



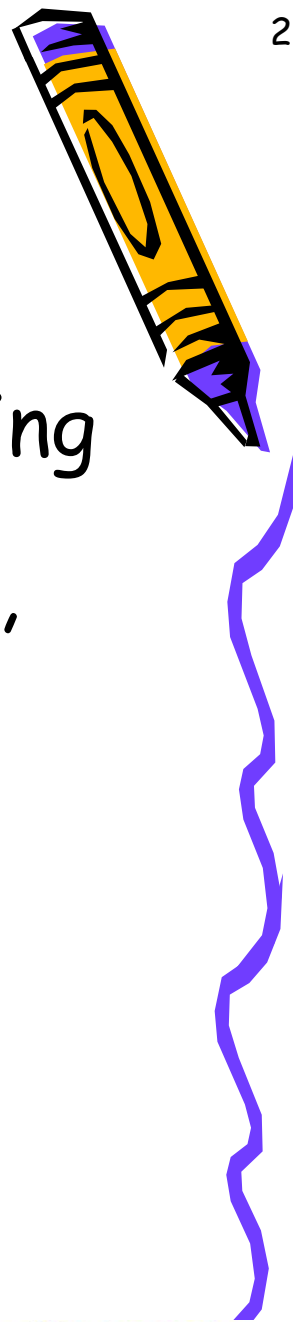
Research in Public Schools

Important considerations when planning your research



Is it research?

- A **systematic investigation**, including research development, testing, evaluation, surveys, questionnaires, and/or interviews, designed to develop or contribute to the **knowledge base**.
- Do you plan to publish, present, or archive findings?

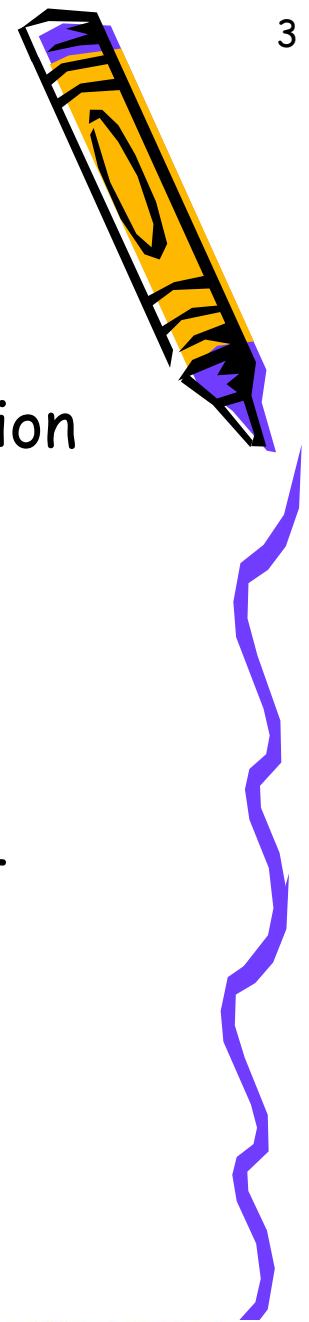


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Human subjects?



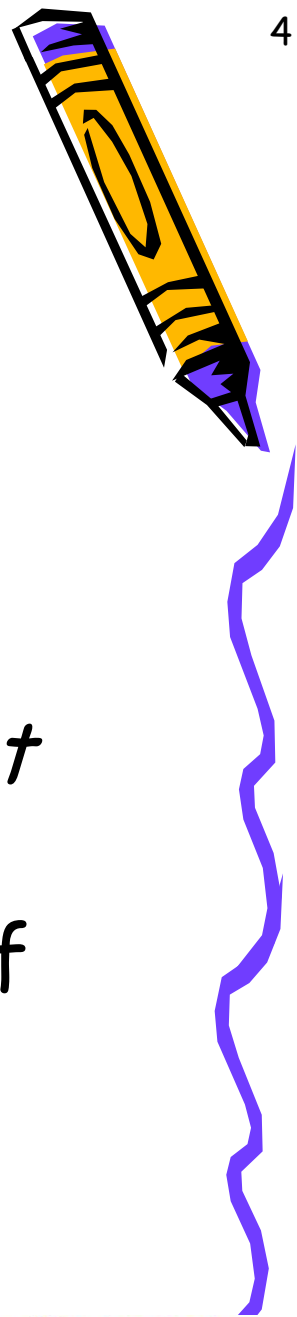
- Does the research project involve an interaction with a living person (face-to-face, by mail, by phone, by email, etc.)?
- Will you seek data about the person (i.e., behavior, beliefs, experiences, medical or economic status)?
- Does this research involve archival data about individuals?
- Will identifiable private data be obtained in a form associable with the individual?



