CICERO OVERVIEW

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IRB Administrator

Human Research Protections Office

Office of Academic Affairs – Research Compliance

HUMAN RESEARCH PROTECTIONS PROGRAM

Human Research Protections Program (HRPP)

- Comprehensive system
- Ensures the protections of the rights and welfare of human research participants
- HRPP Plan describes roles and responsibilities

Human Research Protections Program

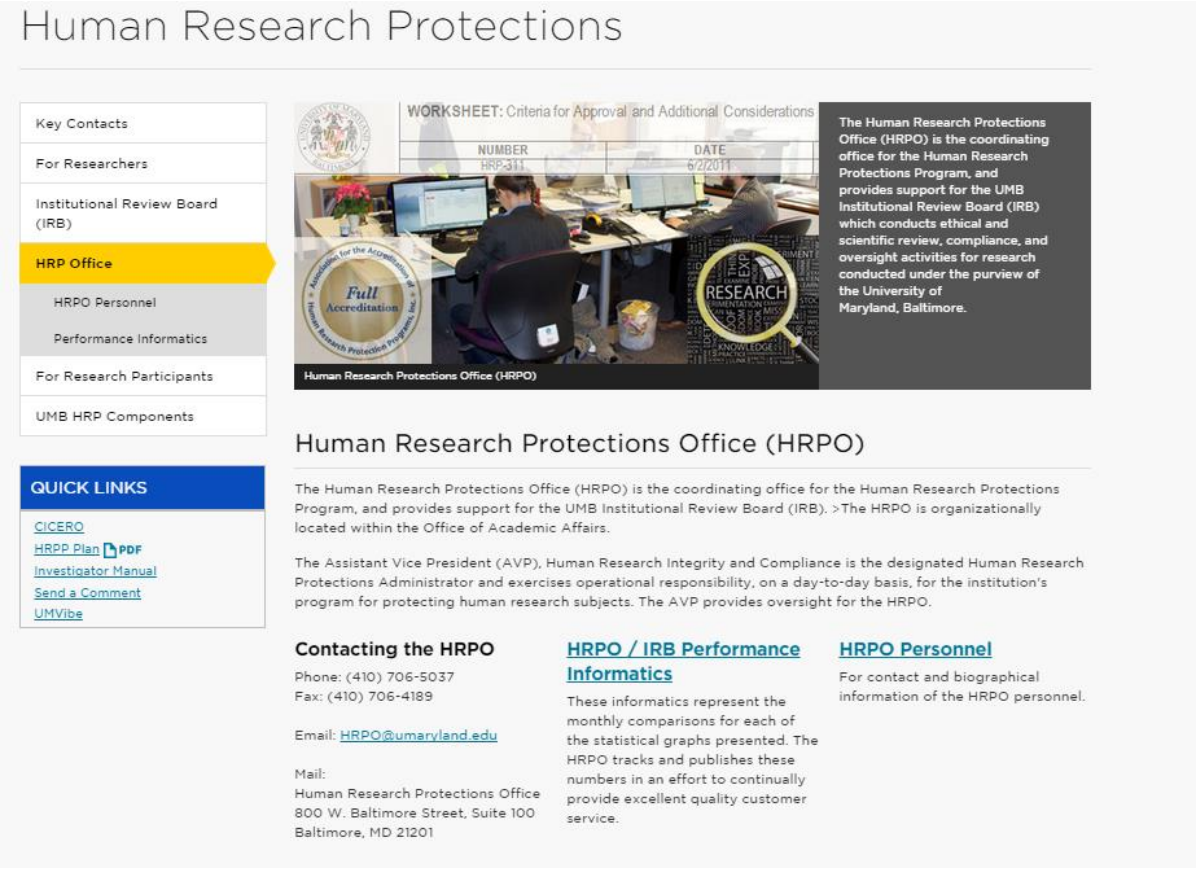
Components include:

- Institutional Official
- Institutional Review Board (IRB)
- Human Research Protections Office (HRPO)
- University Counsel
- Conflict of Interest Officer/Advisory Committee
- Investigational Drug Services
- Institutional Biosafety/Radiation Safety Committees
- Investigators/Research Team

