Introduction to Human Subjects Protections and the IRB

UW Human Subjects Division

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Global Health

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Topics for this presentation

- History and ethical principles
- Which activities need IRB review?
- Different types of IRB review
- What is the IRB looking for?
- Common mistakes

What is an IRB (Institutional Review Board)?

Research Abuses and the Creation of Research Ethics Codes

The Belmont Report (1979)

- Respect for Persons
- Beneficence
- Justice in distributing burdens and benefits

Human Subjects Regulations 45 CFR 46

- **Criteria for IRB approval of research**
  - Informed consent will be obtained and documented
  - Risks are minimized
  - Risks are reasonable in relation to anticipated benefits
  - Protect privacy and confidentiality
  - Provisions for monitoring of data to ensure safety
  - Extra protections for vulnerable populations
  - Selection of subjects is equitable

What needs IRB review?

Is it research?

- Research is “a **systematic** investigation designed to develop or contribute to **generalizable** knowledge”
  - Program evaluations and QA/QI activities?
  - GUIDANCE: Is it Research?

What needs IRB review?

Is it research with human subjects?

- Human subject is “an individual about whom a researcher obtains
  - data through interaction or intervention and/or
  - private, identifiable information”
- WORKSHEET: Human Subjects Research

If something is "research with human subjects"…

- Exempt - No IRB review – minimal risk
- Expedited IRB review – minimal risk
- IRB review by the convened board ("full board review") – greater than minimal risk

If something is "research with human subjects"…

Minimal Risk – probability and magnitude of harm or discomfort anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

If something is "research with human subjects"…

Exempt Status

- Six categories of methods
  - Surveys, interviews, educational tests, observations of public behavior
- *At UW*: a seventh category of exemption
  - No federal funding
  - Benign interventions, interactions, observations with adults
- Research has to be minimal risk

If something is "research with human subjects"…

Expedited IRB review

- Done by one "designated" reviewer
- Seven categories of methods
- Research has to be minimal risk

If something is "research with human subjects"…

Full Board IRB Review

- Composition of IRB
  - at least 5 voting members
  - varying backgrounds (race, gender, culture)
  - appropriate expertise

What the IRB wants to know

- From the subject's perspective:
  - First contact/recruitment
  - Consent process
  - Study procedures
  - Follow up
  - How you will store and protect data and/or specimens

Vulnerable Populations

- Pregnant women, fetuses, and neonates
- Prisoners
- Children
- Mentally disabled persons
- Cognitive impairment
- Economically or educationally disadvantaged persons

After the Initial Approval

- Renew approval (usually annually)
- Get approval for changes to study (modification)
- Report problems
- Close study when finished

Common Mistakes!