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Should I file an IRB application?



- See "Section D. Human Subjects Regulations Decision Charts," beginning on page 38 of the *UT Martin Faculty, Staff, and Student Handbook for Studies Involving Human Participants* to determine if you should file an IRB application.



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Why do I need to file an IRB application?



- Ethical research practices demand it.
- Federal regulations require it.
- All human subjects research must have prior IRB approval.
- A "Federal-wide Assurance" binds UT Martin to uphold ethical and regulatory requirements in human subject research, regardless of funding.



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The Belmont Report

- Defines the ethical principles and guidelines for the protection of human subjects of research:

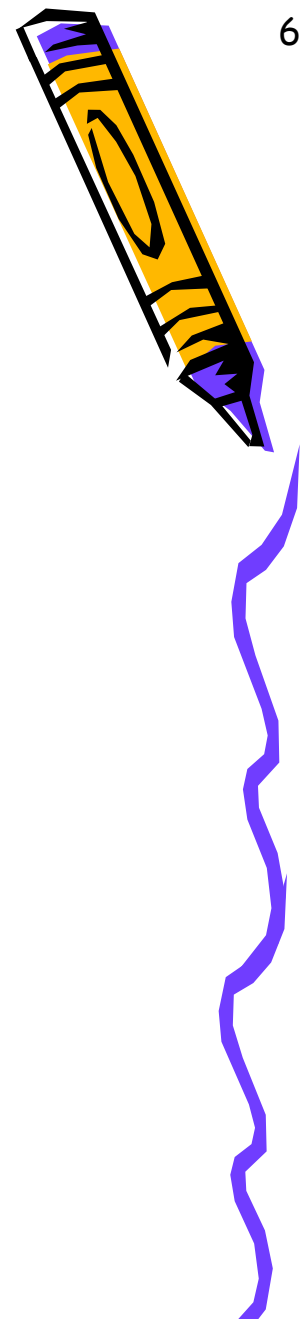
Respect for Persons
Beneficence
Justice

National Commission for the Protection of Human
Subjects of Biomedical and Behavioral Research, 1979



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Respect for Persons

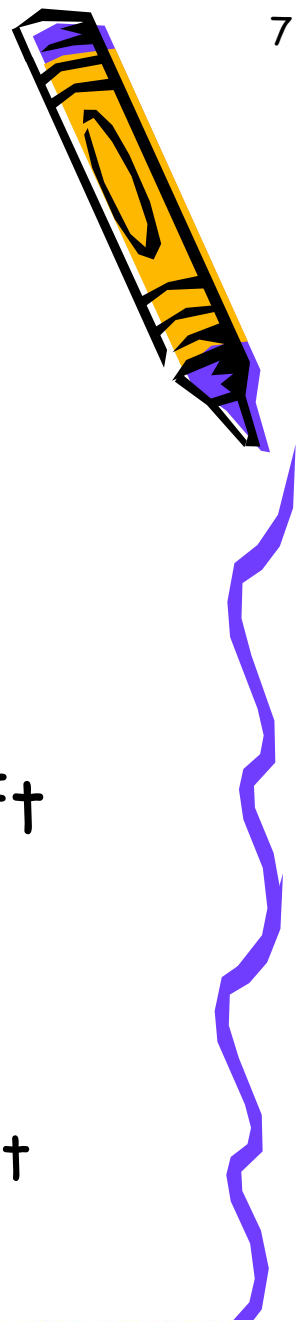
- Treat individuals as autonomous agents.
- Don't use people solely as a means to an end.
- Allow people to choose for themselves.
- Recognize a fundamental right to be left alone.
- Extra protections for vulnerable populations.
- **Practical applications:** informed consent and privacy protections.



