

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. Some are in the top left, some in the bottom right, and others are smaller and more numerous in the center and bottom left.

MOTIONS OF THE IRB

BEN MOOSO

OUTLINE

- WHAT IS A MOTION?
- MOTIONS FOR NEW STUDIES, AMENDMENTS, AND RENEWALS
- MOTIONS FOR REPORTABLE EVENTS
- MOTIONS FOR ANY APPROVED STUDIES

WHAT IS A MOTION?

- A MOTION IS A PROPOSAL THAT A SPECIFIC DECISION OR ACTION BE MADE/TAKEN
- MOTIONS ARE TYPICALLY MADE BY THE PRIMARY REVIEWER OF THE AGENDA ITEM
- MOTIONS MAY BE CONTROVERSIAL AND DECISIONS ON MOTIONS NEED NOT BE UNANIMOUS
- MOTIONS PASS BY A SIMPLE MAJORITY OF THE VOTING MEMBERS PRESENT
- THE FULL LIST OF MOTIONS CAN BE FOUND IN SECTION 5.3.11 OF SOP [OIA-041](#)
- THE DEFINITIONS ON THE FOLLOWING SLIDES CAN BE FOUND IN SOP [OIA-001](#)

MOTIONS FOR NEW STUDIES, AMENDMENTS, AND RENEWALS

- APPROVE
 - ALL CRITERIA FOR APPROVAL ARE MET AS-IS.
 - NO REVISIONS ARE NEEDED.
- APPROVE PENDING
 - THE CRITERIA FOR APPROVAL ARE NOT MET
 - THE CRITERIA FOR APPROVAL WILL BE MET IF SPECIFIC MODIFICATIONS ARE MADE OR THE PI CONFIRMS CERTAIN INFORMATION THAT THE COMMITTEE HAS INFERRED FROM COMMUNICATIONS OR THE APPLICATION.
 - E.G. “CONFIRM THAT 20 SUBJECTS WILL BE ENROLLED LOCALLY AND REVISE DOCUMENTS TO CONSISTENTLY STATE 20 SUBJECTS ARE TO BE ENROLLED HERE.”
- DEFER
 - THE CRITERIA FOR APPROVAL ARE NOT MET
 - THE COMMITTEE CAN RECOMMEND CHANGES TO MAKE THE STUDY APPROVABLE OR THE COMMITTEE NEEDS ADDITIONAL INFORMATION.
 - E.G. “WILL SUBJECTS BE RANDOMIZED 1:1, 1:2, 1:1:1, OR SOME OTHER SCHEMA?” OR “PLEASE CLARIFY HOW YOU WILL PROTECT THE CONFIDENTIALITY OF RECORDS IN THIS STUDY.”
- DISAPPROVE
 - THE CRITERIA FOR APPROVAL ARE NOT MET
 - THE COMMITTEE HAS NO RECOMMENDATIONS THAT MIGHT MAKE THE STUDY APPROVABLE.

