WE DID IT ANYWAY!
MOVING FORWARD AMID DELAYS
LINDA PETREE, CIP – DIRECTOR, UNM OFFICE OF THE IRB

UNM’S PROGRAM

• PRIMARILY SBER
• SOME BIOMEDICAL RESEARCH
• ~400 ACTIVE PROJECTS
• 15% FEDERALLY FUNDED
• 50% STUDENT RESEARCH
• 6% INVOLVE PRISONERS
• 10% INVOLVE CHILDREN
• 11 FULL BOARD MEMBERS
• 9 MINIMAL RISK REVIEWERS
• 2 GRADUATE STUDENT MEMBERS
• 1 FULL BOARD MEETING/MONTH
• 4 MINIMAL RISK MEETINGS/MONTH
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

• COMPRIZED 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