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Beneficence

- Maximize benefits.
- Minimize risks.
 - **Practical applications:** study design, risk-benefit analysis, competent investigators.



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Justice

- Burdens and benefits of research should be distributed equitably.
- Treat people fairly.
 - **Practical applications:** selection of subjects, recruitment, populations under study.



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Conflict Among Ethical Principles



Respect for Persons

Beneficence ————— Justice

- Principles carry equal moral weight.
- Tension was anticipated and expected.
- Requires subjective judgment calls.
- Reasonable people will disagree.

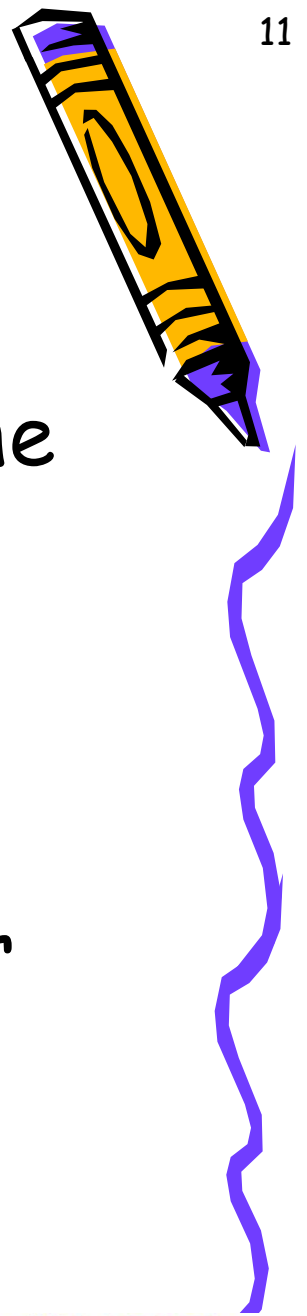


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The Common Rule

- Standardizes Federal policy for the Protection of Human Subjects
 - June 18, 1991
 - Adopted by 21 federal agencies
- Based on a system of assurances
- Provides additional protections for vulnerable populations



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Dual Roles



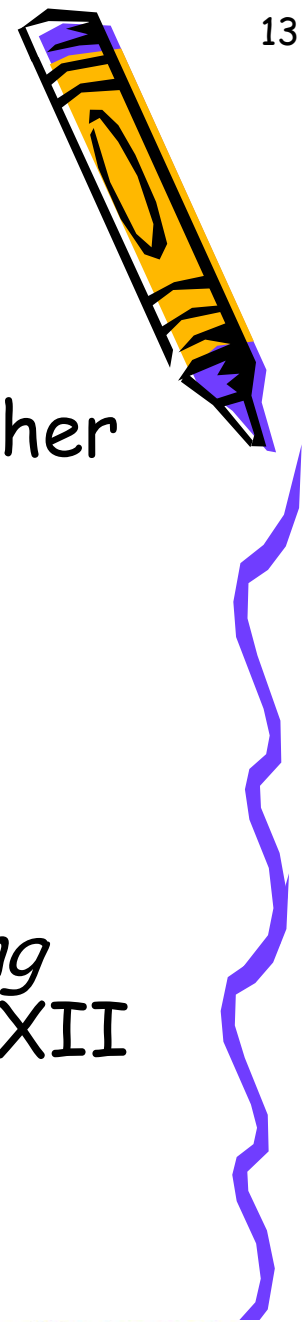
- Researchers who are employed by a school, such as teachers returning for graduate degrees, must be aware of their dual roles.
- As a researcher, they do not have legitimate access to information that they may consult daily as a teacher.



