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# IRB AND HUMAN SUBJECTS REVIEW

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# POLICY

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- ALL PROJECTS/THESES NEED A DEPARTMENT REVIEW, INCLUDING EXEMPT STUDIES
  - EVEN IF YOUR WORK IS UNDER AN EXISTING APPROVED STUDY
- VULNERABLE POPULATIONS &/OR FUNDED RESEARCH NEEDS UNIVERSITY REVIEW AS WELL



# HUMAN SUBJECTS

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UNIVERSITY SITE:

[Http://www.csufresno.edu/humansubjects/](http://www.csufresno.edu/humansubjects/)

Policies

Application

Checklist

Sample memos

Sample forms



# MAJOR ETHICAL ISSUES THAT GET ATTENTION

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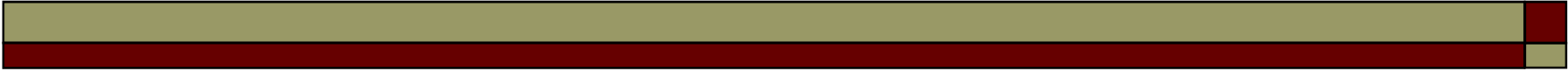
- ❑ VOLUNTARY PARTICIPATION
- ❑ INFORMED CONSENT
- ❑ RIGHT TO SERVICES/DENIAL OF TREATMENT
- ❑ NO HARM
- ❑ ANONYMITY/CONFIDENTIALITY & EXCEPTIONS
- ❑ COMPENSATION
- ❑ RESEARCHER DECEPTION, FRAUD AND MISREPRESENTATION



# VULNERABLE POPULATIONS

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- FEDERAL GUIDELINES
  - PREGNANT WOMEN
  - MINORS
  - INSTITUTIONALIZED PERSONS
- BUT DON'T SOCIAL WORKERS  
TYPICALLY WORK WITH OTHER  
“VULNERABLE POPULATIONS”?



## ABILITY TO MAKE INFORMED DECISION TO PARTICIPATE & IMPLICATIONS OF THE STUDY ACTIVITY

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- Cognitive impairment compromising understanding/ability to consent
- Activities that create undue risk
- Practice & Research are inherently unequal – with social worker/researcher having more power/authority
  - Sources of influence on behavior
    - Compensation (e.g., money, benefits)
    - Control over other “goods” (e.g. service benefits, grades)
    - Social desirability



# BE KIND TO REVIEWERS (DON'T UPSET THEM)

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- TRY TO KEEP TO THE UNIVERSITY OUTLINE
- INCLUDE ALL EXPECTED INFO PLUS ATTACHMENTS & DETAILS RELEVANT TO YOUR STUDY
- WRITE CLEARLY – SPELL CHECK, GRAMMAR CHECK
- REMEMBER TO EXPLAIN – THEY DON'T KNOW WHAT YOU ARE DOING



# DSWE DEPARTMENT REVIEW

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- PREPARE YOUR PROPOSAL USING UNIVERSITY OUTLINE/CH. 3
  - REMEMBER TO ADAPT/ADDRESS THINGS RELEVANT TO YOUR WORK
  - IF ONLY NEED DEPT REVIEW, YOU DO NOT NEED ABSTRACT & RESEARCHER QUALIFICATIONS STATEMENTS
- ATTACH ALL FORMS, INSTRUMENTS, LETTERS OF SUPPORT (COPIES)
- ATTACH COPY OF HUMAN SUBJECTS TRAINING CERTS (YOU & CHAIR)





# DSWE DEPARTMENT REVIEW

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- SUBMIT TO YOUR 292 INSTRUCTOR
  - IF NEEDING FURTHER WORK, S/HE WILL RETURN IT TO YOU FOR REVISION
- HE/SHE REVIEWS & FORWARDS TO DR. CLARKE, IF READY
- DR. CLARKE CIRCULATES TO FACULTY FOR REVIEW
  - APPROVED (POSSIBLY WITH COMMENTS)
  - APPROVAL WITHHELD PENDING REVISIONS
- REVIEW USUALLY TAKES A FEW DAYS TO 1 WEEK



# DSWE RESPONSE

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- ❑ GOES TO YOUR 292 INSTRUCTOR WHO REVIEWS RESPONSE WITH YOU
- ❑ IF APPROVED, RECOMMENDED REVISIONS OVERSEEN BY CHAIR
- ❑ IF APPROVAL WITHHELD, DOCUMENT NEEDS REVISION & RE-REVIEW
- ❑ HIGHLIGHT CHANGES IN REVISION; PROVIDE A BRIEF OVERVIEW OF REVISIONS/ISSUES ADDRESSED



# UNIVERSITY REVIEW

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- PREPARE YOUR PROPOSAL USING UNIVERSITY OUTLINE
  - REMEMBER TO ADAPT/ADDRESS THINGS RELEVANT TO YOUR WORK
  - STICK TO GENERAL OUTLINE AS MUCH AS POSSIBLE; MAKES IT EASIER ON REVIEWERS
- ATTACH ALL FORMS, INSTRUMENTS, LETTERS OF SUPPORT (COPIES)
- ATTACH COPY OF TRAINING CERTS (YOU & CHAIR)



# UNIVERSITY REVIEW

- ~~□ ELECTRONIC SUBMISSION: SCANNED DEPT REVIEW SHEET W/ SIGNATURES AND PROTOCOL (PDF OR SCANNED). OR SUBMIT ORIGINAL TO UNIVERSITY HUMAN SUBJECTS (ARRANGE SUBMISSION WITH YOUR CHAIR)~~
- REVIEW TAKES ABOUT 2 WEEKS
- DECISIONS
  - Approve
  - Approval withheld
  - Need meeting review
- CHAIR NOTIFIED OF DECISION IN WRITING



# SHOULD YOUR PROPOSAL NEED REVISION

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- ❑ PROVIDE A COVER LETTER/MEMO THAT OUTLINES THE CHANGES
- ❑ HIGHLIGHT CHANGES, E.G., ITALICIZE SECTIONS
- ❑ RESUBMIT AS REQUESTED  
(sometimes a single copy to C. Jones is all that is required)
- ❑ FULL REVIEW VS. CHAIR REVIEW



# HUMAN SUBJECTS TRAININGS

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- <http://137.187.172.153/CBTs/Assurance/login.asp>
- <http://www.ogc.fullerton.edu/tutorial/humanIntro.asp>
- <http://phrp.nihtraining.com/users/login.php>