Human Research Protections Office

- Coordinating office for the HRPP
- Provides support for the IRB
  - Oversight of >2,000 research protocols
  - New, Continuing Review, Modification
  - Reportable New Information
  - Meeting activities

Human Research Protections Office



http://www.umaryland.edu/hrp

Institutional Review Board

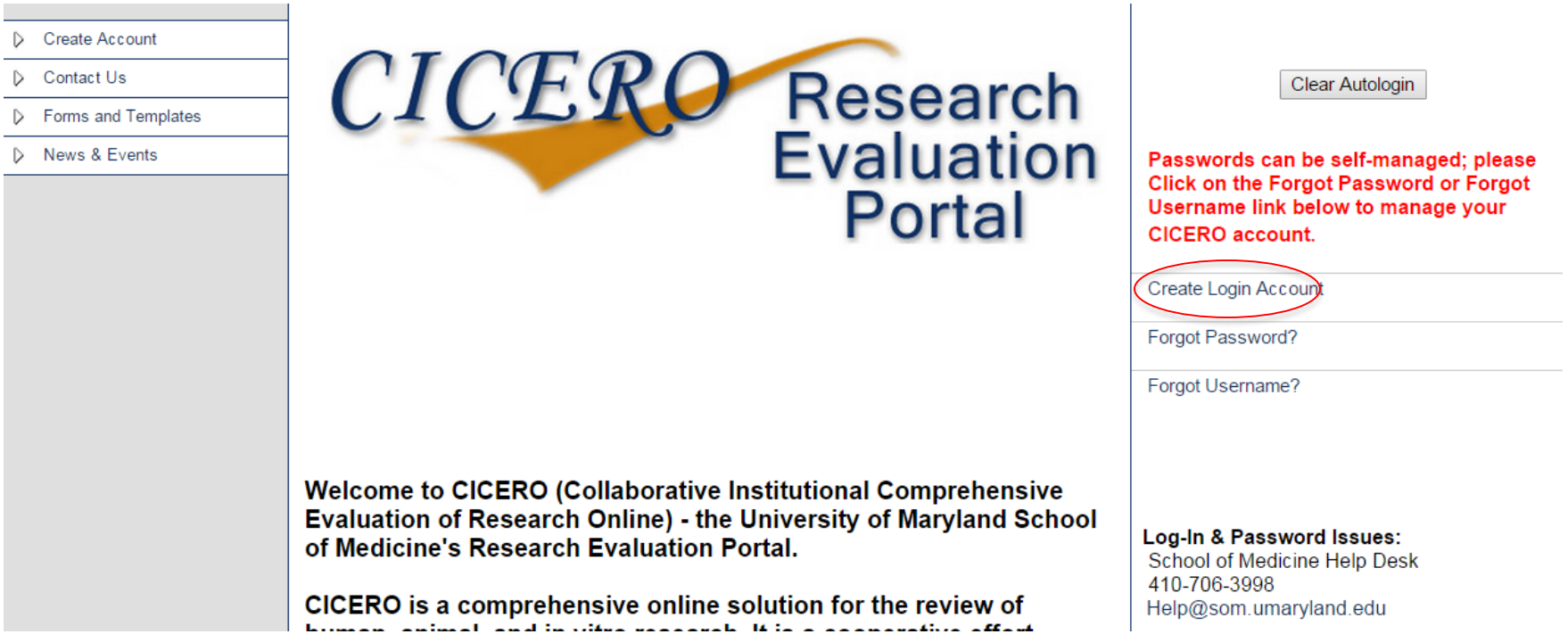
- Organizationally designated IRB must review all Human Research
- Authority:
  - Approve
  - Require modifications to secure approval
  - Disapprove
  - Suspend
  - Terminate
  - Observe consent process and research conduct

COLLABORATIVE INSTITUTIONAL COMPREHENSIVE EVALUATION OF RESEARCH ONLINE (CICERO)

