THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices

Human Subjects Research

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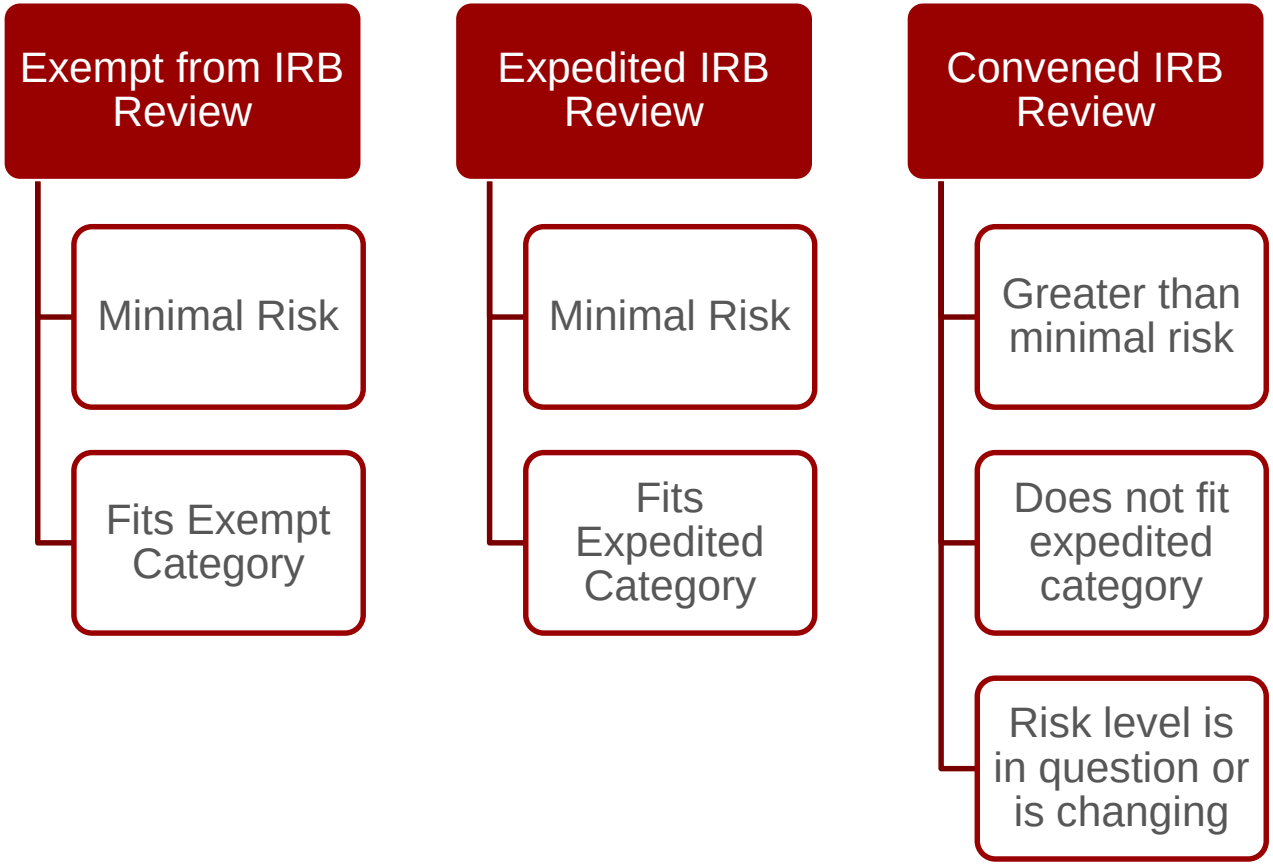
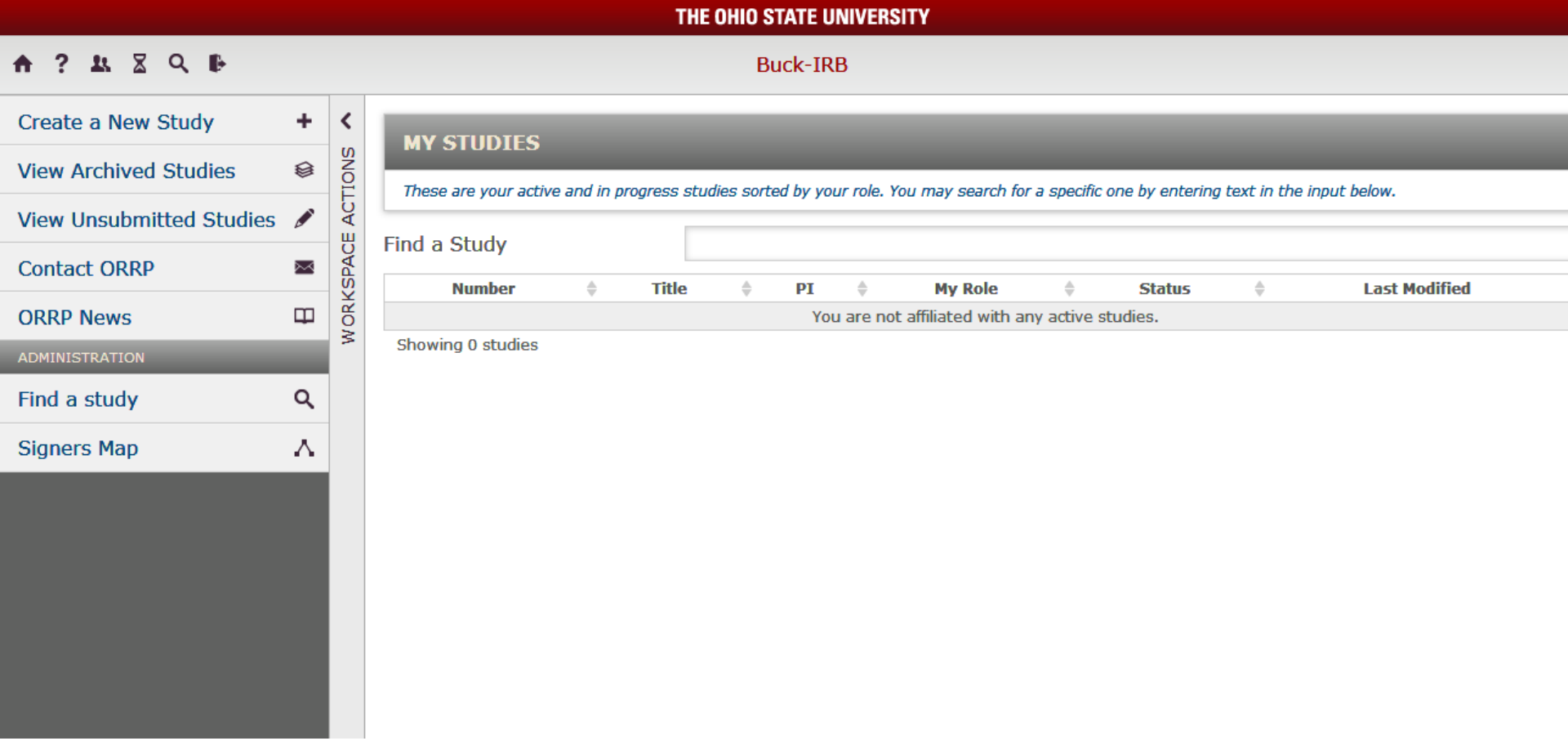
The Continuum of Review





