

# **Human Subjects in Research: Focus on Student Projects**

**Kent Rissmiller, IGSD/SSPS**

**Chair, WPI's Institutional Review Board**



# What is an Institutional Review Board?

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- **A panel created by research institutions, in accordance with federal laws and regulations, to review and give prior approval to research that involves human subjects.**

# What is an Institutional Review Board?

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- **It's not a secret society!**
  - **Kent Rissmiller (SSPS/IGSD)**
  - **Al Hoffman (ME)**
  - **Sharon Johnson (MG)**
  - **Yitzhak Mendelson (BioMed)**
  - **Ruth Smith (HU&A)**
  - **Grant McGimpsey (Assoc. Provost/VP Research)**
  - **Michael Curley (Compliance Officer)**
  - **Tina DeVries (Research Administration)**

# In Brief:

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- **The “Why” of Human subjects research Review**
- **The “What” of human subjects research review – some definitions.**
- **Some human subjects research problems**
- **Some sources for assistance**

# **Belmont Commission Report: “*Ethical Guidelines for the Protection of Human Subjects of Research*” (1979/1998)**

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## **Three Basic Ethical Principles**

### **1. Respect for Persons**

- **Persons should be treated as autonomous agents**
- **Persons with diminished autonomy are entitled to protection**
- **Subjects must participate voluntarily and with adequate information to make appropriate judgments**

# **Belmont Commission Report: “*Ethical Guidelines for the Protection of Human Subjects of Research*” (1979/1998)**

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## **2. Beneficence – an obligation to secure the well-being of others**

- **Do not harm**
- **Respect privacy**
- **Maximize possible benefits and minimize potential harms**
- **Benefits may be to society, rather than the subjects**

# **Belmont Commission Report: “*Ethical Guidelines for the Protection of Human Subjects of Research*” (1979/1998)**

## **3. Distributive Justice**

- **How do we justify treating people differently?**
- **How are burdens and benefits shared?**
- **Research subjects have often been exploited populations (including service men and women, prisoners, the poor, ... students?)**

## **Application of these principles to research means:**

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- **Researchers must:**
  - **Gain the informed consent of the subjects**
  - **Carefully manage and store data**
  - **Assess of risks and benefits of the research**
  - **Use care in subject selection**
- **“Benefits of research” implies that the research is useful. This might raise questions about research design.**

# What's a "Human Subject?"

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**46 CFR 102 (f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains**

- (1) Data through intervention or interaction with the individual, or**
- (2) Identifiable private information.**

# What's "Research?"

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- 46 CFR 102 (d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

# Bottom Line:

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- **If you or your students are involved in human subjects research – seek IRB approval.**
- **When you realize that you or your students will become involved in human subjects research – seek IRB approval.**
- **If you or your students don't know if you are involved in human subjects research – consult an IRB member!**

# **“Research Scenario 1”**

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- **A CS professor is developing an educational computer game aimed at middle school students. He wants to “play test” the game in a computer lab with a group of 12-13 year olds.**
- **Does he need IRB approval?**

# “Research Scenarios”

Cal State University – Monterey <http://grants.csumb.edu/site/x3374.xml>

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A photography student is preparing his/her Capstone Project in VPA. The subject of interest focuses upon fishermen bringing in a catch. The student wishes to capture the daily effort of the event and takes pictures, both close up and distant, of workers hauling in the nets, working on the boat and resting.

Does the student need IRB approval?

*[What if the project will be shown publicly with other student work at the end of the semester?]*

# “Research” Scenarios

Cal State University – Monterey <http://grants.csumb.edu/site/x3374.xml>

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A professor sets an assignment for students in his/her class to interview local residents have them discuss their opinions and actions as local community members involved in an ecological issue.

# “Research” Scenarios

Cal State University – Monterey <http://grants.csumb.edu/site/x3374.xml>

*This will most likely be a Level I consent as it involves adults. Students will have to prepare questions that they submit along with the Human Subject Form and indicate if they are going to tape or videotape the interviews. If either of those two formats are going to be used, the student will also have to indicate where the data will be kept (for a 3-year period) if the data is to be used for professional presentations.*

*If the data is being taped only to ensure accuracy of the interview responses and if the data is only appropriate for that particular class and tapes will be erased once the assignment is prepared, then the data does not need to be stored.*

*The professor will have to read and sign off on the Human Subject Review form. All letters of consent must describe the project in language that the participants can easily understand and the participants know that at any time they can withdraw from the project. The student needs give an overview of the kinds of questions that are going to be asked.*

# Isn't this going overboard?

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# Some “Research” is exempt from IRB review

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- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
  - (i) research on regular and special education instructional strategies, or
  - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 46 CFR 101 (b)

# “Exempt Research”

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(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 46 CFR 101(b)

# “Exempt Research”

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(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. 46 CFR 101(b) (Other exemptions appear in the regulations.)

# **“Research Scenario”**

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- **A project team working for a Department of Natural Resources is given the task of interviewing charter fishing boat operators to determine their activities and assess fish populations.**
- **Can this research receive an exemption?**

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- **Who decides whether research qualifies as exempt?**
  - **The IRB.... Why?**

# What if research is not exempt?

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- **Expedited Review** - for minimal risks
  - IRB Chair or 1-2 other members will review application and research protocol and Informed Consent Form and approve following any needed clarification or revision.

# What if research is not exempt?

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- **Full Review** – when more than minimal risk is presented.
  - Full review requires a board meeting.
  - This takes time!

# Informed Consent

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- **Is a formal, signed Informed Consent Statement always required?**

# Research Scenario

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**Students working on a project for a museum plan to talk to children and school groups, as they prepare to leave the museum, about their day. The students are interested in learning about the exhibits that are most memorable or exciting to the children.**

# **Hoo Haa! The IRB approved your research. Now What?**

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- **Follow Through!**
- **Adverse Event Reporting**
- **Modifications of Research Protocol**
- **Annual Reports or Continuation of Study**

# Purpose of Human Studies Review

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- **To protect human subjects participating in research studies.**
  - **By educating investigators regarding ethical practices**
  - **By ensuring that their research practices meet community, national standards**
- **To reduce the number and severity of adverse incidents, and**
- **Mitigate liability of investigators, WPI**

# Where to Apply / Get Help?

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- **WPI's IRB**

- <http://www.wpi.edu/Admin/Research/IRB/>
- <http://www.wpi.edu/Admin/Research/IRB/members.html>