CICERO

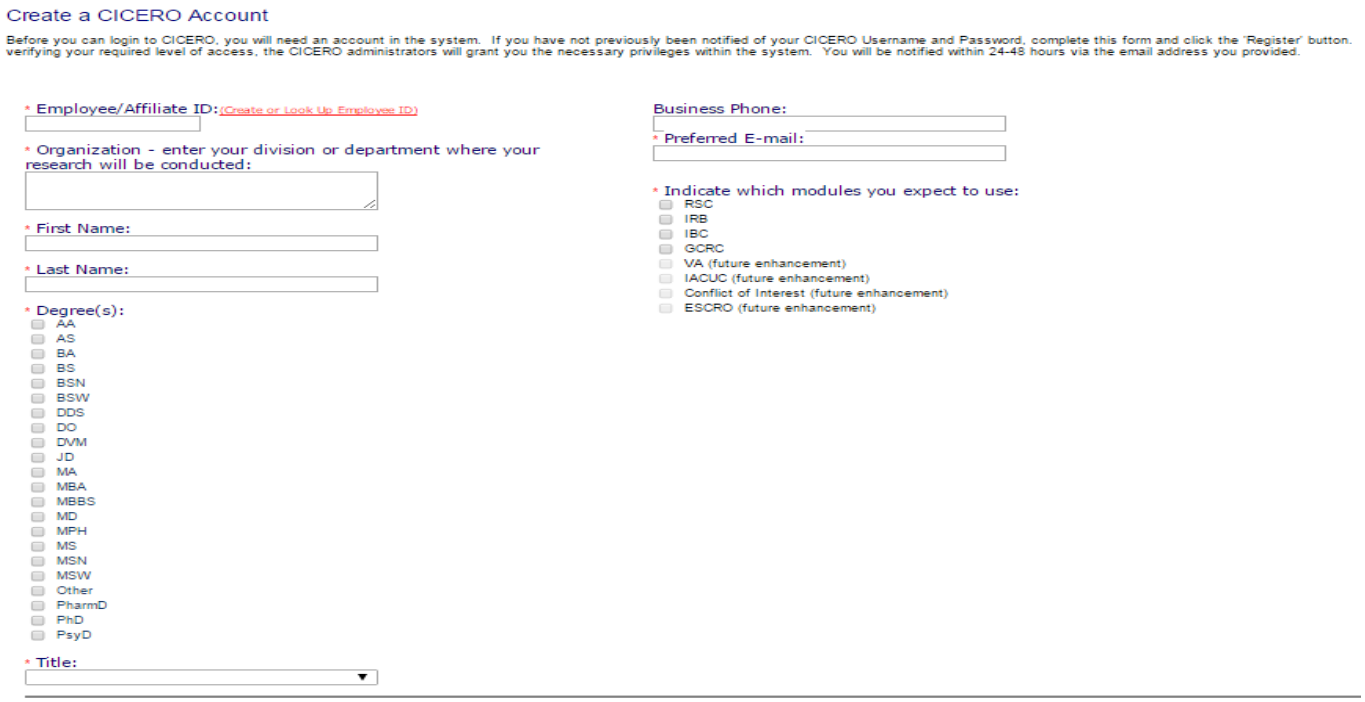
- Internet based electronic system
- Supports multiple committees
  - Institutional Review Board
  - Institutional Biosafety Committee
  - Radiation Safety Committee
  - General Clinical Research Center
  - Conflict of Interest

Requesting a CICERO account



cicero.umaryland.edu

Requesting a CICERO account



Create a CICERO Account

Before you can login to CICERO, you will need an account in the system. If you have not previously been notified of your CICERO Username and Password, complete this form and click the 'Register' button. verifying your required level of access, the CICERO administrators will grant you the necessary privileges within the system. You will be notified within 24-48 hours via the email address you provided.

* Employee/Affiliate ID: (Create or Look Up Employee ID)

* Organization - enter your division or department where your research will be conducted:

* First Name:

* Last Name:

* Degree(s):
- AA
- AS
- BA
- BS
- BSN
- BSW
- DDS
- DO
- DVM
- JD
- MA
- MBA
- MBBS
- MD
- MPH
- MS
- MSN
- MSW
- Other
- PharmD
- PhD
- PsyD

* Title:

Business Phone:

* Preferred E-mail:

* Indicate which modules you expect to use:
- RSC
- IRB
- IBC
- GCRC
- VA (future enhancement)
- IACUC (future enhancement)
- Conflict of Interest (future enhancement)
- ESCRO (future enhancement)

Accounts may take up to 48 hours to be created.