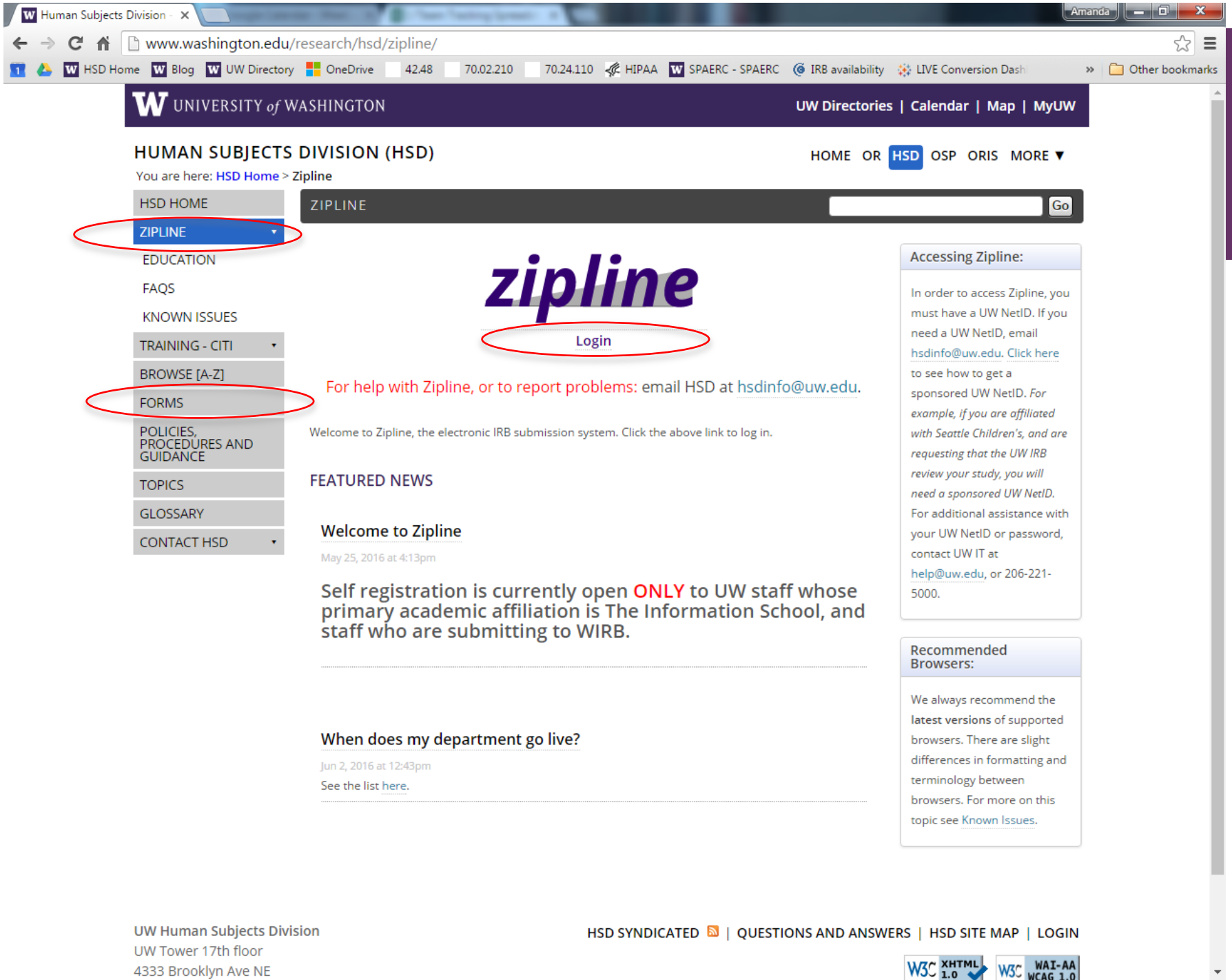
- Incomplete applications (ex. Didn't provide consent form or left questions blank)
- Not enough info about procedures
- Using too much technical jargon
- Not planning ahead – leave enough time for review
  - Exempt 1-2 weeks
  - Expedited 4-6 weeks
  - Full board > 6 weeks

IRB Review at UW

Zipline electronic IRB system will be rolled out to Global Health starting on June 15, 2016