MOTIONS FOR REPORTABLE EVENTS

- NON-COMPLIANCE, NEITHER SERIOUS NOR CONTINUING
 - THE EVENT REPRESENTS NON-COMPLIANCE, BUT DOES NOT RISE TO THE LEVEL OF SERIOUS OR CONTINUING NON-COMPLIANCE
 - NON-COMPLIANCE - A FAILURE TO COMPLY WITH THE REQUIREMENTS OF AN APPLICABLE LAW, REGULATION, OR INSTITUTIONAL POLICY PERTAINING TO THE PROTECTION OF HUMAN SUBJECTS, OR WITH THE REQUIREMENTS OR DETERMINATIONS OF AN IRB THAT POSES A RISK OF HARM TO SUBJECT'S RIGHTS, SAFETY OR WELFARE, OR THE INTEGRITY OF THE RESEARCH DATA.
- CONTINUING NON-COMPLIANCE
 - THE EVENT REPRESENTS NON-COMPLIANCE AND THE NON-COMPLIANCE IS CONTINUING
 - CONTINUING NON-COMPLIANCE - A PATTERN OF NON-COMPLIANCE THAT INDICATES AN INABILITY OR UNWILLINGNESS TO COMPLY WITH APPLICABLE LAWS, REGULATIONS, OR INSTITUTIONAL POLICIES PERTAINING TO THE PROTECTION OF HUMAN SUBJECTS AND/OR WITH THE REQUIREMENTS OR DETERMINATIONS OF AN IRB
- SERIOUS NON-COMPLIANCE
 - THE EVENT REPRESENTS NON-COMPLIANCE AND THE NON-COMPLIANCE IS SERIOUS
 - SERIOUS NON-COMPLIANCE - FAILURE TO COMPLY WITH APPLICABLE LAWS, REGULATIONS, OR INSTITUTIONAL POLICIES PERTAINING TO THE PROTECTION OF HUMAN SUBJECTS AND/OR WITH THE REQUIREMENTS OR DETERMINATIONS OF AN IRB THAT HAS A SIGNIFICANT ADVERSE IMPACT (I.E. HARMS) EITHER ON THE RIGHTS OR WELFARE OF PARTICIPANTS OR ON THE INTEGRITY OF THE DATA
- SERIOUS AND CONTINUING NON-COMPLIANCE
 - THE EVENT REPRESENTS NON-COMPLIANCE AND THE NON-COMPLIANCE IS BOTH SERIOUS AND CONTINUING

MOTIONS FOR REPORTABLE EVENTS (CONTINUED)

- UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSO/UPR)
 - THE EVENT IS UNEXPECTED BECAUSE IT IS EITHER NOT LISTED IN THE PROTOCOL, ICF, AND IB OR BECAUSE IT OCCURS AT A GREATER FREQUENCY OR SEVERITY THAN PREVIOUSLY ANTICIPATED
 - THERE IS A REASONABLE POSSIBILITY (GREATER THAN OR EQUAL TO 50% CHANCE) THAT THE EVENT IS RELATED TO THE STUDY PARTICIPATION
 - THE EVENT SUGGESTS THAT THE RESEARCH PLACES SUBJECTS OR OTHER AT A GREATER RISK OF HARM THAN WAS PREVIOUSLY KNOWN OR RECOGNIZED
- ACKNOWLEDGE
 - THE EVENT DOES NOT REPRESENT ANY KIND OF NON-COMPLIANCE OR A UPR
 - THE EVENT MAY REPRESENT A MINOR DEVIATION
 - MINOR DEVIATION - A CHANGE TO, OR FAILURE TO ADHERE TO, THE RESEARCH PROTOCOL OR APPLICABLE OIA REQUIREMENTS THAT DOES NOT POSE A RISK OF HARM TO THE HUMAN SUBJECT'S RIGHTS, SAFETY OR WELFARE, OR TO THE INTEGRITY OF THE RESEARCH DATA, AND DOES NOT RISE TO THE LEVEL OF NON-COMPLIANCE
- DEFER
 - MORE INFORMATION IS NEEDED TO BE ABLE TO DETERMINE WHETHER THE EVENT CONSTITUTES ANY KIND OF NON-COMPLIANCE, A UPR, OR NONE OF THE ABOVE

MOTIONS FOR ANY APPROVED STUDIES

- SUSPEND

- AN ACTION TAKEN TO TEMPORARILY OR PERMANENTLY WITHDRAW IRB APPROVAL FOR SOME OR ALL RESEARCH PROCEDURES, SHORT OF TERMINATION.
- SUSPENDED STUDIES REMAIN OPEN AND ARE SUBJECT TO CONTINUING REVIEW.
- AN ENROLLMENT HOLD IS NOT A SUSPENSION OF IRB APPROVAL.

- TERMINATE

- AN ACTION TAKEN TO PERMANENTLY WITHDRAW IRB APPROVAL OF ALL RESEARCH PROCEDURES.
- TERMINATED STUDIES ARE PERMANENTLY CLOSED AND DO NOT REQUIRE CONTINUING REVIEW.