

The background of the slide is a light gray gradient with several realistic water droplets of various sizes scattered across it. The droplets have highlights and shadows, giving them a three-dimensional appearance. The main title is centered in the upper half of the slide.

IRB MEMBER REVIEW & DISCUSSION

IRB MEMBER TRAINING NOVEMBER 2016

TOPICS FOR DISCUSSION

- THE ROLE OF THE PRIMARY/SECONDARY/CONTINUING REVIEW/MODIFICATION REVIEWER
- THE ROLE OF MEMBERS WHO ARE NOT ASSIGNED TO THE STUDY
- THE ROLE OF THE CHAIR
- THE ROLE OF THE REGULATORY REPRESENTATIVE
- THE ROLE OF IRB STAFF

PRIMARY REVIEWER

- RESPONSIBLE FOR THE ENTIRE SUBMISSION
- SUGGESTED APPROACH: START WITH THE INFORMED CONSENT FORM - IF YOU CAN'T FOLLOW WHAT IS BEING ASKED SOLELY FROM THE CONSENT FORM, THEN THERE IS WORK TO BE DONE
- DO MEMBERS REVIEW THE ATTACHED PROTOCOL OR ONLINE APPLICATION FIRST?
- HOW MUCH DOCUMENT COMPARING IS APPROPRIATE?
 - IRB STAFF DOES SOME INITIAL COMPARING USING THE ATTACHED COMPLETENESS CHECK DOCUMENT!
 - CONTRADICTORY ISSUES WILL BE LISTED IN THE ADMINISTRATIVE STIPULATIONS
- TO COMPLETE THE REVIEW - USE THE NEW MEMBER FORMS AVAILABLE ON THE IRB WEBSITE!
[HTTP://WWW.UPENN.EDU/IRB/MISSION-INSTITUTIONAL-REVIEW-BOARD-IRB/IRB-MEMBER-TOOLBOX](http://www.upenn.edu/irb/mission-institutional-review-board-irb/irb-member-toolbox)
- REMAIN FOCUSED ON THE APPROVAL CRITERIA AND HUMAN PARTICIPANT PROTECTIONS ISSUES
- REVIEW THE ADMINISTRATIVE STIPULATIONS AND ANY ADDITIONAL NOTES PROVIDED IN THE AGENDA RELATED TO ITEMS NEEDED TO BE COVERED DURING THE REVIEW

SECONDARY REVIEW (CONSENT FORM)

- START WITH THE CONSENT FORM (SAME AS PRIMARY REVIEW ADVICE)
- REVIEW PROTOCOL AND OTHER DOCUMENTS AS NEEDED TO ASSURE THAT THE INFORMED CONSENT FORM IS ACCURATE – WHAT DOCUMENTS ARE THE MOST HELPFUL?
- REVIEW THE CONSENT PROCESS DESCRIBED IN THE APPLICATION – DOES IT ALIGN WITH THE COMPLEXITY/LENGTH OF CONSENT FORM
- CONSIDER ANY SPECIAL PROTECTIONS NEEDED FOR THE TARGETED POPULATION
- REVIEW THE ADMINISTRATIVE STIPULATIONS AND AGENDA NOTES TO DETERMINE IF ANY GLARING CONSENT FORM ISSUES/INCONSISTENCIES/MISSING INFORMATION WERE ALREADY IDENTIFIED
- PROVIDE MARKED/TRACKED (PREFERRED) CONSENT FORM WITH COMMENTARY SUPPORTING WHY YOU ARE REQUIRING REVISIONS (STIPULATIONS) OR IDENTIFYING A PROPOSED REVISION AS A RECOMMENDATION ONLY

CONTINUING REVIEW

- CR FORM, PROGRESS REPORT, AND ADDITIONAL REPORTS PROVIDE STATUS OF THE STUDY
- PREVIOUSLY APPROVED STUDY DOCUMENTS ARE THERE TO PROVIDE INFORMATION FOR YOUR REFERENCE
- HOW MUCH TIME DO YOU SPEND REVIEWING THE PROGRESS REPORT VS. THE PREVIOUSLY APPROVED DOCUMENTS
- WHEN DO YOU REVIEW THE AGENDA NOTES AND THE DOCUMENTS UPLOADED TO THE COMMENTS SECTION
- PRESENTATION SHOULD FOCUS NOT ON THE PROGRESS DURING THE LAST APPROVAL PERIOD
 - ALL MEMBERS SHOULD HAVE PREVIOUSLY FAMILIARIZED THEMSELVES WITH THE PROTOCOL
 - DISCUSSION SHOULD FOCUS ON ISSUES/CONCERNS RELATED TO WHETHER THE STUDY SHOULD BE ALLOWED TO CONTINUE FOR ANOTHER YEAR, OR IF THERE SHOULD BE ANY ALTERATION TO THE CURRENT RISK LEVEL OR REVIEW PERIOD

