University of Phoenix®

# IRB submissions for researchers

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# Federal Regulations

- The University of Phoenix IRB has a federal-wide assurance (FWA), which is recognized by the federal Office of Human Research Protection (OHRP).
- The FWA is an **agreement** between UOPX and the Department of Health and Human Services (HHS) **to comply with federal regulations** regarding human subjects research (45 CFR 46).
  - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

# Where can you find the UOPX IRB?

On the Research Hub:

http://research.phoenix.edu/content/institutional-review-board

IRBNet

http://irbnet.org

IRBNet is a 3rd party, web-based, software designed to conduct IRB reviews.

IRBNet is used for all IRB reviews at UOPX.

Researchers self-register and affiliate with the UOPX IRB.

# IRBNet Guidance Documents

- IRBNet ***Forms and Templates Library***
  - All needed guidance and instructions for all IRB scenarios. The main three are:

    - **READ ME FIRST**: UOPX IRB Process
    - **Guidance** – IRB Application
    - **FAQs** - Submissions, Revisions, and Resubmissions

# IRB Review Process

**UOPX IRB review process**

1. Pre-Review/Administrative Review (Locking / unlocking)
2. Content Review
    - Exempt
    - Expedited
    - Full Committee

# Submission Types vs. Review Types

- Submission Types:
  - New (Initial submission)
  - Revision (re-submission)
  - Response (re-submission)
  - Amendment (re-submission)
  - Continuing (re-submission)

- Review Types:
  - Exempt
  - Expedited
  - Full Board

Note: *More information and guidance can be found in:* ***GUIDANCE - IRBNet Instructions for Initial Submission*** *and* ***GUIDANCE - IRBNet Instructions for Resubmissions***

Note: *Researchers can learn more by reviewing:* ***GUIDANCE - OHRP Decision Tree Checklists (Determining Type of IRB Review).***

# Decisions

- **Regardless of review type, possible decisions are:**
  - Exempt
  - Approved
  - Approved with conditions
  - Information required
  - Modification required

Note: *"Exempt" can be **both** a review type, **and** a decision.*

- **A resubmission package is needed if the decision is:**

- Approved with conditions
- Information required
- Modification required

Note: *Explanations for ALL decisions can be found in **Understanding IRB Reviews, Actions and Decision Letters** in the forms and templates library.*

# Permissions

- Getting access to people or data for research usually requires cooperation from, associations, organizations, etc.
- Permissions should be obtained before submission to the IRB, but the actual recruiting cannot happen until after IRB approval is obtained.
- Permissions forms are used to verify cooperation.
    - Signed Data Access form
    - Signed Premises, Recruitment, and Naming (PRN) form
- Researchers attach signed permissions to their IRBNet package as supplemental documents.

•IRBNet forms and templates library: **GUIDANCE – Permissions**

# Recruitment

- Recruitment is the identification and selection of human subjects for research.
- Recruitment is not “Informed Consent”.  Informed Consent comes after recruitment.
- Recruitment materials such as announcements, flyers, letters and/or scripts should include the following:
    - Description of the research purpose
    - Name of the researcher, university affiliation, contact information
    - Eligibility criteria
    - Time commitment required
    - Location of the research

- IRBNet forms and templates library: **GUIDANCE – Recruitment**

# Informed Consent

- "Informed Consent" is the process for obtaining *individual* study participants.
- Informed Consent is usually a form that participants sign prior to participating in the research.
- It provides comprehensive information regarding the study's purpose, any possible risks and/or benefits, time required, tasks required, etc.
- In some cases, the informed consent process can altered and/or waived based on risks and on study design.

•IRBNet forms and templates library:

•**GUIDANCE – Informed Consent**

•**GUIDANCE – Online Surveys and IRB Review**

# Recap with an example

- Researchers first get permissions to recruit their participants.
    - Then they must be approved by the IRB
- Researchers then recruit their participants via letters, announcements, etc.
- Once enough people have agreed to participate, each must be individually “Consented” via an informed consent process.

For example:

1. Permission to recruit teachers at a local school is obtained from the school’s Principal.
2. Researcher submits to the IRB and is approved.
3. Researcher invites all the teachers at that school to participate in the study.
4. Ten teachers agree to participate. The researcher collects informed consents from each of the ten teachers.

•IRBNet forms and templates library:

•**GUIDANCE – Permissions**

•**GUIDANCE – Recruitment**

•**GUIDANCE – Informed Consent**

# Contact the IRB Office

Please contact the IRB Office ***AFTER*** reviewing the guidance in the IRBNet Forms and Templates library.

The IRB office email is: IRB@phoenix.edu.