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# Effective evaluation for a human research education program

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# Effective Evaluation for a Human Research Education Program

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**Problem/Issue Statement:** Many Human Research Protection Programs (HRPPs) have responded to the growing complexity of federal requirements, guidance documents and human subjects review processes with educational programs of various sizes and formats. Offering any type of educational program is costly and time-intensive making program evaluation an integral part. Due to the fragmented nature of most HRPP educational efforts, robust program evaluations are not always in place and good national models are not available. Washington University has developed such a model for its large-scale education program that can be adopted by smaller programs, helping to increase effectiveness while saving time and costly mistakes.

**Description of Program/Research:** Using established qualitative and quantitative program evaluation models, the Education Team began to apply these principles to the comprehensive human research protection program in existence. Information garnered helped guide future efforts and assisted in determining which current offerings, most effective in helping reach goals, were to remain.

*Program development took the following steps*:

1. **Identifying Educational Programs:** Twenty-seven (27) currently available educational outlets for the HRPP education program were identified. This process enabled us to see potential gaps in our educational programming, and subsequently created additional potential programs. (*See Diagram 1*)

2. **Identifying Goals:** The initial assessment structure was completed by identifying intended program goals, based on objectives identified within each of the current 27 educational offerings. (*See Diagram 2*)

3. **Individual educational goals were linked to broader more comprehensive outcomes/aims.** (*See Diagram 3*)

4. **Identifying Stakeholders impacted by the programs**: Primary Stakeholders were identified as: Faculty Investigators, Research Staff, Student Researchers, Students, IRB Members, IRB Staff, St. Louis Community, National, and International Audiences. (*See Diagram 4*)

To determine if the HRPP education program is meeting its goals and aims, current data collection instruments were evaluated and subsequently enhanced to collect consistent data points across programs. Data points collected include: individuals' first and last names, type of service, date, department/ affiliation, topic. This allows us to track individuals' involvement in the program, frequently used services, and current issues being raised which can then be shown in generated reports. The Education Team is currently working on correlating use of educational programming to IRB concerns related to time to approval, number of contingencies, and issues with non-compliance. Evaluation such as this takes the cooperation of every individual involved in the process and requires dedicated staff time for tracking. The benefits are not only an effective education program tailored to the needs of the audience but also provides a mechanism by which institutional leadership can be apprised of educational needs and efforts being made to meet those needs. This is also a system by which individuals can be held accountable for learning and knowledge related to compliance issues.

**Additional Information:** This program evaluation is unique in that it is being done on offerings designed for those engaged or interested in human subjects research using adult education learning theory where little information regarding program effectiveness has been disseminated widely. Results of these efforts will be made public via the Washington University Human Research Protection Program Digital Commons Open Access Library found at: http://digitalcommons.wustl.edu/hrpo/

*References:* Cronbach LJ; Ambron SR ; Dornbusch SM ; Hess RD; R C Hornik RC; Phillips DC ; Walker DF ; Weiner; SS. Toward Reform of Program Evaluation. San Fransisco, CA, US: Jossey-Bass Publishers (1980); Patton, MQ. Qualitative Evaluation Methods. Thousand Oaks, CA: Sage Publications (1980); Posavac, Emil J.; Carey, Raymond G. Program Evaluation: Methods and Case Studies (5th ed.). Englewood Cliffs, NJ, US: Prentice-Hall, Inc. (1997).

The SWAT! (*Staff With Answers Today!*) Program offers a staff member "On Call" during all business hours and four total Office Hours sessions per week. In order to meet goals like "More Efficient IRB Application" and "Informed Research Community," data from each individual SWAT! contact are collected (e.g. Name, Department, Issue Addressed, etc.). This allows us to correlate SWAT! consumer data with IRB application data, which enables us to identify potential educational topics, help us better understand the needs of our research community, and demonstrate the overall effectiveness of the program.

The below chart correlates SWAT! consumers by department with IRB application rates for each month. As noted above, this specific measure enables us to demonstrate that we are partnering with key institutional stakeholders in an educational context to achieve more efficient application timelines and better overall compliance.

**New Submission by SWAT! Individual Contact (Percentage) Jan-Aug 2013**

The HRPO open access collection makes resources available in a convenient, searchable format. The open access collection is PubMed and Google searchable. Google Analytics automates the collection of usage and visitor data. The below diagram represents basic usage statistics for the dates indicated. Additional visitor data enables us to demonstrate that this educational program is addressing the intended populations served (e.g. "International," "National," and "Research Staff").

For example, our visitor data indicates that the following representative entries from among 36 countries have accessed this open access collection and downloaded items:

- **Washington University in St. Louis**: 2,380
- **IRBForum.org**: 1,508
- **US-Based Universities**: 1,362
- **Veteran's Administration/Military**: 249
- **Federal** (e.g. NIH and FDA): 208

**COLLECTION SUMMARY**
10/1/2012 - 10/1/2013

| Creation Date | 10/1/12 | Total Pages Viewed | 7,379 | Total Items Downloaded | 2,832 |
| Total Items | 108 | Countries Represented | 36 | Items Downloaded at Least Once | 103 |