http://www.washington.edu/research/hsd/zipline/

- Document management system
  - Zipline Smart Forms
  - IRB Protocol
  - Associated study documents (consent, recruitment, instruments)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Welcome to Zipline, the electronic IRB submission system. Click the above link to log in.
FEATURED NEWS
Welcome to Zipline
May 25, 2016 at 4:13pm
Self registration is currently open ONLY to UW staff whose primary academic affiliation is The Information School, and staff who are submitting to WIRB.
When does my department go live?
Jun 2, 2016 at 12:43pm
See the list here.
Accessing Zipline:
In order to access Zipline, you must have a UW NetID. If you need a UW NetID, email hsdinfo@uw.edu. Click here to see how to get a sponsored UW NetID. For example, if you are affiliated with Seattle Children's, and are requesting that the UW IRB review your study, you will need a sponsored UW NetID. For additional assistance with your UW NetID or password, contact UW IT at help@uw.edu, or 206-221-5000.
Recommended Browsers:
We always recommend the latest versions of supported browsers. There are slight differences in formatting and terminology between browsers. For more on this topic see Known Issues.
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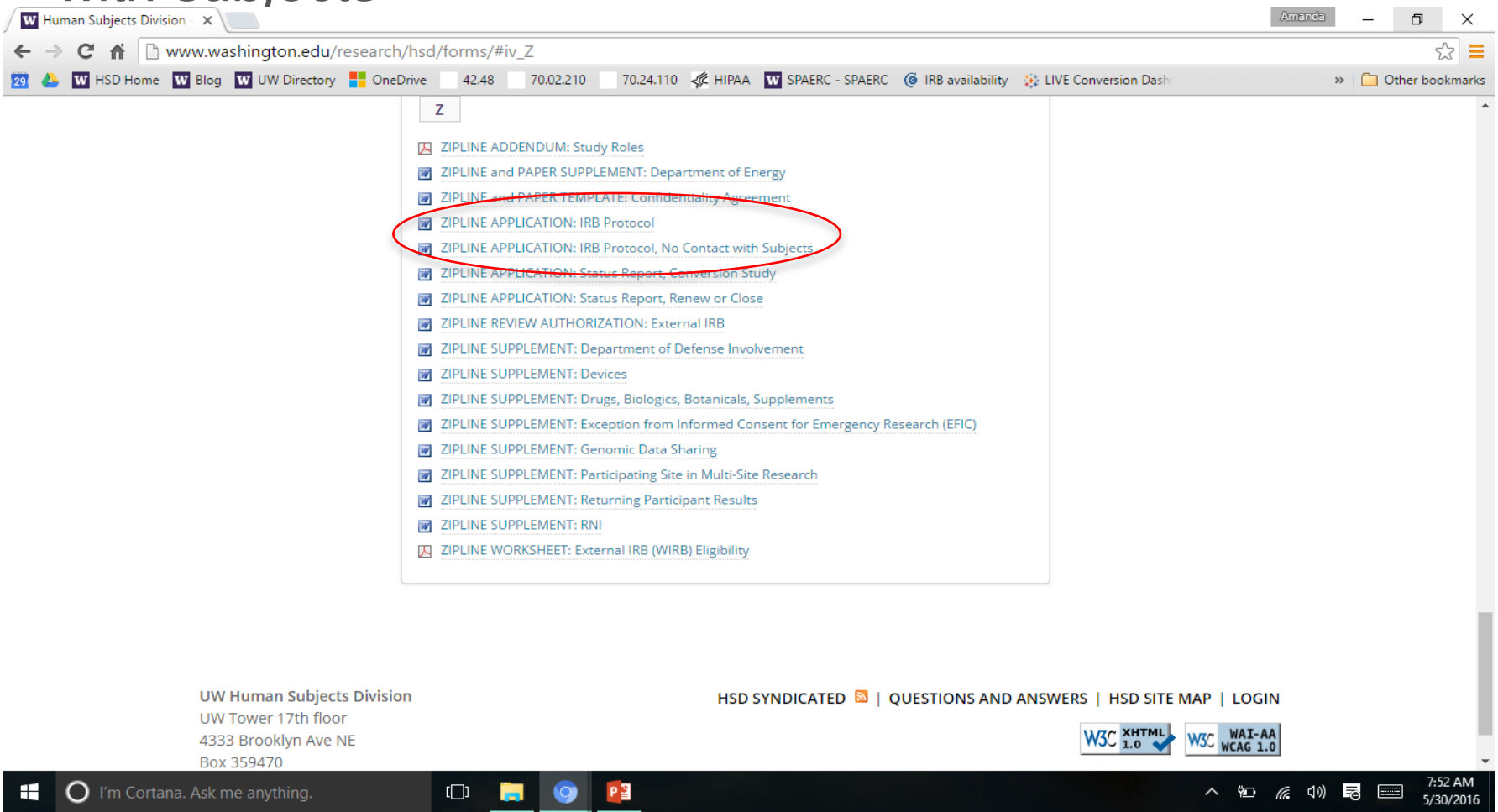
How to apply?

- *ZIPLINE APPLICATION IRB Protocol*
- *ZIPLINE APPLICATION IRB Protocol, No contact with subjects*



For questions or to sign up for HSD's email newsletter:

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