

Ethics and  
Protecting *Human Subjects*  
  
Class 22

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Agenda

- 3:00-3:15 Krista's Presentation
- 3:15-3:25 Quiz
- 3:25-3:50 Ethics and Protecting Human Subjects

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Quiz

- What is the difference between tethered, interconnected, and standalone PHRs? What are the benefits of each?
- What are some barriers for PHR adoption?

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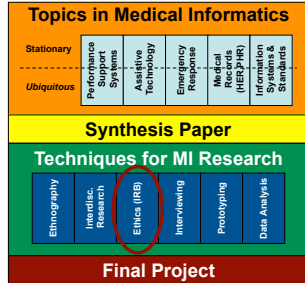
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## Where are we?



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## Why Do We Need HIPAA/IRB?

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## Nuremberg Code

- Established 1948
- 23 Germans tried for war crimes
- Medical experiments on thousands of people without their consent
- **Result: Voluntary human subject consent is absolutely essential (voluntary participation and informed consent)**



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## Kefauver Amendments

- Established 1962
- Late 1950s pregnant women given thalidomide to reduce nausea and help with sleep
- Patients did not know thalidomide was not FDA approved
- Over 12,000 babies born with deformities
- **Result: Drug manufacturers must prove to FDA the effectiveness before marketing**




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## Belmont Report and IRB Creation

- Belmont (1979) & IRB (1974)
- In 1932 400 black, poor, low literacy share croppers were infected with syphilis
- Participants were not informed about the disease, just about incentives (free care, free hot meal, and \$35/\$50 in the event of death)
- In 1947 penicillin was invented... participants were not offered it.
- Study was not stopped until 1973!!!
- **Result: Informed consent; Independent review; Risks should not exceed benefits; Protect human subjects**




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## Ethical Considerations from the Belmont Report

Principle	Application
<b>Respect for persons</b> <ul style="list-style-type: none"> <li>• Individuals should be treated as autonomous agents</li> <li>• Persons with diminished autonomy are entitled to protection.</li> </ul>	<b>Informed consent</b> <ul style="list-style-type: none"> <li>• Subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them</li> <li>• The consent process must include three elements:                             <ul style="list-style-type: none"> <li>○ information,</li> <li>○ comprehension, and</li> <li>○ voluntary participation</li> </ul> </li> </ul>
<b>Beneficence</b> <ul style="list-style-type: none"> <li>• Human subjects should not be harmed</li> <li>• Research should maximize possible benefits and minimize possible harms.</li> </ul>	<b>Assessment of risks and benefits</b> <ul style="list-style-type: none"> <li>• The nature and scope of risks and benefits must be assessed in a systematic manner</li> </ul>
<b>Justice</b> <ul style="list-style-type: none"> <li>• The benefits and risks of research must be distributed fairly.</li> </ul>	<b>Selection of subjects</b> <ul style="list-style-type: none"> <li>• There must be fair procedures and outcomes in the selection of research subjects</li> </ul>

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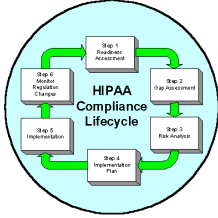
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# HIPAA

- Established in 1996 (most recently amended in 2006)
- Title I: Protects people during times of change with insurance coverage
- Title II: National standards for electronic transactions and identifiers
- *Intention: Improve efficiency and effectiveness of the healthcare system*



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# IRB and Businesses

- Varies from business to business if there is an IRB
- If you work with a university, you must go through the university IRB too
- If you work with a hospital, you must go through the hospital IRB too

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# When do I submit a study to the IRB?

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## When do I submit a study to the IRB?

- Take the IRB Test (Colorado calls it a Human Research Committee): <http://www.colorado.edu/VResearch/HRC/EducationalTools.html>
- Plan your study (IRB feedback takes 14+ days! You cannot contact anyone for recruiting, etc. until you get approval)
- Decide what kind of HRC/IRB form to submit
- Submit a form
- Wait for IRB results. If changes are needed, fix immediately and resubmit.
- Conduct study following the protocol approved by the IRB

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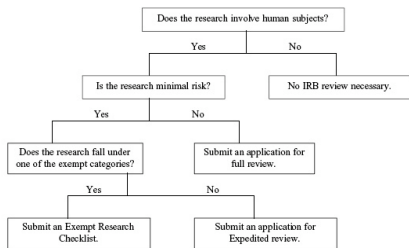
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## What do I submit to the IRB?



