Usability Working Group Presents …..

Human Subjects: To Apply or Not Apply:

That is the Question.

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LIBRARIES

INDIANA UNIVERSITY

Bloomington

Overview

- Act 1: Introduce the Usability Working Group
- Act 2: Overview of Human Subjects Process
- Act 3: Awakening for the Libraries … the Human Subjects Process Revisited

Act 1: Usability Working Group

William Blake
Oberon, Titania and Puck with Fairies Dancing
c. 1785

Usability Working Group: Charge

The Indiana University Libraries Usability Working Group (UWG) will inform, facilitate and promote usability and accessibility initiatives for online services (e.g., digital collections, the Libraries' web site and intranet, etc.) provided by the Bloomington Libraries in support of teaching, learning and research. The UWG will bring together usability practitioners from the Libraries and serve an advisory role for user assessment issues by providing guidance and coordination for usability and accessibility activities conducted to improve the online services offered by the Bloomington Libraries.

Usability Working Group: Members

- Tara Bazler, Manager, User Experience Group, UITS
- Michelle Dalmau (Chair), Digital Projects & Usability Librarian, Digital Library Program
- Julie Hardesty, Programmer/Analyst, Library Information Technology/UITS
- Mark Notess, Development Manager & Usability Specialist, Digital Library Program
- Mary Popp, Public Services Librarian, Library Information Technology
- Nikki Roberg, Usability & Interface Specialist, Digital Library Program

Usability Working Group: Goals

- Serve as a forum for communication, collaboration, and knowledge-sharing among usability practitioners in the Bloomington Libraries
- Promote awareness of usability concepts and techniques and foster a culture that values user-centered design in the Bloomington Libraries
- Develop effective strategies, policies and tools for ongoing user assessment
- Establish usability and accessibility guidelines and best practices
- **Establish guidelines for Human Subjects Committee (HSC) approval**
- Promote the publication and presentation of usability-related research within the Libraries and to the greater community of practice
- Identify and/or provide user assessment-related training needs and opportunities

Usability Working Group: Impetus for Change

- UITS (User Experience Group)
  - Application development, enterprise-wide systems (e.g., Webmail)
  - Short development cycles
- Libraries
  - Application development, enterprise-wide systems (e.g., IUCAT)
  - Research and development (e.g., Sakaibrary)
  - Shorter development cycles
- Digital Library Program
  - Application development, many grant-funded systems (e.g., Cushman)
  - Research and development (e.g., Variations2)
  - Longer development cycles

Act 2: Overview of the Human Subjects Process

John Everett Millais
Ophelia
1852

Protection of Human Subjects

If I am just talking with people about....I'm not doing anything to them--there are no experiments, no clinical trials, do I need human subjects approval?

Yes (and we are not kidding). Federal regulations define human subjects research broadly to cover interactions as well as interventions with human subjects for research purposes. So. . . surveys, interviews, questionnaires and oral history interviews, etc. are all covered by the federal regulations. And, yes, you need prior committee approval. Most of this type of ***research***, however, qualifies as "Exempt".

http://www.research.indiana.edu/rschcomp/faq.html

Human Subjects Compliance

- Tutorials
  - Protection of Human Subjects Research
  - Protection of Human Subjects in Non-Biomedical Research
- Certification Test

Human Subjects Compliance: Application

- Exempt, Expedited or Full Review
  - Each application contains unique set of questions
- Accompanying Materials to Submit:
  - Recruitment script
  - Instruments: questionnaires, forms, script, etc.
  - Consent forms (signed and unsigned)
- Faculty Sponsor

Human Subjects Compliance: Exempt

- Surveys and interviews with no personal identifiers collected; use of existing data (e.g., log data) with no accompanying personal identifiers

