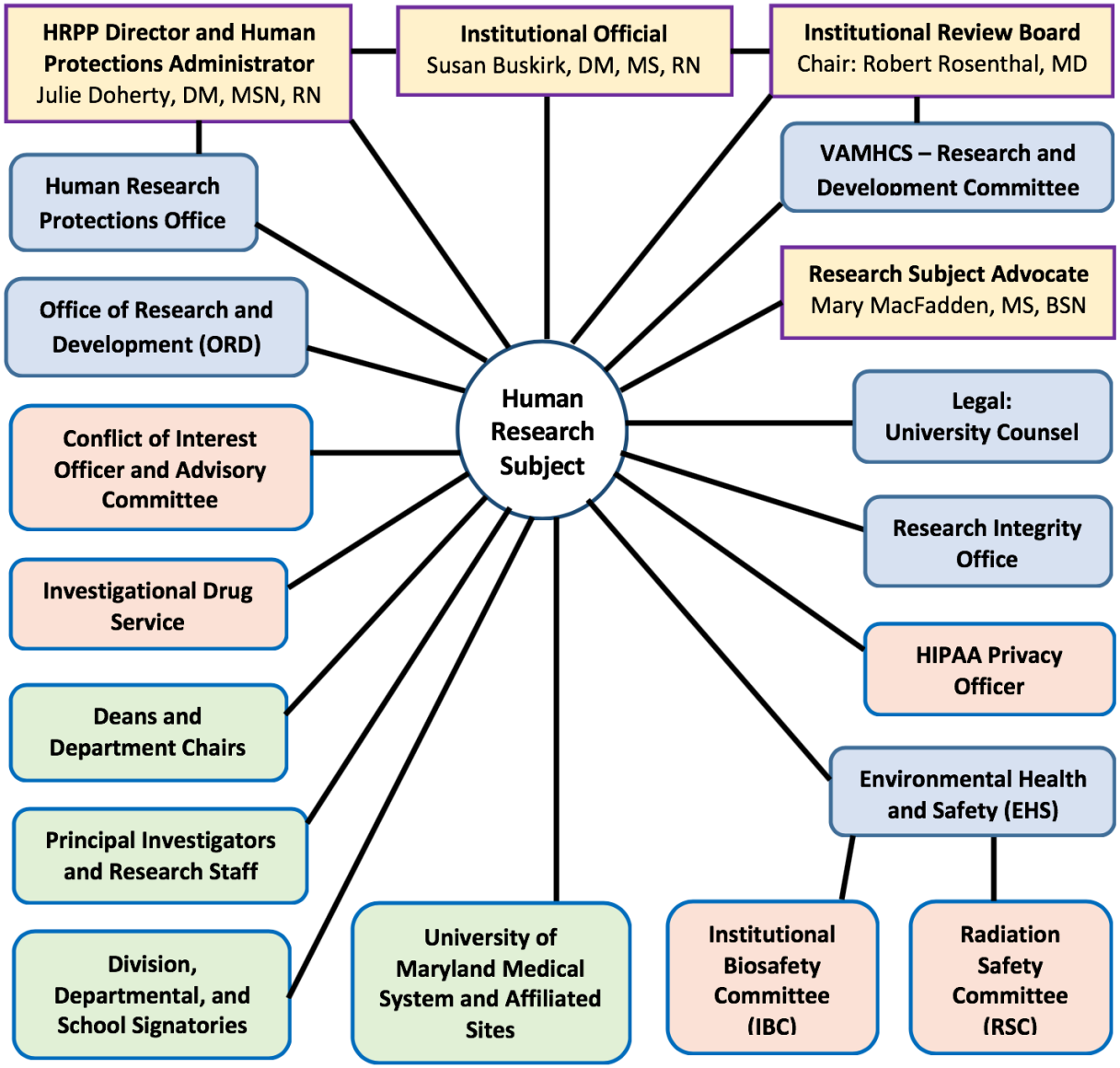
Office of Accountability & Compliance
November 17, 2022