Pages Viewed By Month

Items Downloaded By Month

## Diagram 2

**PROGRAM**
CITI Training
New IRB Member Training
IRB Member Education
IRB Chair Education
HRPO Staff Training
myIRB Training
SWAT! (On Call/Office Hours)
Study Initiation Visit
IND/IDE Training
HRPO On Demand Education
Compliance Education
HRPO Website/Blog
Conferences (Intramural)
Conferences (Extramural)
Open Access Library
Ethics Series
Podcasts/Media
Necessary Elements
Brown Bag Series
R.C.R. Credit Activities
St. Louis IRB Consortium
CEnR Task Force
WU IRB History Project
Research Toolkits
Community Outreach
Research Projects
Publishing

**GOALS**
Decrease in Non-Compliance
More Efficient Application Review
Informed IRB Members
Informed HRPO Staff
Informed Research Community
Institutional Research Data
Published Findings/ Ed. Guidance
Community Visibility

### Key:
■ Implemented Program
■ Collaborative Program
■ Program In Progress

## Diagram 1

**PROGRAM**
CITI Training
New IRB Member Training
IRB Member Education
IRB Chair Education
HRPO Staff Training
myIRB Training
SWAT! (On Call/Office Hours)
Study Initiation Visit
IND/IDE Training
HRPO On Demand Education
Compliance Education
HRPO Website/Blog
Conferences (Intramural)
Conferences (Extramural)
Open Access Library
Ethics Series
Podcasts/Media
Necessary Elements
Brown Bag Series
R.C.R. Credit Activities
St. Louis IRB Consortium
CEnR Task Force
WU IRB History Project
Research Toolkits
Community Outreach
Research Projects
Publishing

**Study Initiation Visits:** These visits occur after IRB approval has been received, but prior to the implementation of the study. Using templates, staff discusses key compliance and administration issues relevant to the conduct of the given study. Studies are selected for the Study Initiation Visit based on risk of compliance infraction due to study design, complexity, novelty, lack of research team experience and/or previous experiences.

**HRPO On Demand:** This consists of a structured set of topics and presentations that can be given at any time. Current On Demand topics include: Biobanking, Investigational Devices, IRB 101, Research Databases, Recruitment, and Translational Research.

**HRPO Digital Commons,** http://digitalcommons.wustl.edu/hrpo/: the HRPO open access collection makes resources available in a convenient, searchable format. The open access collection is PubMed and Google searchable. These educational materials are useful for HUMAN RESEARCH PROTECTION PROGRAM (HRPP) staff development, IRB member training, the education of researchers and students, and raising community awareness. Materials are broken into four major categories: Conferences, Human Research Protection Program (HRPP), HRPO Podcasts and HRPO Publications.

**Research Projects:** To maintain quality and to contribute to generalizable knowledge concerning the conduct of human subjects research, HRPO participates or initiates research. Examples include: participation in national or IRB surveys, criteria assessments for IRB meetings, program evaluation, health literacy efforts, diversity and international initiatives.

## HRPO
## --
## *Human Research Protection Office*

## Diagram 3

**PROGRAM**
CITI Training
New IRB Member Training
IRB Member Education
IRB Chair Education
HRPO Staff Training
myIRB Training
SWAT! (On Call/Office Hours)
Study Initiation Visit
IND/IDE Training
HRPO On Demand Education
Compliance Education
HRPO Website/Blog
Conferences (Intramural)
Conferences (Extramural)
Open Access Library
Ethics Series
Podcasts/Media
Necessary Elements
Brown Bag Series
R.C.R. Credit Activities
St. Louis IRB Consortium
CEnR Task Force
WU IRB History Project
Research Toolkits
Community Outreach
Research Projects
Publishing

**GOALS**
Decrease in Non-Compliance
More Efficient Application Review
Informed IRB Members
Informed HRPO Staff
Informed Research Community
Institutional Research Data
Published Findings/ Ed. Guidance
Community Visibility

**OUTCOMES**
IRB/HRPO Staff Proficiency
Expansion of Ethical and Regulatory Discourse
Awareness and Transparency for the Research Community
Community Engagement and Awareness
Novel IRB Research And Publication

## Educational Program by Population Served

| | HRPO Website/Blog | Open Access Library | Podcasts/Media | Conferences (Intramural) | Publications | CITI Training | Ethics Series | HRPO On Demand Education | R.C.R. Credit Activities | New IRB Member Training | SWAT! (On Call/Office Hours) | myIRB Training | WU IRB History Project | CEnR Task Force | Necessary Elements | Research Projects | Research Toolkits | Member Education | Study Initiation Visit | Conference Education | Brown Bag Series | IRB Chair Education | HRPO Staff Training | IND/IDE Training | Community Outreach | St. Louis IRB Consortium |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| HRPO Staff | | | | | | | | | | | | | | | | | | | | | | | | | | |
| IRB Members | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Faculty Investigators | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Research Staff | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Students as Researchers | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Students as Students | | | | | | | | | | | | | | | | | | | | | | | | | | |
| WUSTL | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Research Participants | | | | | | | | | | | | | | | | | | | | | | | | | | |
| St. Louis Comm. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| National | | | | | | | | | | | | | | | | | | | | | | | | | | |
| International | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | 11 | 11 | 11 | 10 | 8 | 7 | 7 | 6 | 6 | 5 | 5 | 4 | 4 | 4 | 4 | 3 | 3 | 3 | 3 | 3 | 2 | 2 | 2 | 2 | 1 | 1 |

**Diagram 4**

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