The Principal Investigator (PI)

- Bears ultimate responsibility for assuring compliance with all UMB HRPP policies and procedures for the protection of human participants
- Must be a full time (>51% effort) Professor, Associate Professor or Assistant Professor at UMB
- PI Privileges must be added to a CICERO account
- Students and fellows are not permitted to be PIs

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

Getting Started

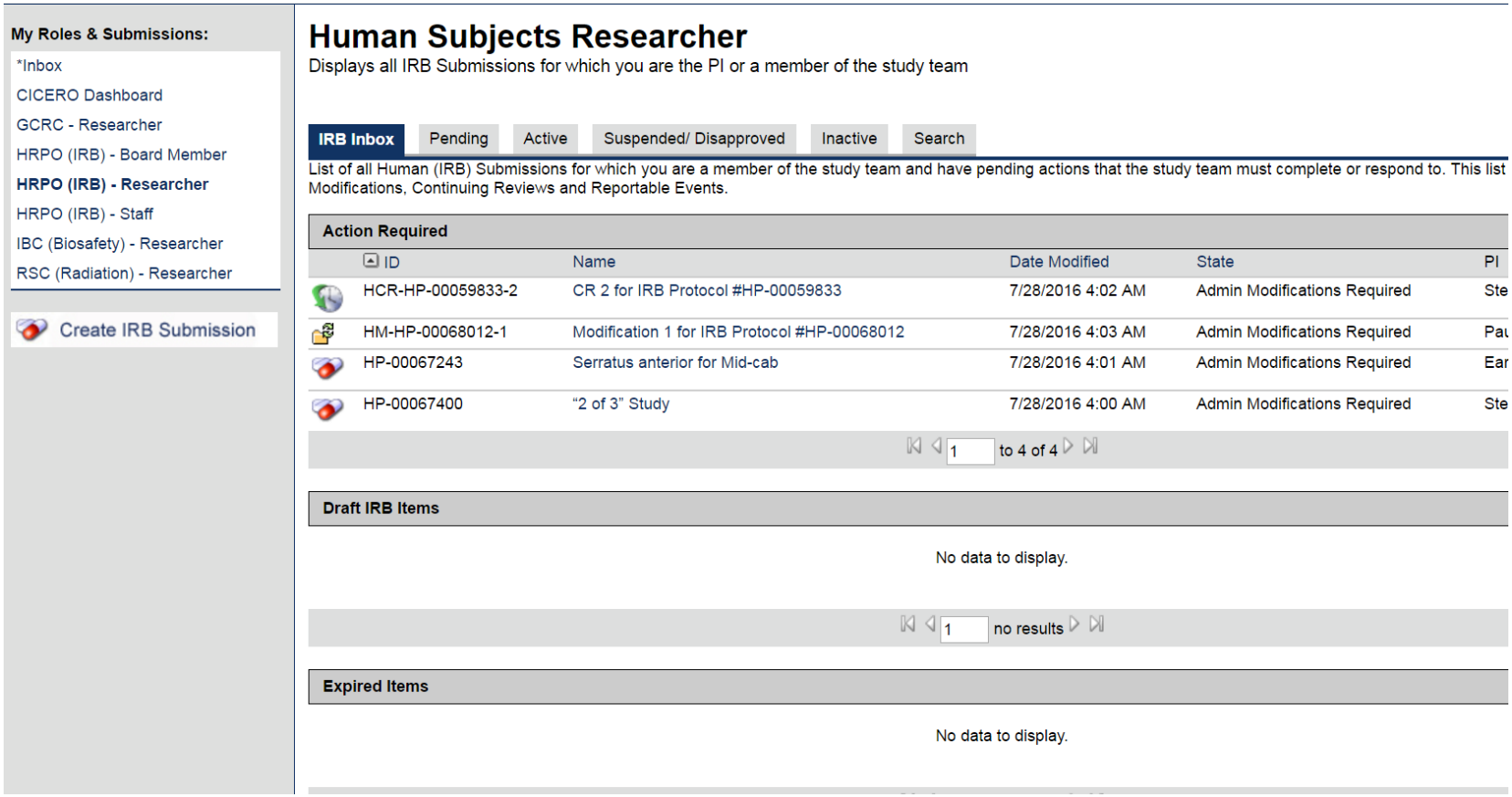
- HRPO Website: www.umaryland.edu/hrp
- Investigator Manual
- HRPP Plan
- RNI Bulletin
- Instructional Videos
  - CICERO Instructional Videos
  - IRB Process Videos
  - HRP Lecture Videos