HUMAN RESEARCH PROTECTIONS PROGRAM


HRPP Director and Human Protections Administrator
Julie Doherty, DM, MSN, RN
Institutional Official
Susan Buskirk, DM, MS, RN
Institutional Review Board
Chair: Robert Rosenthal, MD
Human Research Protections Office
VAMHCS – Research and Development Committee
Office of Research and Development (ORD)
Research Subject Advocate
Mary MacFadden, MS, BSN
Human Research Subject
Conflict of Interest Officer and Advisory Committee
Legal: University Counsel
Investigational Drug Service
Research Integrity Office
HIPAA Privacy Officer
Deans and Department Chairs
Environmental Health and Safety (EHS)
Principal Investigators and Research Staff
Division, Departmental, and School Signatories
University of Maryland Medical System and Affiliated Sites
Institutional Biosafety Committee (IBC)
Radiation Safety Committee (RSC)

The compliance date for the revised Common Rule cooperative research sIRB mandate (§46.114) is January 20, 2020 f
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Reliance Mandates

- NIH -Single IRB for Multi-Site Research
  - Compliance date: January 25, 2018
- Revised Common Rule 45 CFR 46 - Single IRB for Cooperative Research
  - Compliance date: January 20, 2020

Common Rule 45 CFR 46 - Single IRB for Cooperative Research

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.

The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

sIRB –Common Rule

- *The following research is not subject to this provision:*

  (i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

sIRB – Common Rule

- ***Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.***
- *(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.*

sIRB Common Rule

- Exceptions:
  - Research approved prior to January 2020

Common Rule Agencies

- Department of Agriculture
- Department of Energy
- NASA
- Department of Commerce
- Agency for International Development
- Department of Defense
- Department of Education
- Department of Homeland Security
- Department of Veterans Affairs
- Department of Labor

Common Rule Agencies

- Environmental Protection Agency
- Department of Health and Human Services
- National Science Foundation
- Department of Transportation
- Office of the Director of National Intelligence
- Central Intelligence Agency
- Consumer Product Safety Commission
- Social Security Administration

sIRB - NIH

- The National Institutes of Health (NIH) issued this policy on the use of a single Institutional Review Board (IRB) for multi-site research

- Establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.

sIRB NIH

- Goal
  - Enhance and streamline the IRB review process in the context of multi-site research
  - Research can proceed as effectively and expeditiously as possible.

sIRB -NIH

- Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections.
- The shift in workload away from conducting redundant reviews is also expected to allow IRBs to concentrate more time and attention on the review of single site protocols, thereby enhancing research oversight.

Food and Drug Administration

- The Food and Drug Administration (FDA) is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices.
- FDA is not considered a Common Rule agency because its regulations differ from the Common Rule. However, FDA is required to harmonize with the Common Rule whenever permitted by law (see section 1002 of the 21st Century Cures Act, Public Law 114-255)

Food and Drug Administration

- On September 28, 2022, the U.S. Food and Drug Administration ("FDA") issued two Notices of Proposed Rule Making to harmonize FDA's regulations pertaining to human subjects research and the review of cooperative research by a single institutional review board with those of the Federal Policy for the Protection of Human Subjects.

Stay tuned……..

Processes

* Reliance on an external IRB
  - Multi-site/cooperative
  - CICERO -Truncated application
  - Regardless of funding

* UMB is IRB of record
  - Multi-site/cooperative
  - CICERO –Full application
  - Regardless of funding

Reliance Processes

- CICERO
  - Departmental review
  - Ancillary reviews
    - Conflict of interest
    - Radiation Safety (RSC)
    - Institutional Biosafety (IBC)
    - Investigational Drug Service
    - GCRC (as applicable)

Reliance

- SMART IRB
  - Platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy (effective date: January 25, 2018).
  - https://smartirb.org/
  - Provides an easy way for investigators and institutions to track and document reliance arrangements on a study-by-study basis.