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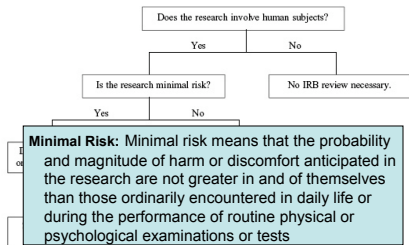
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## What do I submit to the IRB?



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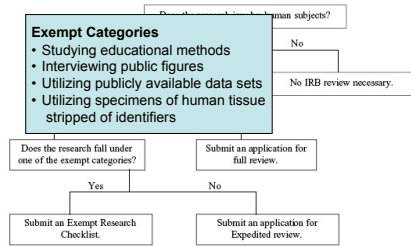
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## What do I submit to the IRB?




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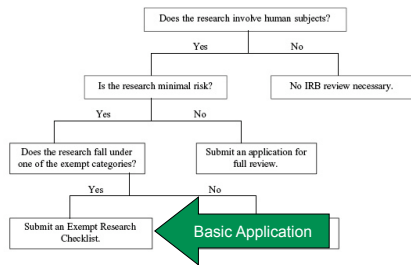
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## What do I submit to the IRB?




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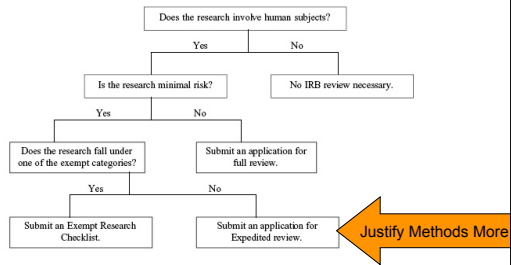
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## What do I submit to the IRB?




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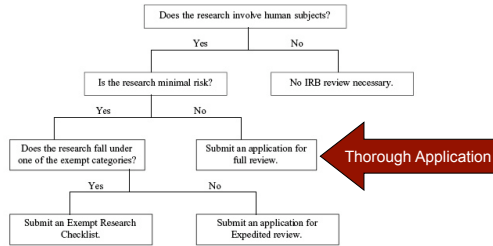
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## What do I submit to the IRB?



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## The IRB Write-Up

- Visit the IRB
- Ask people to see their approved write-ups
  - If possible, ask to see what they originally received, IRB feedback, and changes made
- Be neat
- Be organized
- Be thorough and specific
  - **No:** *Participants will be compensated for participation.*
  - **YES:** *We will give participants a \$10 gift card for Target for their participation in our study at the end of the last meeting of our study.*
- Give yourself enough time for recruitment, collection, and analysis
  - I say I will keep the data for 1-3 years depending on the study.

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## The Write-Up

- Why my study is exempt (use tree)
- Describe study (4th grade reading level, non-technical)
- Describe recruiting habits (who am I recruiting and why)
- Describe how study will be conducted
- Informed Consent
  - Study description
  - Benefits
  - Confidentiality
  - Contact (Yours and IRB)
  - Participation
  - Signature and Date
  - IRB Approval Number
- ALL associated study material (transcripts, data collection probes, how study will be evaluated, recruiting material)

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## Ooops...I forgot...

- Any changes (even room changes) MUST be approved by IRB...have to submit an amendment (1-3 pages)

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## What if I have a problem?

- Who did the participant contact?
  - You?
    - Stop your study until problem is rectified
    - Consult with you manager
    - Consult with IRB
  - IRB?
    - Stop your study
    - May have to go through another review
    - Consult with Manager

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## Do I have to submit an IRB proposal for my final project?

### What would qualify as a class project?

Any systematic observation, intervention, or use of identifiable private information by a student that is designed to develop or contribute to student learning, and for which publication or dissemination of findings outside an instructional setting is not anticipated.

### Who reviews my proposed class project if I am only doing the project for my class?

Your instructor will conduct a preliminary review of your class project and work with a departmental liaison appointed by the HRC for class project approval. *This is why we have so many intermediate deliverables...so I can make sure the study is progressing okay.*

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# Looking forward

- Wednesday – Guest Speaker, Steve E. Ross, MD
- Friday - Interviewing

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