NEWS FROM NIH

EXPANDED DEFINITION OF A CLINICAL TRIAL

SINGLE IRB POLICY

EFFECTIVE 1/25/18

(EXPANDED) DEFINITION OF A CLINICAL TRIAL

- DOES THE STUDY INVOLVE HUMAN PARTICIPANTS?
- ARE THE PARTICIPANTS PROSPECTIVELY ASSIGNED TO AN INTERVENTION?
- IS THE STUDY DESIGNED TO EVALUATE THE EFFECT OF THE INTERVENTION ON THE PARTICIPANTS?
- IS THE EFFECT BEING EVALUATED A HEALTH-RELATED BIOMEDICAL OR BEHAVIORAL OUTCOME?

NOTE: IF THE ANSWERS TO ALL OF THESE QUESTIONS IS "YES," THE STUDY IS A CLINICAL TRIAL. IF THE ANSWER TO ANY OF THE QUESTIONS IS "NO," THE STUDY IS NOT A CLINICAL TRIAL.

WHAT IF IT IS A CLINICAL TRIAL?

- MUST USE AN FOA THAT SPECIFICALLY ALLOWS FOR THE SUBMISSION OF CLINICAL TRIAL APPLICATIONS FOR DUE DATES BEGINNING JANUARY 25, 2018
- ALL NIH-FUNDED CLINICAL INVESTIGATORS AND CLINICAL TRIAL STAFF WHO ARE INVOLVED IN THE DESIGN, CONDUCT, OVERSIGHT, OR MANAGEMENT OF CLINICAL TRIALS MUST BE TRAINED IN GOOD CLINICAL PRACTICE (GCP).
- THE APPROPRIATE GCP TRAINING MODULE CAN BE FOUND ON UC BERKELEY'S CITI PROGRAM: HTTPS://CPHS.BERKELEY.EDU/QUICKGUIDECITITRAINING.PDF
- ADDITIONALLY, ALL NIH-FUNDED CLINICAL TRIALS ARE EXPECTED TO REGISTER AND SUBMIT RESULTS INFORMATION TO CLINICALTRIALS.GOV
- THE LINK TO THE STUDY'S SPECIFIC CLINICAL TRIALS WEBSITE SHOULD BE STATED IN INFORMED CONSENT DOCUMENTS.

SINGLE IRB

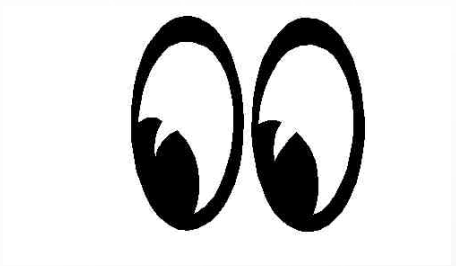
- **MUST** USE A SINGLE IRB FOR:
- NON-EXEMPT, DOMESTIC, MULTI-SITE "CLINICAL TRIALS
- EVERY SITE MUST BE CONDUCTING THE SAME PROTOCOL
- APPLICANTS WILL BE EXPECTED TO INCLUDE A PLAN FOR THE USE OF A SINGLE IRB IN THE APPLICATION

- **PERTAINS TO:**
  - APPLICATIONS WITH DUE DATES ON OR AFTER JANUARY 25, 2018, AND
  - CONTRACT SOLICITATIONS PUBLISHED ON OR AFTER JANUARY 25, 2018

SINGLE IRB

- ACTIVITIES OF THE SINGLE IRB WILL GENERALLY FALL INTO TWO CATEGORIES:
- **PRIMARY ACTIVITIES** REFER TO THE ACTIVITIES ASSOCIATED WITH CONDUCTING THE ETHICAL REVIEW OF THE PROPOSED RESEARCH PROTOCOL THAT WILL BE CARRIED OUT AT ALL OF THE PARTICIPATING SITES AND THE REVIEW OF THE TEMPLATE INFORMED CONSENT DOCUMENT DESCRIBING THE STUDY.
- **SECONDARY ACTIVITIES** REFER TO THE ACTIVITIES ASSOCIATED WITH THE REVIEW OF SITE-SPECIFIC CONSIDERATIONS FOR ALL OF THE PARTICIPATING SITES, INCLUDING INVESTIGATOR QUALIFICATIONS, INSTITUTIONAL CAPABILITIES, STATE/LOCAL REGULATORY REQUIREMENTS, AND COMMUNITY ETHOS. (INITIAL APPROVAL AND OVERSIGHT RESPONSIBILITIES).

SINGLE IRB



- **PRIMARY ACTIVITIES** SHOULD BE CHARGED AS **INDIRECT COSTS** IF THOSE ACTIVITIES ARE INCLUDED IN AN ORGANIZATION'S FEDERALLY-APPROVED INDIRECT COST RATE AGREEMENT.
- **SECONDARY ACTIVITIES** MAY BE CHARGED AS **DIRECT COSTS,** WITH APPROPRIATE BUDGET JUSTIFICATION.
- **FOR MORE INFORMATION CONTACT: THE OFFICE FOR PROTECTION OF HUMAN SUBJECTS (OPHS)**
  - HTTPS://GRANTS.NIH.GOV/POLICY/CLINICAL-TRIALS/SINGLE-IRB-POLICY-MULTI-SITE-RESEARCH.HTM
  - HTTPS://GRANTS.NIH.GOV/POLICY/CLINICAL-TRIALS.HTM