To Access Buck-IRB: go.osu.edu/Buck-IRB

Initial IRB Submission Application Screening

Personnel

- PI Eligible, CO-I, Key Personnel, External Personnel, CITI, COI

Funding

- Grant Provided, Congruent with Protocol

Location of Research

- LOS Provided, Non-OSU Engaged Sites

Type of Research

- Exempt, Expedited, Convened, Not Human Subjects

Other Institutional Approvals

- CSRC, IBC, Radiation Safety, Maternal Fetal Safety

Research Methods & Procedures

- Protocol, Data Collection, Surveys, Instruments, Drugs/Devices, Gene Transfer, Data or Specimen Repositories, Genetic Testing

Initial IRB Submission Application Screening

Informed Consent

- Informed Consent, Parental Permission, Assent
- Consent by Legally Authorized Representative
- Verbal Script, Short Form, Alteration or Waivers

Recruitment Materials and Process

Use of Disclosure of PHI

- HIPAA Authorization Form
- Partial or Full Waiver, Alteration

Research Populations

- Pregnant women, fetuses, or neonates, Children, Prisoners, Adults with Decisional Impairment, Non-English speaking individuals, Students or Employees







Investigator Guidance

Templates and Sample Research Documents

- Consent, Assent, & Parental Permission
- Short Form Consent for Non-English Speaking Participants
- Verbal Consent Script and Contact Information Card
  - Translated Contact Information Cards
- HIPAA Research Authorization
  - Translated Authorization Forms
- Guidelines for Writing a Research Protocol
- Guidelines for Writing a Banking/Repository Protocol
- Event Reporting Form *(for studies approved prior to 11/17/14 and not migrated into Buck-IRB)*
- Final Study Report Form *(for all non-exempt studies)*