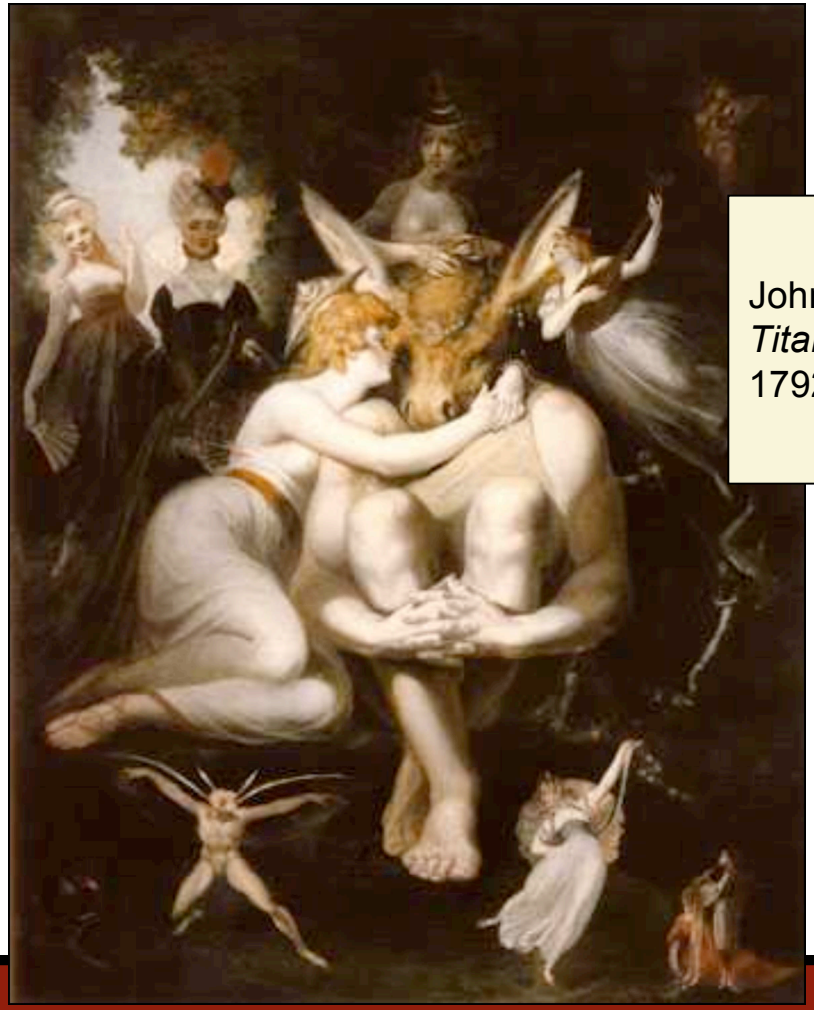
Human Subjects Compliance: Expedited

- Prospective collection of biological specimens for research purposes by noninvasive means. **Examples of biological specimens:** (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or it routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat);
- Usability-related categories:
  - Collection of data from voice, video, digital, or image recordings made for research purposes.
  - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Human Subjects Compliance: Review Process

- Exempt applications can take 1-2 weeks to review
- Expedited can take 1-3 weeks
- Committee seldom accepts application as-is; revisions are necessary
- Recruitment is not allowed until official approval has been received by campus mail

Act 3: Awakening for the Libraries … the Human Subjects Process Revisited



John Henry Fuseli
Titania Embracing Bottom
1792-1793

Background for Streamlining the Process

- We had been told we had to go through the human subjects committee to get approval for any user studies, because
  - we were doing “research”
  - we sometimes wanted to publish results or talk about them publicly
- But the IRB process is very heavyweight and seems designed for potentially dangerous research, which ours is not

How Does the IRB Define "Research"

- "Research is defined by the Department of Health and Human Services as 'a systematic investigation, including research development testing and evaluation, designed to develop or contribute to generalizable knowledge.' Such 'systematic investigations' may involve various invasive or non-invasive procedures including interviews, surveys, simple observation, administration of questionnaires, or review of records."
- A good rule of thumb for determining whether or not a particular project qualifies as research is to consider whether or not the investigation is undertaken with the intention of publishing or presenting the findings in some form or forum outside of the institution.

Non-Biomedical Tutorial, Section 4:3

How Does the IRB Define "Research:" Equivocal Cases

- "The Federal definition of "research" is narrower than our everyday use of the term. In some cases it can be difficult to make the determination that an undeniable research project (in the broad sense) also counts as research in this narrow sense and is, therefore, subject to Federal regulations and IRB oversight."
  - Oral Histories
  - **Quality Improvement, Quality Assurance**
  - IU Classroom Assignments
  - **Existing Data**

Non-Biomedical Tutorial, Section 4:5

Issues with the Human Subjects Process

- Inconsistent approval feedback
- Participation-inhibiting consent procedure
- Requests for documents already provided
- Inconsistent process for K-12 teachers as subjects
- Complicated applications with external partners and co-investigators
- General applicability to usability research

Formal and Informal Survey about IRB Process

- Posted survey to various lists to understand human subjects policies and how they effect usability work at other institutions
- Conducted literature review
- Spoke to colleagues at other institutions

"DLF respondents were aware of IRB requirements. Some expressed frustration with their IRBs turnaround time and rules. Others had negotiated blanket approval for the library to conduct surveys, focus groups, and protocols and therefore did not need to allow time to get IRB approval for each study" (Denise Troll Covey, *Usage and Usability Assessment: Library Practices and Concerns*, p. 57).

Our Proposal

- **Strong tradition of assessment at UITS/IUB Libraries**. We work on products like IUCAT, OneStart and Oncourse. We develop dozens of informational and interactive websites.
- We **need to do user studies as part of the design process** for IU applications and websites--we have a responsibility to IU faculty, staff, and students, as well as to Indiana taxpayers, to make IU applications and websites easy to use.
- **Our user studies span a broad range of low risk activities** such as usability tests, focus groups, interviews, surveys, analysis of log data, and field studies. Nearly all our studies are of IU faculty, staff, and students.
- **User studies that are part of product development have to be flexible and inexpensive**. These studies are only secondarily research. They are primarily product development activities. However, **we do want the option of making our findings public**, through posting of technical reports on the web, giving talks, or even writing articles.

Our Proposal, Con't

- **We fully support the overall goals of IRB process**. Human subjects need to be treated ethically, and IU's ability to attract and conduct sponsored research also needs to be protected.
- We have heard of other institutions **finding creative yet responsible ways to streamline the process** for studies that support internal product development

The Meeting, 9/29/2007

- Two UWG members met with IRB rep to discuss our proposal
  - we'd like a streamlined process
  - could we get "blanket" approval for a sequence of studies?
  - could we get approval for an application template for a particular kind of study we do often?

Our Takeaways

- For most of our user studies, we don't need to ask for IRB approval, unless the work is also tied to a research objective
- If we're not sure we'll go through IRB, just to be safe, and to be good IU citizens
- If we later want to use data gathered during development for a research project, we can take that to the IRB as a proposal to do research on existing institutional data

References

- Usability Working Group Wiki
- Research Compliance at IU

Questions? Comments!

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Thanks to Mark Notess for contributing content