

NIH Human Subjects (HS) Protection for Extramural Projects

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OPRR System

- OPRR was responsible for HHS policies and Assurances **PLUS** the NIH Peer Review HS coding system
- Code numbers reflected assurances, HS concerns and/or comments in projects
- Only OPRR could change codes that were bars to awards
- OPRR did not track IRB certifications
- When OPRR moved to HHS, it no longer had responsibilities for NIH awards

New OHRP and Agency Roles (June 2000)

- Each Agency is responsible for its own policies and procedures for protecting human subjects and for reporting to OHRP
- Each Agency is to establish a contact point, restricted award procedures, and a monitoring plan

New NIH Policy Responsibilities

- OEP is the NIH contact point responsible for establishing NIH policies for:
 - (1) the coding of projects involving human subjects;
 - (2) the issuance of awards that involve human subjects;
 - (3) the review of fundable applications with human subjects concerns noted in the summary statement; and
 - (4) developing a monitoring plan for HS awards to submit to OHRP

OEP Approach

- “Think tank” group analyzed prior NIH procedures and codes for human subjects protection
- Identified issues and drafted flow chart and new codes for human subjects projects
- Established NIH Human Subjects Protection Liaison Committee of IC representatives for advice and oversight
- Established procedures for issuing restricted awards

New definition of Concerns

- Human Subjects Subcommittee recommendation is to only identify risks to human subjects as concerns

Human Subjects Concern: Any actual or potential unacceptable risk, or inadequate protection against risk, to human subjects

- Common definition for reviewers, SRAs, and program officials to use in evaluating research

Not Included: Assurances or IRB certifications

- Revise Human Subjects section of PHS 398 Application

HS Continuing Education and Updates for NIH Staff

- Scientific Review Administrator (SRA) Responsibilities
- Program Official Responsibilities
- Grants Management Responsibilities
- Contracting Officer Responsibilities

OEP Responsibilities

- Contact point for HS policies for coding, issuing awards, resolving HS concerns, and developing monitoring plans
- Chair NIH Human Subjects Protection Liaison Committee of IC representatives
- Concur in Resolution of HS concerns and remove bars-to-award