Investigator Guide – Human Subjects Research Overview

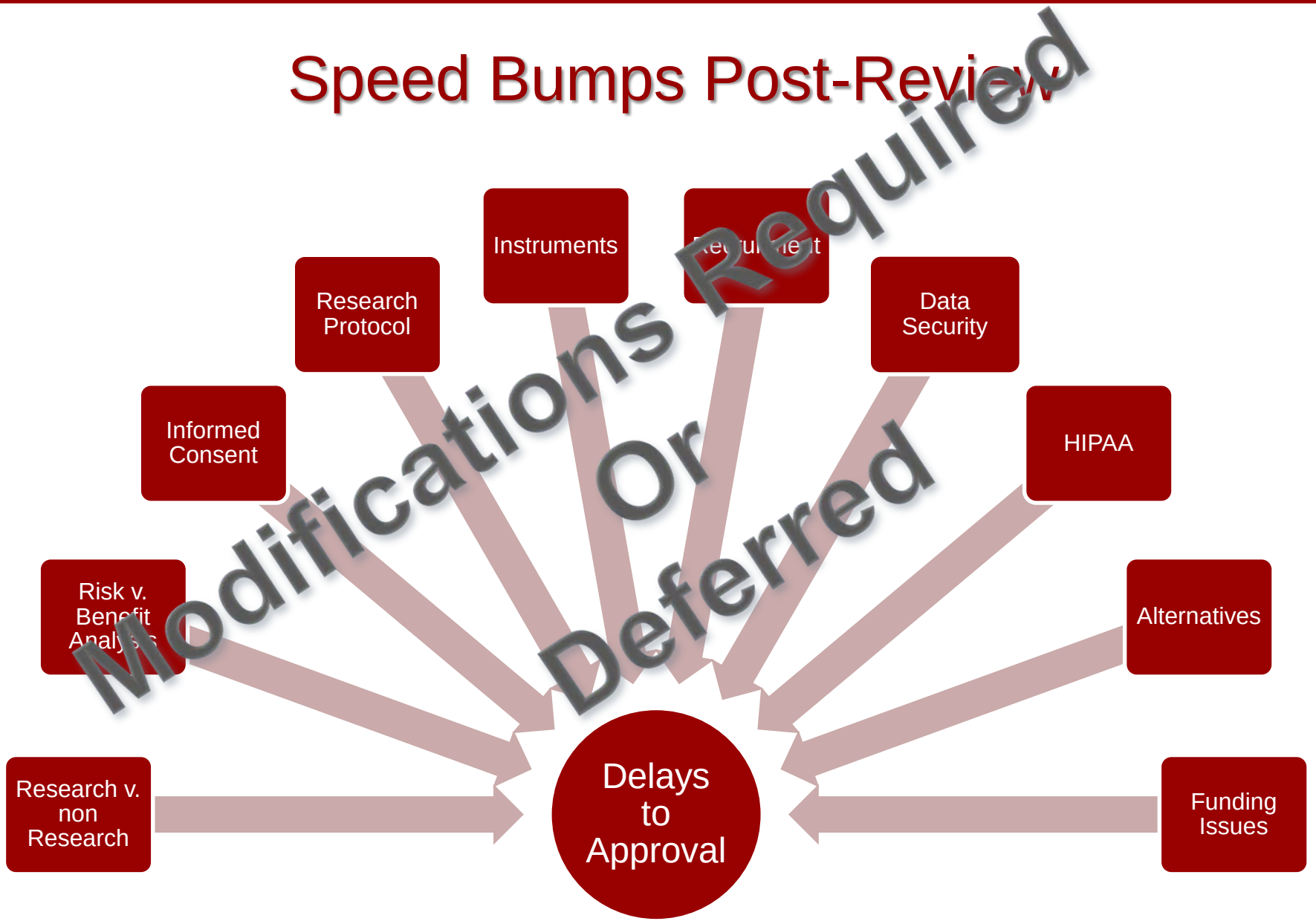
- Table of Contents

Administrative Speed Bumps

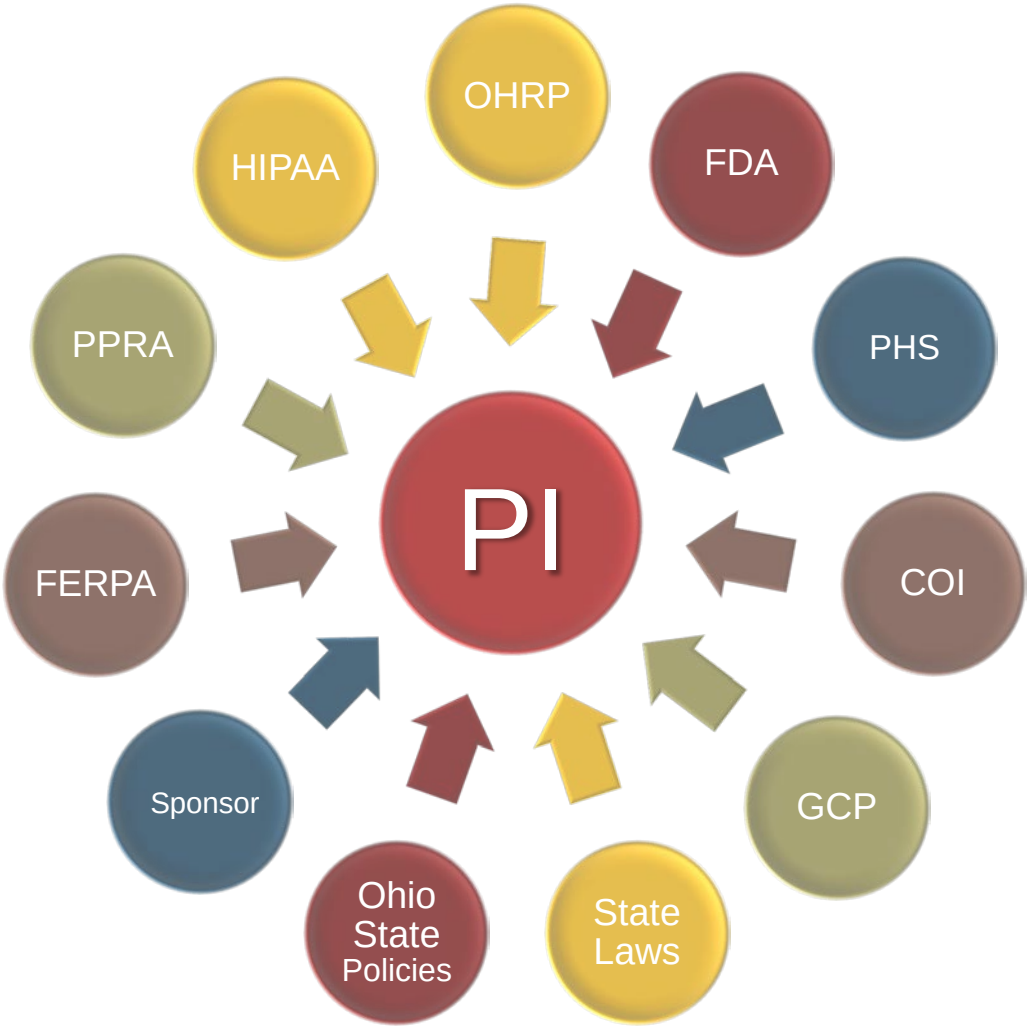
- Incorrect Review Process Selected
  - Exempt vs. Expedited vs. Convened
  - Biomedical vs. Cancer vs. Behavioral vs. WIRB vs. Other
- Incomplete or conflicting documents
- Incomplete or conflicting answers
- Insufficient information
- Data collection forms not provided
- Instruments not provided
- Grant not provided
- Internal and External Personnel not provided
- Multisite research (IRB approval or IRB agreement)
- IRB or Individual Investigator Agreements needed
- CITI and COI incomplete
- Signature delay