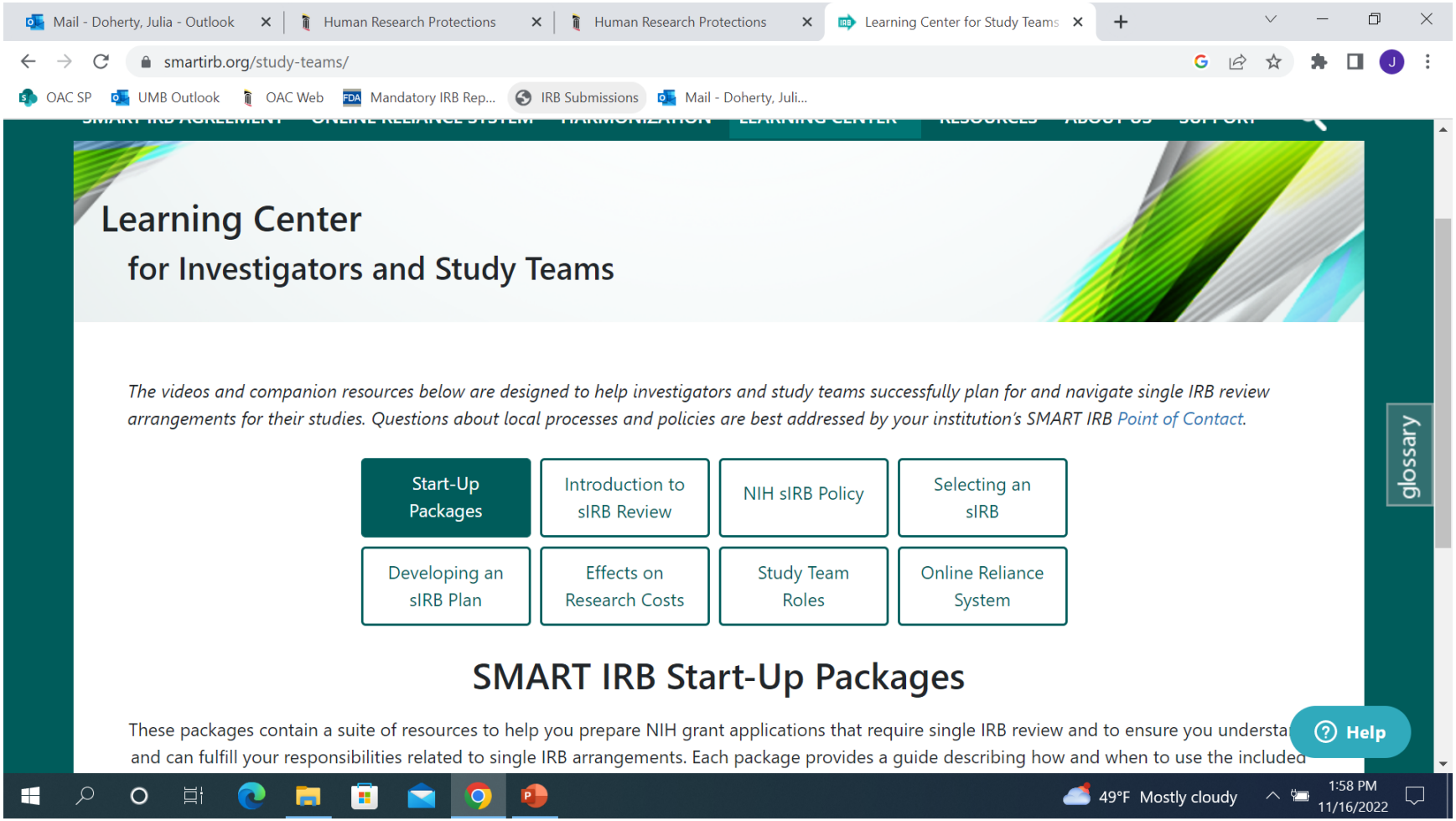
SMART IRB

- SMART IRB
  - Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform
  - Designed to harmonize and streamline the IRB review process for multisite studies, while ensuring a high level of protection for research participants.

SMART IRB

- Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation, regardless of funding status.