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Children



- Children are identified by OHRP and other federal agencies as a **vulnerable population**.
- There are special rules for their protection.
- See the *UT Martin Faculty, Staff, and Student Handbook for Studies Involving Human Participants*, especially Section XII A, beginning on page 50.

- Also 45 CFR 46



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Student Records

- Federal laws protect information in student records.
- In some cases, parents have authority over the kinds of questions researchers can ask their children.



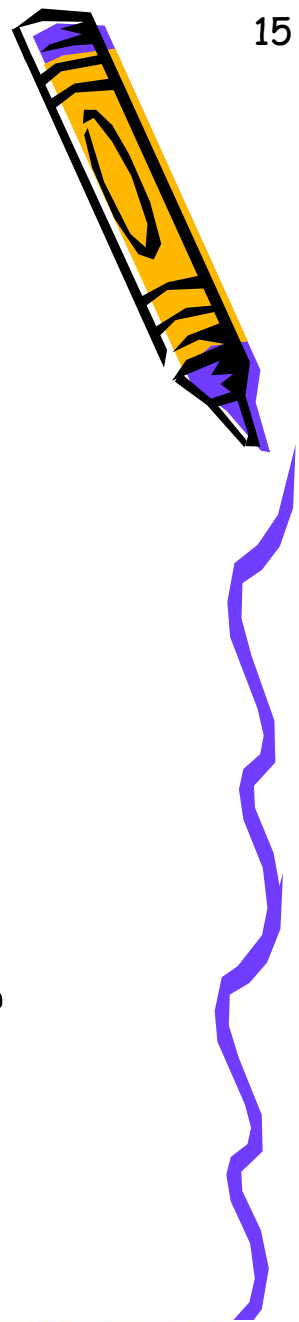
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Multiple levels of protection

- While authority structures may vary, researchers may need to confer with
 - Teachers
 - Principals
 - District supervisors
 - School Boards
- All of whom can be held responsible for the children in their care.



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Family Education Rights and Privacy Act



- FERPA gives parents certain rights over the contents of their children's records.
- Generally, schools must have written permission before releasing any identifiable information



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FERPA, continued

- Some records, such as "Directory information" may be disclosed to certain parties, such as organizations conducting research, without consent.
- Such disclosures may be used by researchers **ONLY** when invoked by a school, district, or state department of instruction initiating a study.



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Allowable disclosures

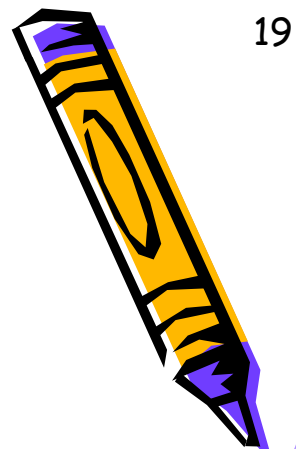
- "Directory information" includes such things as
 - Student's name, address, telephone number
 - Date and place of birth
 - Honors and awards
 - Dates of attendance



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Allowable disclosures, continued



- Schools must inform parents that directory information is not protected.
- Schools must allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them.

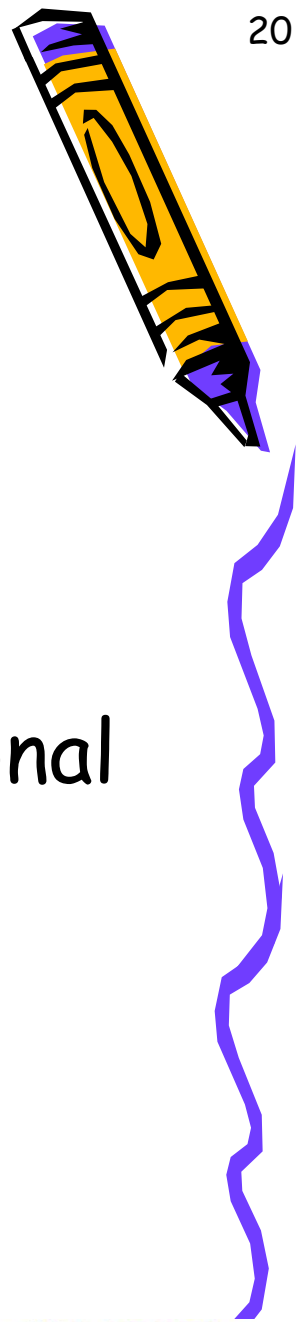


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Protection of Pupil Rights Amendment

- PPRA gives parents some level of control over their child's participation in third-party survey research or exposure to instructional materials developed by research.



