Preparing a Successful IRB Application

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Goals for today

- Departmental regulatory support
- IRB approval strategies
Departmental regulatory support

- Email Karen Adams for a consultation
- Include a 1-2 paragraph overview of the proposed study
  - purpose
  - study design
  - study setting
  - procedures
  - subject population
- Attached relevant information (protocol, grant proposal)
- Set up a time to meet
- Review follow-up guidance
- If needed, provide 1st draft of IRB application by email
- Be available for follow-up and proof reading

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IRB approval strategies
#1. Plan ahead
#2. Know who has jurisdiction

UW Human Subjects Division:  
http://www.washington.edu/research/hsd/docs/1642

Engagement worksheet:  
http://www.washington.edu/research/hsd/docs/1652

Seattle Children’s Human Subjects Protection Program:  
http://www.seattlechildrens.org/research/support-services/institutional-review-board/about/
#3. Identify level of review

- Regulated research?
- Human subjects?
- Exempt from IRB approval?
- "Minimal risk" review?
- Full IRB review?

UW Human Subjects Division:
http://www.washington.edu/research/hsd/docs/1253
http://www.washington.edu/research/hsd/docs/1654
#4. Be aware of the rules

- Impact of regulations
- Institution-specific view
- Identify areas of flexibility
#5. Use current forms and templates

- Download documents from the IRB website
- Sign up for updates

http://uwfoundation.org/convio/subscription_management.asp

Office of Research
--Grants eNewsletter
--Human Subjects Research

UW Human Subjects Division:
http://www.washington.edu/research/hsd/
Seattle Children’s Human Subjects Protection Program:
http://www.seattlechildrens.org/research/support-services/institutional-review-board/
#6. Write with clear, simple language

- Write from scratch
- Use lay language
- Define clinical terminology
- Use the active voice
#7. Separate research from routine care
#8. Assess risks and benefits accurately

- Provide balanced overview of research risks
- Explain how you will minimize risks
- Assess the anticipated research benefits

HHS Risk/benefit analysis:
http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm
#9. Be complete

- Answer every question
- Provide enough detail
- Include a study protocol if available
#10. Proofread carefully
#11. Market your IRB Application

- Presentation is essential
- Talk with the IRB Administrators/Analysts
- Be available
- Curb frustrations
- The power of “Thank you”
Additional resources

Code of Federal Regulations (45 CFR 46)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

UW Department of Anesthesiology and Pain Medicine
http://depts.washington.edu/anesth/research/irb/index.shtml

Other contacts:
UW Human Subjects Division: 206-543-0098

Seattle Children’s Human Subjects Protection Program: 206-987-7804