SMART IRB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Learning Center for Study Teams
smartirb.org/study-teams/
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UMB Outlook
OAC Web
Mandatory IRB Rep...
IRB Submissions
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Learning Center
for Investigators and Study Teams
The videos and companion resources below are designed to help investigators and study teams successfully plan for and navigate single IRB review arrangements for their studies. Questions about local processes and policies are best addressed by your institution's SMART IRB Point of Contact.
Start-Up Packages
Introduction to sIRB Review
NIH sIRB Policy
Selecting an sIRB
Developing an sIRB Plan
Effects on Research Costs
Study Team Roles
Online Reliance System
glossary
SMART IRB Start-Up Packages
These packages contain a suite of resources to help you prepare NIH grant applications that require single IRB review and to ensure you understa
and can fulfill your responsibilities related to single IRB arrangements. Each package provides a guide describing how and when to use the included
Help
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SMART IRB

- SMART IRB
  - Is not an IRB
  - Rather, it's a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System)
  - Provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements.

SMART IRB

- Master Common Reciprocal Institutional Review Board Authorization Agreement
- Institutional Profile
- 1042 participating institutions
  - CTSA hubs and affiliates, universities, academic medical centers, community hospitals, cancer centers, independent IRB organizations

SMART IRB

- Master Reciprocal Agreement
- Reliance requests
  - Institutional official
  - Reviewed individually
  - Approved/acknowledged on a case-by-case basis

RESOURCES

RELIANCE PROCESSES

- Consult with the UMB Human Research Protections Office prior to grant submissions and IRB submissions
  - Reliance on external IRB
  - Grant letter of support