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8 Sensitive topics for PPRA



- Political affiliations or beliefs of student or student's parents
- Mental and psychological problems of student or student's family
- Sexual behaviors or attitudes
- Illegal, anti-social, self-incriminating, or demeaning behavior
- Critical appraisals of other individuals with whom respondents have close family relationships



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8 Sensitive topics for PPRA, continued



- Legally recognized privileged or analogous relationships, such as those with lawyers, ministers, physicians
- Religious practices, affiliations, or beliefs of student or student's parents
- Income (other than that required to determine eligibility for participation in programs or receiving financial assistance)



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PPRA and US Dept of Education



- For any survey, funded in whole or in part by the US Department of Education, that asks students to provide information about any of the eight sensitive topics, parental permission for the students to participate **cannot** be waived.



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PPRA and NCLB

- NCLB, in 2001, granted parents additional rights regarding the content of any survey administered in public schools, regardless of US Dept. of Ed funding
- Every public school system must develop policy that informs parents of their rights to inspect third-party surveys and related instructional materials and to request that their children not participate.



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Informed Consent

- Informed consent is a **basic tenet** under Respect for Persons in the Belmont Report
- The Common Rule **requires** that parental permission be either secured or waived for research involving third-party surveys or instructional materials, in accordance to criteria established in the Rule.
 - The UT Martin IRB requires documentation of how the researcher will obtain informed consent (parental permission and the child's assent, when appropriate)



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The Consent Paradigm

- Requires that the parents or legal guardians give permission for their children to become research subjects
- Requires that children, when developmentally appropriate, provide assent.



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Waivers for Parental Permission



- Subpart D allows waivers under four criteria
- In each case, the researcher must provide **compelling** evidence and documentation of the need for a waiver to the IRB



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The UT Martin IRB

- Only the IRB can make the determination to waive informed consent, parental permission, and/or assent requirements for research conducted through this campus



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The Common Rule, IRB and PPRA



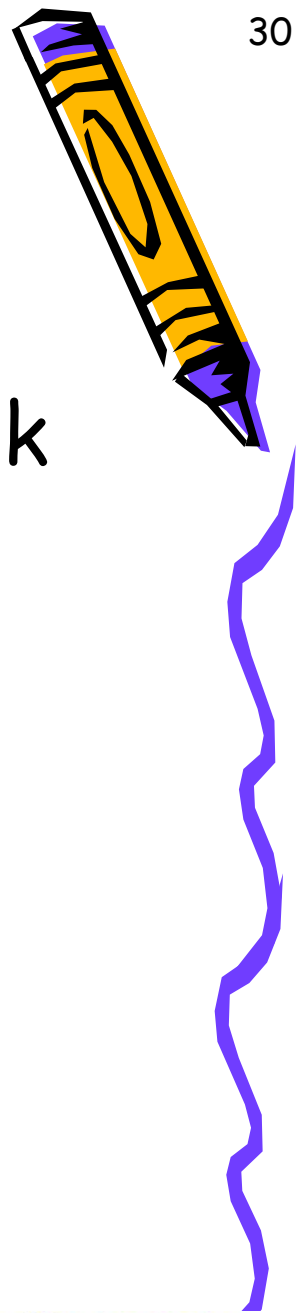
- Even if the IRB waived the requirement to secure written parental permission in accordance with the Common Rule, PPRA requires that, in accordance with school system procedures, parents must be notified about the research to take place and given the opportunity to ask that their children not participate.



