**Wednesday, May 24, 2023**

**Fundamentals of Clinical Research Lecture Series**

**Session 1:** Everything You Wanted to Know About the IRB and Then Some

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**Presentation Resources List:**

* Job Aid to help prevent difficulties logging into Med School sites while on the Clinical Network (copy also attached to email) - [RMS Job Aid Clinical and Other External User Log in tips](https://umassmed.sharepoint.com/sites/RMS/IRB/eIRB%20Job%20Aids%20%20Other%20Materials/Forms/AllItems.aspx?id=%2Fsites%2FRMS%2FIRB%2FeIRB%20Job%20Aids%20%20Other%20Materials%2FAccount%20and%20Log%20In%20related%20Information%20%28RMS%20eIRB%29%2FRMS%20Job%20Aid%20Clinical%20and%20Other%20External%20User%20Log%20in%20tips%202%2D23%2D2022%2Epdf&parent=%2Fsites%2FRMS%2FIRB%2FeIRB%20Job%20Aids%20%20Other%20Materials%2FAccount%20and%20Log%20In%20related%20Information%20%28RMS%20eIRB%29)
* **Link to the UMass Chan IRB’s PUBLIC facing website**: [**https://www.umassmed.edu/ccts/irb/**](https://www.umassmed.edu/ccts/irb/)
  + Sub pages:
    - Getting Started Page: <https://www.umassmed.edu/ccts/irb/getting-started2/>
    - Getting Started PDFs – will need to log in with umassmed.edu credentials (copies also attached to email):
      * For Coordinators and students: [Click Here](https://umassmed.sharepoint.com/:b:/r/sites/RMS/IRB/eIRB%20Job%20Aids%20%20Other%20Materials/.Getting%20Started%20with%20Clinical%20Research%20%26%20IRB/Coordinators%26Students%20-%20Getting%20Started%20w%20Clinical%20Research%20at%20UMassChan%202022.09.28.pdf?csf=1&web=1&e=5dHbrx)
      * For PIs: [Click Here](https://umassmed.sharepoint.com/sites/RMS/IRB/eIRB%20Job%20Aids%20%20Other%20Materials/Forms/AllItems.aspx?id=%2Fsites%2FRMS%2FIRB%2FeIRB%20Job%20Aids%20%20Other%20Materials%2F%2EGetting%20Started%20with%20Clinical%20Research%20%26%20IRB%2FInvestigators%20%2DGetting%20Started%20w%20Clinical%20Research%20at%20UMassChan%202022%2E09%2E28%2Epdf&parent=%2Fsites%2FRMS%2FIRB%2FeIRB%20Job%20Aids%20%20Other%20Materials%2F%2EGetting%20Started%20with%20Clinical%20Research%20%26%20IRB)
* **Link to IRB Sharepoint website:** [**https://umassmed.sharepoint.com/sites/RMS/IRB**](https://umassmed.sharepoint.com/sites/RMS/IRB)

(NOTE: must log in using umassmed.edu credentials to access SharePoint sites)

* + Sub pages:
    - RMS eIRB log in [Direct Link](https://irb.umassmed.edu/) (NOTE: must log in using umassmed.edu credentials to access)
    - [IRB Virtual Office Hours Page](https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/eIRB%20Office%20Hours%20page.aspx) –
      * Schedule of times and Zoom link are located here. Drop in via Zoom when we’re scheduled to be there to get answers to your IRB questions!
    - [IRB Training Page](https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/eIRB%20Training%20Resources.aspx?Mode=Edit) – we recommend you watch all the videos, but the ones mentioned in the presentation were:
      * eIRB Training Course 2
        + eIRB JobAid File management in eIRB
        + eIRB JobAid Naming Conventions Job Aid
      * HIPAA and the HIPAA Waiver of Authorization form Video
      * RNI Training Course
      * Continuing Review: First Steps - Where to Begin
    - [IRB Library Page](https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/Library-(SOPs,-Forms,Templates,-Etc).aspx)
      * In Investigator Manual and General Documents folder: [HRP-103 Investigator Manual](https://umassmed.sharepoint.com/sites/RMS/IRB/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Fsites%2FRMS%2FIRB%2FShared%20Documents%2FToolkit%2FInvestigator%20Manual%20%26%20General%20Documents%20%28100%2D108%29&FolderCTID=0x0120005C4B6A519ADDB04AB1C84DE333A1450E)
      * In Worksheets folder - [HRP-310-Worksheet-Human Research Determination document](https://umassmed.sharepoint.com/:w:/r/sites/RMS/IRB/Shared%20Documents/Toolkit/Worksheets%20(300-399)/HRP-310%20-%20WORKSHEET%20-%20Human%20Research%20Determination.docx?d=wcfbca30eb2e94156be245e5b76d6f720&csf=1&web=1&e=V8W8bf) - use for guidance, do not fill out/submit to the IRB
      * In Templates folder:
        + Case Study Report Form template – do not submit to the IRB
        + HIPAA Waiver of Authorization form template
        + Fact Sheet template
        + HRP-502 Consent Document and HIPAA Authorization form template (ICF)
        + HRP-503 Investigator Study Plan (ISP)
        + Request for Not Human Subjects Research form template
    - [IRB FAQ Page](https://umassmed.sharepoint.com/sites/RMS/IRB/SitePages/Frequently-Asked-Questions.aspx)
    - Friendly reminder to check the IRB News Section on the Main page for announcements and updates!
* **Additional Resources for Data Collection, Storage, Sharing, and Destruction**
  + [IT Best Practices SharePoint page](https://umassmed.sharepoint.com/sites/information-technology/SitePages/Information-Technology-Best-Practices.aspx?OR=Teams-HL&CT=1684347230669&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzA0MDIwMjcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)
  + IRB/Library collaboration video (Link coming soon! Will send out once it’s available)
  + HRP-503 ISP template instructions
* **List of HIPAA PHI Identifiers and additional information:**
  + <https://privacyruleandresearch.nih.gov/pr_08.asp>
* **UMCCTS Protocol Review Committee (PRC)**
  + <https://www.umassmed.edu/ccts/research-resources/protocol-review-committee/>
* **Additional Departments/Resources that may have the answers you need:**
  + Your mentor/PI
  + Proofreaders
  + NIH pages and instructions: <https://grants.nih.gov/grants/how-to-apply-application-guide.html>
  + UMass Chan IT [Research Technology](https://umassmed.sharepoint.com/sites/information-technology/SitePages/services-Research-Technology.aspx)
  + UMass Chan [Lamar Soutter Library](https://library.umassmed.edu/)
  + UMass Chan [Grants and Contracts Administration](https://umassmed.sharepoint.com/sites/gca)
  + UMCCTS [Research Informatics Core,](https://www.umassmed.edu/research-informatics/)  [Community Engagement](https://www.umassmed.edu/ccts/community/programs-and-resources/creating-research-teams/), [Tissue & Tumor Bank](https://www.umassmed.edu/tissue-and-tumor-bank/)