CREATING A SUBMISSION

CICERO Inbox

- Displays all submissions for which you are the PI or a member of the study team
- Roles
  - HRPO (IRB) – Researcher
  - GCRC – Researcher
  - IBC (Biosafety) – Researcher
  - RSC (Radiation) – Researcher

CICERO Inbox



CICERO Inbox

- Pending (in review process)
  - New, CR, Mod, RNI
- Active
  - Approved, Exempt, NHSR, External IRB
- Inactive
  - Closed, Withdrawn

Creating a New Application

Click 

button in the left column of the CICERO inbox.

Creating a New Application

Fill out the CICERO application completely and accurately

- Smart Form
- Any questions with a RED asterisk "*" require a response
- Help Text can be found throughout where the HELP icon is visible

Creating a New Application

Introduction Page

1 * Abbreviated Title:

2 * Full Title:

3 * Select Type of Submission:

- IRB Application
- Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- Emergency Use
- Unsure if this proposal requires IRB review (Not Human Subject Research)
- Continuing Review of a Previously Approved BRAAN Application

Clear

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

Unsure if this requires IRB review

- Research: Systematic investigation designed to contribute to generalizable knowledge
  - Quality improvement
- Human Subjects:
  - Interaction or intervention; or
  - Private and identifiable information
- FDA

Submitting a New Application

- Only the PI can submit a new IRB application
- Researchers are responsible to not conduct human research without prior IRB review and approval (or not human subjects research determination)
- Department Scientific and Feasibility Review
- Specialty Review (Pediatrics, Cancer Center)

HRPO/IRB Review

- Pre-review
- Level of Review
  - Research?
  - Human Subjects Research?
  - Engaged?
  - Exempt
  - Expedited Procedure
  - Convened IRB
- Post Review
  - Expedited vs. Convened IRB

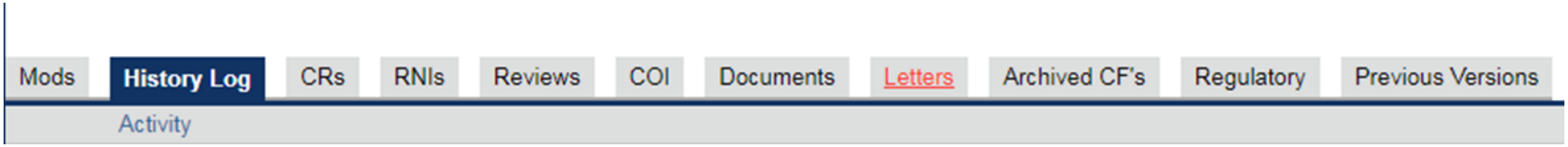
IRB Determinations

- Approve
  - Stamped Consent(s)
- Modifications Required to Secure Approval
- Defer
- Disapprove