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Exempt activities under the Common Rule



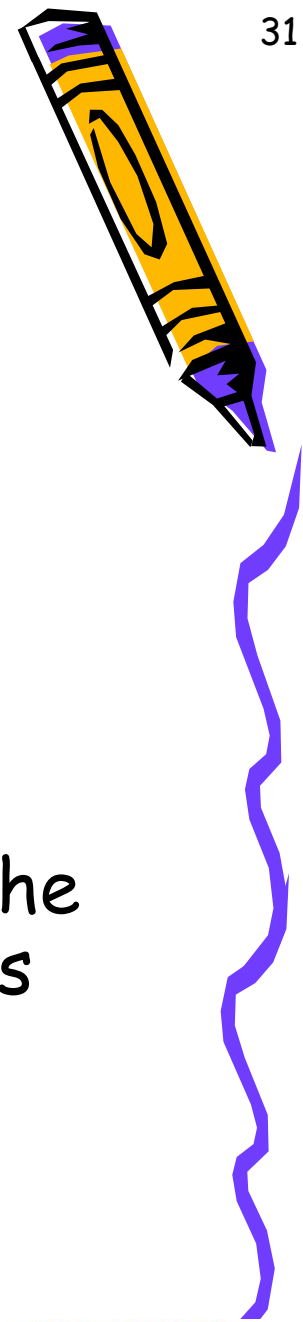
- Activities that pose little or no risk to the potential subjects
- See the *Handbook* for categories, definitions, and exceptions
- Subpart D limits the use of exemption criteria for research involving children.



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Activities that do not qualify for exemption



Under Subpart D, the following activities with school children do not qualify for exemption:

- Research involving surveys
- Research involving interviews
- Observations of public behavior when the researcher participates in the activities being observed



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Potential coercion

- Even with parental permission, children must be allowed to provide assent as appropriate for their age and maturity.
- It is very important that assent processes be designed to avoid even the perception of possible coercion



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Research-related risks

- Care must be taken to insure that students are not ostracized by their peers based on their participation in a research study.



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Child abuse and neglect

- Researchers must be aware of their state and local reporting requirements when they suspect child abuse or neglect
- They must also inform parents and older children that confidentiality may be limited by these requirements



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Additional resources

- The *UT Martin Faculty, Staff, and Student Handbook for Studies Involving Human Subjects* and the required forms for filing an application for IRB review are available online at <http://www.utm.edu/departments/rgc/irb.php>



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Recommended training

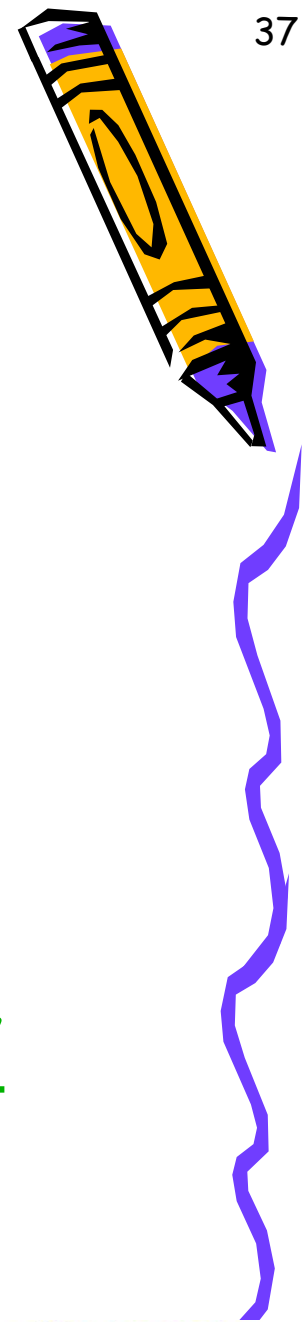
- UT Martin subscribes to an approved online training program regarding Human Subjects Research
- This online training is available at no cost to faculty, staff, and students of UT Martin
- Contact the UT Martin ORGC for information on access to this training



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