Incomplete PI Notified

Speed Bumps Post-Review



Regulations, Policies, & Standards



Principal Investigator

- Scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects
- Technical and administrative oversight of the research
- Responsible leader of the team, makes important study-related decisions

Research Team

An **individual** (or **organization**) becomes "engaged" in human subjects research when for non-exempt research, the following are obtained:

- Data about research participants through intervention or interaction
- Identifiable private information about research participants
- Informed consent of research participants

Principal Investigator & Research Team Responsibilities

Ultimately responsible for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local laws, and university policies

Education
Delegation
Training
Communication
Monitoring
Data Management
Recordkeeping
Reporting

Education, Delegation, & Training

Qualified Research Team Members
- CVs, job descriptions, COI

Defined Roles and Responsibilities
- IRB approval of external personnel, delegation logs

Human Subjects Training
- CITI, RCR, GCP, Other

Study Specific Training
- Protocol, SOPs, study initiation, training checklist

Document!

Communication and Monitoring

Communication Plan:

- Various communication vehicles
- Study start-up meeting
- Recurring meetings
- IRB, sponsor, and regulatory entities

Monitoring Plan:

- Consent process and documentation
- Participant enrollment
- Eligibility
- Randomization assignment
- Investigational product accountability
- Event reporting
- Protocol compliance

Document!

Data Management & Record Keeping

Data Management Plan
- Responsibilities, format, access
- De-identified vs. Coded

Data Collection Tools
- Paper, electronic

Data Integrity & Validity
- Queries, source documentation

Security and Privacy (PPI and PHI)

Confidentiality

Record Maintenance

Data Retention

Reporting

Routine Reporting:

- Continuing review
- Change in research
- Change in supportive funding
- Change in personnel
- Final study report

Event Reporting: Unanticipated Problems

- SAEs
- Not following the approved protocol
- Use of incorrect version of consent form/script
- Lack of consent or authorization
- Staff working on protocol without prior IRB approval
- Enacting amendments without prior IRB approval
- Use of unapproved documents
- Participant complaints
- Change in risk level
- Other (loss of study data or forms, breach of confidentiality)

Best Practices

- Adequate PI oversight
- Obtain appropriate approvals
  - Amendments, Continuing Review, Personnel
- Approval of research staff prior to initiating research tasks
- Adequate training and education of research team
- Obtain voluntary informed consent
  - Required elements, ethical process
  - Sign and date, provide a copy, maintain original
  - Version control
- Enroll eligible participants
- Follow the approved protocol
- Use the currently approved documents

Best Practices (Cont.)

- Provide participants with compensation as approved
- Report events in a timely manner
- Maintain confidentiality and security of personally identifiable data
- Ensure grant and protocol congruency
- Manage investigational product
- Report accurate and reliable data
- Maintain research records 3 years after study closure
  - Protocol, consent, regulatory records
- Maintain primary data 5 years after study closure

Questions?


OSU.EDU
Help BuckeyeLink Map Find People Webmail Search Ohio State
OFFICE OF RESEARCH
Office of Responsible Research Practices
THE OHIO STATE UNIVERSITY
Home About Us Animal Care and Use Biosafety Human Subjects Resources Contact Us News
Protecting Human Subjects in Research at Ohio State
Human Subjects
The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP's primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.
NEWS
Spring 2015 IRB Newsletter now available
POSTED: MARCH 26, 2015
New System for IRB and Exempt Submissions