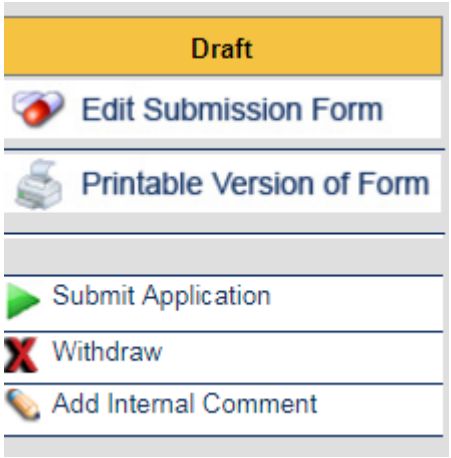
Main CICERO History Log

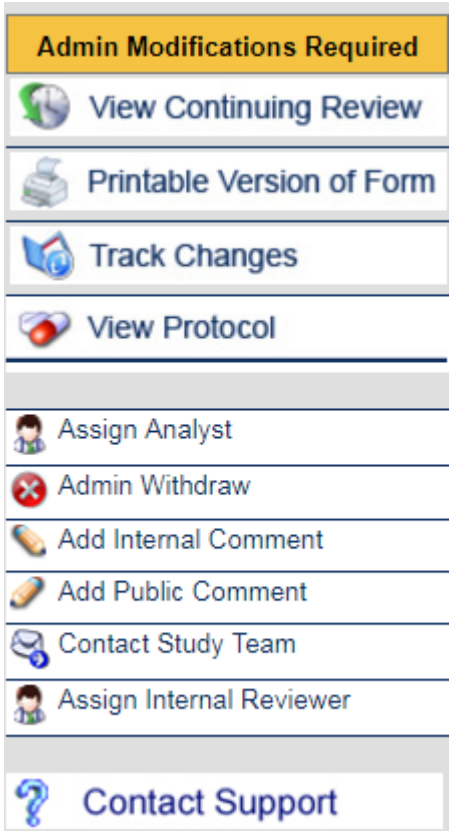
Title: ABBREVIATED TITLE (HP-000XXXXX)

PI:	**NAME**	**Date Approved:**	**4/20/2017**
PI Organization:	**DEPT**	**Approval Expires:**	**4/19/2018**
Submission Type:	**IRB Protocol**	**COEUS Number:**	
Review Path:	**Expedited or Full Review**		



States and Activities





After Initial Approval

Continuing Review:

- The IRB must conduct continuing review at intervals appropriate to the degree of risk, but not less than once per year.
- Submit at least SIX WEEKS PRIOR to the expiration date.
  - Notifications
- Use “Create Continuing Review” activity to the left of the main protocol workspace.
- If this activity does not appear, a draft may already have been created.
- Expedited or convened IRB?

After Initial Approval

Modifications to previously approved research

- Use “Create Modification” activity to the left of the main protocol workspace.
- Only one modification can be in process at a time.
- If a modification is in process, consents cannot be stamped.
- Expedited or convened IRB?

After Initial Approval

Reportable New Information

- Use 

activity found to the left of the main protocol workspace.
- RNI Bulletin: http://www.umaryland.edu/hrp/for-researchers/study-conduct/
- Must be submitted within 5 business days of becoming aware.
- If it doesn't meet one of the categories, the information can be submitted via a modification (when appropriate) or at the time of continuing review.

Study Closure

- To be eligible:
  - Data collection is complete.
  - There is no more participant contact.
  - The only research activity being conducted (if any) is data analysis of de-identified data.
- A closure report must be submitted within 45 days of study closure, but no later than 6 weeks prior to study expiration.
- Use the “Create Study Closure” activity to the left of the main protocol workspace.
  - SmartForm begins the same as Continuing Review

Communication via CICERO

- Internal Comments
- Public Comments
- Contact HRPO
- Contact Study Team
- Determination Letters

RESOURCES

Ask questions!

- HRPO Operations Team
- HRPP Directors
- IRB Executive Committee
- IT Support
- Contact information is available at http://www.umaryland.edu/hrp/hrp-office/hrpo-personnel/ or http://www.umaryland.edu/hrp/institutional-review-board-irb/executive-committee/

Training and Education

- Clinical Research Training and Mentoring Program (CRTMP)
  - Assists with designing, submitting or revising protocols
  - Meets personally with investigators
- HRPP Education and Training

Questions?

Human Research Protections Office
Office of Academic Affairs, Research Compliance
620 W. Lexington Street, 2nd Floor
410-706-5037
hrpo@umaryland.edu
www.umaryland.edu/hrp

Contact Information

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