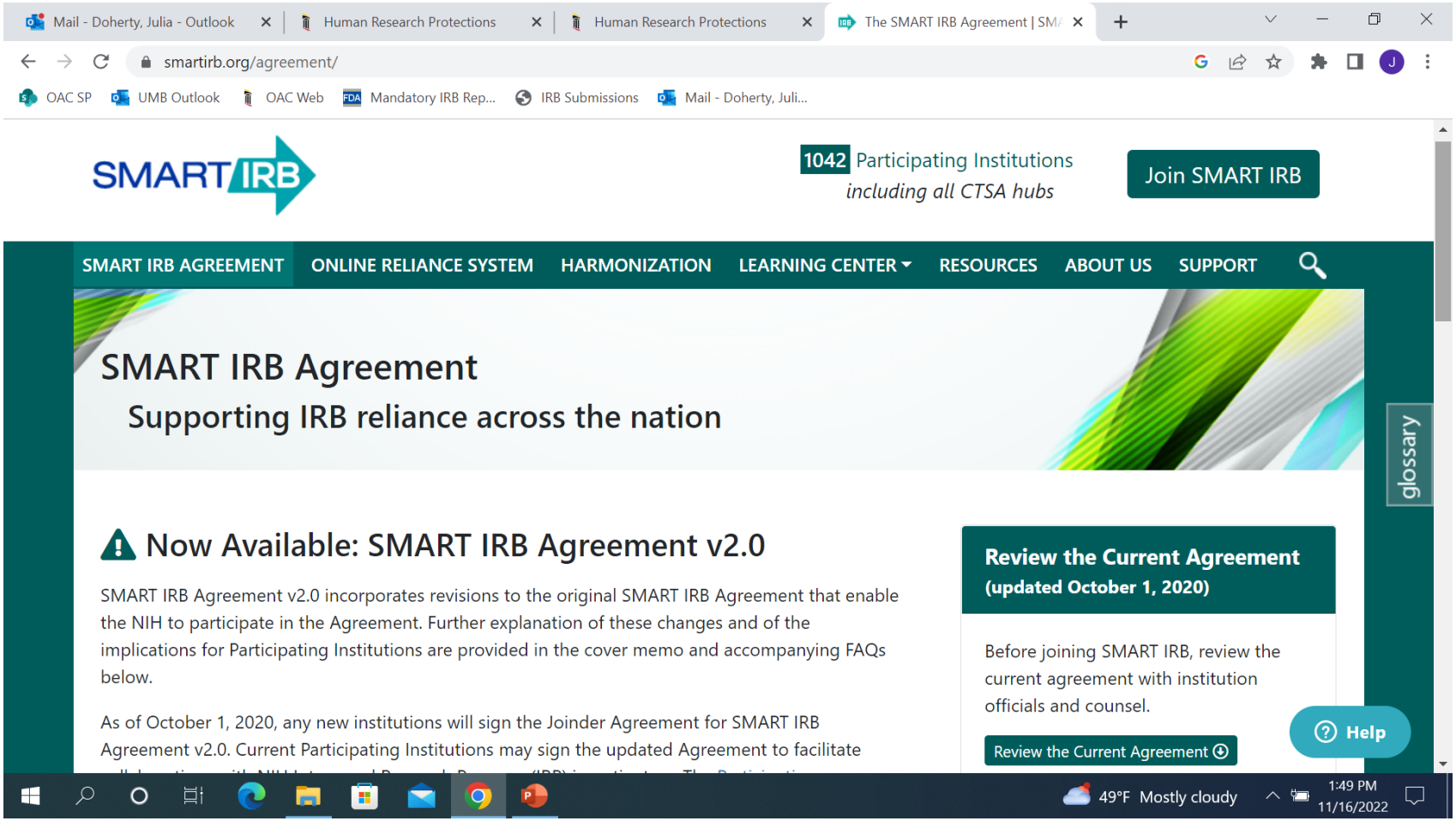
Getting Started

Required Trainings:

- Collaborative Institutional Training Initiative (CITI)
  - www.citiprogram.org
  - Course in the Protection of Human Subjects
  - Good Clinical Practices (NIH)
  - Affiliate with University of Maryland, Baltimore or Baltimore, MD-512 (VA)
  - *Note: CICERO account and CITI account are not linked!*
- HIPAA 125: Privacy and Security Review
- HIPAA 201: Human Research

