



THREE DISTINCT REVIEW TRACKS

FED FUNDED MINIMAL RISK

- EXEMPT
- EXPEDITED
- MINIMAL RISK REVIEWER

NON-FED FUNDED MINIMAL RISK

- EXPAND EQUIVALENT PROTECTIONS
- COMBINE FED CATEGORIES+ INTO "RESEARCH CATEGORIES"
- NO CR REQUIREMENT
- MINIMAL RISK REVIEWER

GREATER THAN MINIMAL RISK

- FUNDED OR NOT
- APPLY FEDERAL REGS
- FULL BOARD REVIEW

MINIMAL RISK REVIEW COMMITTEES

- COMPRISED OF ≥ 2 ALTERNATE MEMBERS OF THE IRB
- MUST SERVE ON FULL BOARD FOR AT LEAST 3 MONTHS
- TRAINED ON EXPEDITED, EXEMPT REGULATIONS AND MR REVIEW SOPS
- REVIEW INDIVIDUAL PROJECTS THEN MEET TO DISCUSS ISSUES/CONCERNS
- CONTINUING EDUCATION PROVIDED; STAFF VERIFY ACCURACY OF CHECKLISTS
- ENSURES REVIEWS ARE COMPLETED ACCURATELY AND ON TIME

NEW MR RESEARCH CATEGORIES

- EDUCATIONAL RESEARCH
- SURVEY, FOCUS GROUP, INTERVIEW RESEARCH (INCL. AUDIO/VISUAL RECORDING)
- COLLECTIONS OF BIOLOGICAL SPECIMENS THROUGH NONINVASIVE MEANS
- COLLECTION OF DATA THROUGH NON-INVASIVE PROCEDURES
- SECONDARY RESEARCH
- REPOSITORIES

GENERAL CHANGES

- NO LONGER REQUIRE PROJECT TEAM AMENDMENTS
- INCREASE ADMINISTRATIVE REVIEWS OF AMENDMENTS BY STAFF
- NO LONGER 'APPROVAL STAMP' DOCUMENTS (CONSENT FORMS, RECRUITMENT MATERIALS)
- REMOVING CR REQUIREMENT FROM MINIMAL RISK PROJECTS (CAN BE RECOMMENDED BY MR REVIEWER)
- IMPLEMENT POST APPROVAL MONITORING (PAM) PROGRAM



WHAT MR PROJECTS MIGHT REQUIRE CR?

- SUBPARTS/VULNERABLE POPULATIONS
- CRIMINAL BEHAVIOR
- SUBSTANCE ABUSE/MENTAL HEALTH DATA
- EXTERNAL SITES (INCLUDING SECONDARY SCHOOLS)
- COMPLEX RESEARCH DESIGN



WHAT DO WE DO INSTEAD OF CR? PAM!

- ADMINISTRATIVE CHECK-IN
- IRB DIRECTED SELF-ASSESSMENT
- STANDARD AUDIT
- CONSENT DOCUMENT REVIEW
- CONSENT PROCESS OBSERVATION
- PROJECT TEAM REVIEW



WHAT'S NEXT?

- **SEE WHAT HAPPENS IN JULY – MODIFY FEDERAL FUNDING SOPS AS NEEDED**
- **ANALYZE METRICS TO ASSESS IMPACT TO OUR PROGRAM**
- **OUR GOAL:**
 - DECREASE REGULATORY AND ADMINISTRATIVE BURDEN WHILE INCREASING RESEARCHER ACCESS TO EDUCATION AND MONITORING**