Individual Orientation for New IRB Members Outline

**ORI contacts and role**
- ORI Description [J:\Master Internal Documents\ORI Functions\ORI description simple.doc](J:\Master Internal Documents\ORI Functions\ORI description simple.doc)
- ORI Statistics (check regarding recent annual report data)
- ORI Contact List [J:\Master Outreach Documents\ORI Contacts.doc](J:\Master Outreach Documents\ORI Contacts.doc)
- ORI Staff by IRB Team [J:\Master Internal Documents\staff by team.doc](J:\Master Internal Documents\staff by team.doc)

**Introductions**
- Complete the [New IRB Member Info for Orientation](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Checklists\260000-Criteria_for_Approval_Reviewer_Checklist_Revised.DOC) half sheet and place on front of each new member’s binder.

**Overview**
- **Types of Review** (IR, MR, CR, Unanticipated, Protocol Violations, Noncompliance) and Mechanisms of Review (What Needs IRB Review, Exempt, Expedited, Full, focus of discussion is on IRB member’s role)
  - **Review Criteria**
    - Criteria for IRB Approval [J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Checklists\260000-Criteria_for_Approval_Reviewer_Checklist_Revised.DOC](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Checklists\260000-Criteria_for_Approval_Reviewer_Checklist_Revised.DOC)
    - Detailed Protocol [J:\Master Internal Documents\Detailed Protocol\DTLD MED-Updated 5-15-07.doc](J:\Master Internal Documents\Detailed Protocol\DTLD MED-Updated 5-15-07.doc)
    - Primary Review Responsibilities [J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Primary Reviewer Responsibilities.doc](J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Primary Reviewer Responsibilities.doc)
    - Expedited Reviewer Signature Page [J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\200000-XP-Reviewer-Sign-page.doc](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\200000-XP-Reviewer-Sign-page.doc)
    - Modification Review Signature Page [J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\F29-Modification_Reviewer_Sign_page.doc](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\F29-Modification_Reviewer_Sign_page.doc)
    - IRB Exemption Certificate Signature Page [J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\210000-ExemptionCertSignPage.doc](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Signature Pages\210000-ExemptionCertSignPage.doc)
    - IRB Continuation Review Primary Reviewer Checklist [J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Checklists\280000-CRPrimaryReviewerCommentForm.doc](J:\Master Outreach Documents\Survival Handbook\F - IRB applications-Forms\Reviewer Documents\Checklists\280000-CRPrimaryReviewerCommentForm.doc)

Discuss member’s specific role on the IRB (ex. Children’s Rep Responsibilities, Prisoner Rep Responsibilities, etc.)

**Meetings**
- IRB assigned meeting date [http://www.research.uky.edu/ori/human/IRBMeetingDates.htm](http://www.research.uky.edu/ori/human/IRBMeetingDates.htm)
  - Importance of attendance
  - Communicating with ORI staff
- **Sample Agenda Packet Cover** [J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Documents For Notebooks\Sample Agenda cover.doc](J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Documents For Notebooks\Sample Agenda cover.doc)
  - Go through agenda packet explaining category headings
- **Explain Vote (1, 2, 3, 4, 5)** [J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Documents For Notebooks\Review Outcome for Full Review.doc](J:\Mandatory IRB Training\New IRB Member Orientation\Individual Orientation for New IRB Members booklet\Documents For Notebooks\Review Outcome for Full Review.doc)
- **IRB EA agenda Instructions** [J:Heather/Training/IRB EA agenda Instructions](J:Heather/Training/IRB EA agenda Instructions)
SOP/Guidance and Educational Materials

- Go through IRB Resource Guide Table of Contents (http://www.research.uky.edu/ori/human/IRBresourceGuide.htm)
- Go through Survival Handbook Table of Contents Including SOPs & PST
- New Faculty FAQs regarding the UK IRB
- Review New IRB Member Training Checklist
- PRIM&R On line Ethical Oversight of Human Subjects Research Course User Guide
- UK IRB Orientation & Exam (Go over IRB member responsibilities)
- Encourage to read Belmont Report
- Discuss Mentor Program (give the individual the name of their mentor)
- Upcoming Training Events

Training

- Review New IRB Member Training Checklist
- PRIM&R On line Ethical Oversight of Human Subjects Research Course User Guide
- UK IRB Orientation & Exam (Go over IRB member responsibilities)
- Encourage to read Belmont Report
- Discuss Mentor Program (give the individual the name of their mentor)
- Upcoming Training Events

Obtain signatures or distribute sheets – NOT double sided as member may sign and scan to return

- Conflict of interest (Discuss Importance)
- Confidentiality Statement
- Preferred Contact Information
- Authorization signature
- IRB Member Representative Survey

Extras

- IRB Acronyms
- Information Technology/Informatics Supplemental Information

Revised 09/6/10, 9/28/11, 2/12/14, 7/28/14; 2/26/16; 12/23/16