Reliance Processes

- Simultaneously
  - Submit in CICERO
  - Submit in SMART IRB
    - Collaborate with other study sites
    - Roles differ based on who is IRB of record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OAC Web
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IRB Submissions
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SMART IRB
1042 Participating Institutions
including all CTSA hubs
Join SMART IRB
SMART IRB AGREEMENT
ONLINE RELIANCE SYSTEM
HARMONIZATION
LEARNING CENTER
RESOURCES
ABOUT US
SUPPORT
SMART IRB Agreement
Supporting IRB reliance across the nation
glossary
Now Available: SMART IRB Agreement v2.0
SMART IRB Agreement v2.0 incorporates revisions to the original SMART IRB Agreement that enable the NIH to participate in the Agreement. Further explanation of these changes and of the implications for Participating Institutions are provided in the cover memo and accompanying FAQs below.
As of October 1, 2020, any new institutions will sign the Joinder Agreement for SMART IRB Agreement v2.0. Current Participating Institutions may sign the updated Agreement to facilitate
Review the Current Agreement
(updated October 1, 2020)
Before joining SMART IRB, review the current agreement with institution officials and counsel.
Review the Current Agreement
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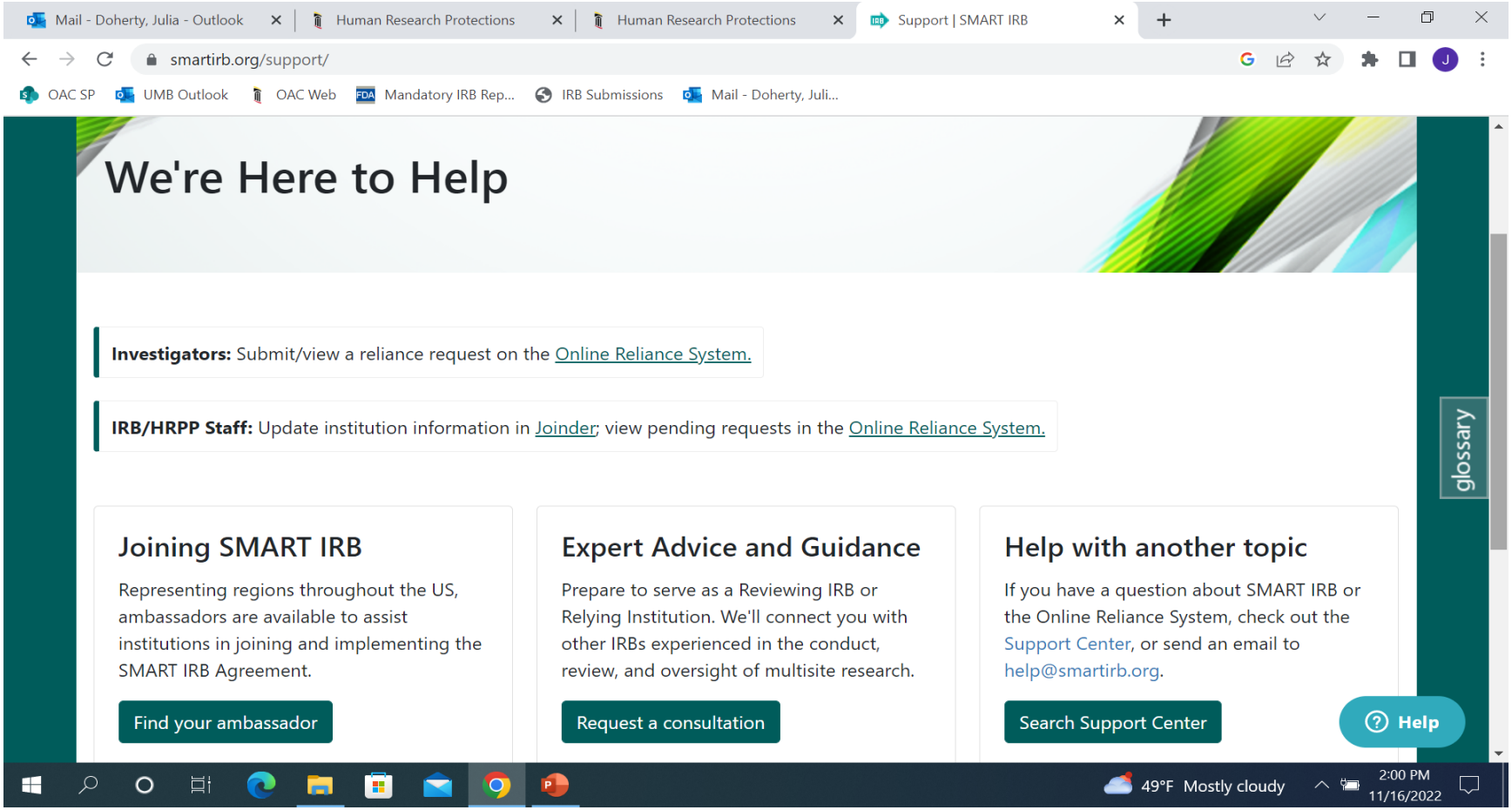
SMART IRB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OAC Web
Mandatory IRB Rep...
IRB Submissions
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We're Here to Help
Investigators: Submit/view a reliance request on the Online Reliance System.
IRB/HRPP Staff: Update institution information in Joinder; view pending requests in the Online Reliance System.
glossary
Joining SMART IRB
Representing regions throughout the US, ambassadors are available to assist institutions in joining and implementing the SMART IRB Agreement.
Find your ambassador
Expert Advice and Guidance
Prepare to serve as a Reviewing IRB or Relying Institution. We'll connect you with other IRBs experienced in the conduct, review, and oversight of multisite research.
Request a consultation
Help with another topic
If you have a question about SMART IRB or the Online Reliance System, check out the Support Center, or send an email to help@smartirb.org.
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Ask questions!

- IRB Reliance Analyst – Scott Evans
  - sevans@umaryland.edu
- IRB Manager – Jan Martinez
  - Jan.Martinez@umaryland.edu
- Assistant Vice President, Research Compliance
  - Julie Doherty – jdoherty@umaryland.edu
- Contact information is available at http://www.umaryland.edu/hrp/hrp-office/hrpo-personnel/

Questions?

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