



IRB MEMBER TRAINING- IRB MEMBERS AND THE HSERA EXPERIENCE

OCTOBER 2016



WHAT'S NEW?

- HSERA specific changes:

- Application changes to align with new forms
 - Where we are now and what is coming next
- Updates to Board Member view

- Other support updates for members:

- PDF Portfolios
- IRB Member Tool Box

HSERA SPECIFIC CHANGES

■ **Application changes:**

- The HSERA Continuing Review System application has been revised to align with the use of the new form
 - Submitters now complete a form downloaded from the IRB website, complete a shortened CR application (2 questions only) and attach all applicable documents prior to submitting
 - IRB Members then review the attached documents instead of scrolling through HSERA for information
- We are piloting the system application revisions with the CR form and will move forward with changes to the other applications (Modification, Deviation, Exception, Reportable Event) in 2017
- The process for initial submissions is not changing now
 - A new application specifically for reliance agreements is in development, however a timeline for implementation has not been determined

HSERA SPECIFIC CHANGES

- For the applications that have not been updated (Modification, Deviation, Exception, Reportable Event)
 - Study teams are encouraged to utilize the new forms for these application types and to answer all of the electronic system application questions with “0” or “NA” or references to the attached documents
 - Compliance with this method has not been consistent – some submissions will not include the attached forms and instead will be completed in the traditional manner
 - We have not been rejecting submissions if they did not use the form, however if a submission is returned for edits we are asking that they complete the new form with their re-submission
 - In cases where a submission is not returned and did not use the new form, the IRB staff is including notes in the letters instructing the study team to download and use the forms for all future submissions
 - If you are assigned one of these types of actions and cannot locate the appropriate form attachment, you should utilize the responses to the electronic system questions
 - If you are ever unsure, please reach out to your board administrator or assistant for clarification in advance of the meeting

HSERA UPDATES FOR BOARD MEMBERS

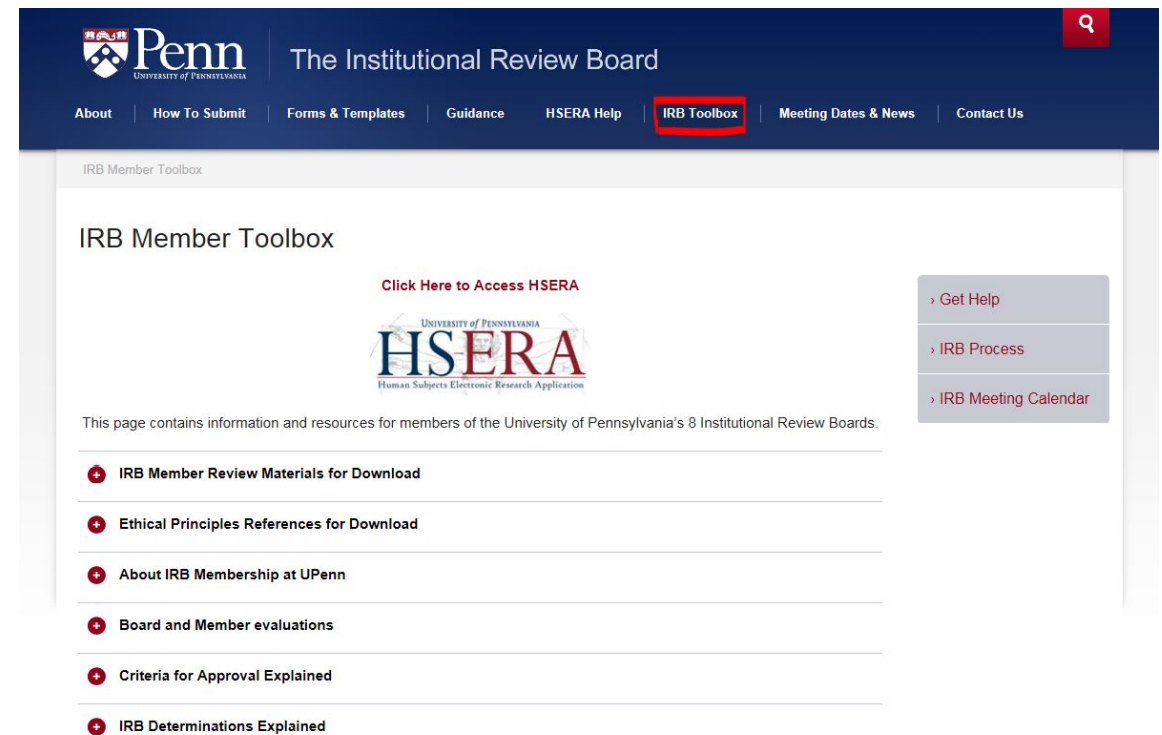
- **Board Member view of applications:**
 - We have requested that the Comments section default to an open view to ensure members have quick access
 - this update has been submitted to the tech team but is not in production yet
 - We have requested that document links change color once a document has been downloaded so that members can be sure they have looked at each document and avoid downloading the same document multiple times.
 - this update has been submitted to the tech team but is not in production yet

SUPPORT FOR IRB MEMBERS

- PDF portfolios to assist with full board agenda items
 - The IRB support staff will create a PDF portfolio for each full board agenda item of all documents relevant to a particular review
 - Documents uploaded by the study team
 - Any email correspondence or documents provided via email
 - The portfolio will be uploaded as an attachment in the comments
 - This will allow members to download one file that contains all documents needed to perform a review
 - The process for this is still being developed and piloted to ensure consistent implementation across boards

SUPPORT FOR IRB MEMBERS

- The old “Regulatory Affairs” website no longer contains any IRB specific information
- All IRB info has been moved to the new website that was launched in 2015- www.upenn.edu/IRB
- IRB Members should bookmark the “IRB Toolbox” tab for quick access to HSERA and IRB tools
- The IRB toolbox includes:
 - A large hyperlink directly to HSERA
 - Review materials and guidance for download
 - Ethical principles references for download
 - Information about IRB membership at Penn



The screenshot shows the top navigation bar of the University of Pennsylvania's Institutional Review Board website. The navigation menu includes: About, How To Submit, Forms & Templates, Guidance, HSERA Help, IRB Toolbox (highlighted with a red box), Meeting Dates & News, and Contact Us. Below the navigation bar, the page title is "IRB Member Toolbox". A prominent link reads "Click Here to Access HSERA" above the HSERA logo (Human Subjects Electronic Research Application). On the right side, there is a vertical menu with three items: "Get Help", "IRB Process", and "IRB Meeting Calendar". The main content area contains a list of resources for IRB members, each with a red plus icon:

- IRB Member Review Materials for Download
- Ethical Principles References for Download
- About IRB Membership at UPenn
- Board and Member evaluations
- Criteria for Approval Explained
- IRB Determinations Explained