MODIFICATION REVIEW

- WHAT DOCUMENTS DO YOU REVIEW FIRST – AGENDA NOTES, SUMMARY OF CHANGES, TRACKED CONSENT?
- THE “REASON FOR CONVENED REVIEW” SECTION OF THE AGENDA NOTES WILL IDENTIFY THE PRIMARY FOCAL POINTS YOUR REVIEW – CAN HELP WITH MORE COMPREHENSIVE MODIFICATIONS DO YOU REFER BACK TO THE PREVIOUSLY APPROVED PROTOCOL WHEN ASSESSING THE IMPACT OF ANY CHANGES?
- HOW MUCH DOCUMENT COMPARING IS APPROPRIATE? - CHECK FOR CONSISTENCY OF CHANGES AMONG THE STUDY DOCUMENTS
 - AGENDA NOTES OR COMMENTS IN HS-ERA WILL INCLUDE ANY ISSUES ALREADY IDENTIFIED BY THE IRB STAFF
- ONLY A BRIEF SUMMARY OF THE PROTOCOL IS NEEDED - PRESENTATION CAN FOCUS ON THE NEW INFORMATION OR THIS NEWLY PROPOSED APPROACH TO THE STUDY. MEMBERS SHOULD ALSO DESCRIBE WHY THE APPROVAL CRITERIA CONTINUE TO BE MET OR TO REQUIRE ANY REVISIONS NECESSARY TO ASSURE THAT THIS IS THE CASE

I AM NOT ASSIGNED TO THE STUDY, WHAT AM I DOING TO PREPARE?

- GOAL: BE FAMILIAR WITH THE ACTIONS ON THE AGENDA. MEMBERS SHOULD KNOW ENOUGH THAT THEY CAN CONTRIBUTE TO THE DISCUSSION AND RAISE ISSUES OR CONCERNS
- INITIAL REVIEWS
 - READ THE INFORMED CONSENT FORM
 - READ THE HS-ERA APPLICATION OR THE PROTOCOL SUMMARY/OVERVIEW (NOT EXPECTED TO REVIEW THE FULL PROTOCOL)
- CONTINUING REVIEW
 - READ THE AGENDA NOTES AND ATTACHED PROGRESS REPORTS
- MODIFICATION
 - READ THE AGENDA NOTES, THE SUMMARY OF CHANGES AND TRACKED CONSENT FORMS
- REPORTABLE EVENT(S)
 - READ AGENDA NOTES, THE SUMMARY OF THE EVENT(S) AND THE PROPOSED CORRECTIVE ACTION PLAN

WHAT IS THE CHAIR DOING TO PREPARE?

- RESPONSIBLE FOR THE ENTIRE MEETING AGENDA
- IS ABLE TO FIELDING QUESTIONS, REVIEW REQUESTS FOR INFORMATION, AND INPUT FROM STAFF AND MEMBERS IN ADVANCE OF THE MEETING
- RAISES THEIR OWN ISSUES AND CONCERNS THAT MAY OR MAY NOT BE RAISED BY THE REVIEWERS OR OTHER MEMBERS
- MAY CONTACT THE PI AS NECESSARY PRIOR TO THE MEETING (MEMBERS MAY DO THIS TOO!)

WHAT IS THE REGULATORY REPRESENTATIVE DOING TO PREPARE?

- FOCUSED ON POTENTIAL REGULATORY ISSUES BASED ON THE CONTEXT OF THE SUBMISSION
 - VULNERABLE POPULATIONS
 - DRUG/DEVICE DETERMINATIONS
 - HELPING MEMBERS/CHAIRS TO PREPARE TO MAKE NONCOMPLIANCE OR UNANTICIPATED PROBLEM DETERMINATIONS
- WORKING WITH THE IRB CHAIR, MEMBERS AND STAFF TO DETERMINE WHAT ISSUES IDENTIFIED PRE-MEETING WARRANT REACHING OUT TO THE PI/STUDY TEAM
- OFFERS FEEDBACK ON ISSUES THAT MAY HAVE BEEN ADDRESSED BY OTHER BOARDS – TRIES TO ENSURE A CONSISTENT APPROACH TO COMPLEX REGULATORY ISSUES

WHAT IS THE IRB STAFF DOING TO PREPARE?

- COMPLETENESS CHECK WITH ASSOCIATED AGENDA NOTES AND ADMINISTRATIVE STIPULATIONS
- ASSIGNING APPROPRIATE REVIEWER(S) BASED ON EXPERTISE, MEMBER ROLE AND VOLUME
- CONTACTING THE PI/STUDY TEAM AS NEEDED TO ADDRESS ANY MISSING/INCONSISTENT INFORMATION THAT MAY AFFECT SCHEDULING FOR CONVENED REVIEW
- PROVIDING SUPPORT TO THE IRB CHAIR AND MEMBERS PRE-MEETING TO ADDRESS ANY SUBSTANTIAL ISSUES RAISED OR TO DISCUSS WHETHER ANY ISSUES RAISED MAY NOT BE WARRANTED AND DON'T REQUIRE DISCUSSION BY THE CONVENED BOARD