Human Subjects Research at

UNIVERSITY of HOUSTON

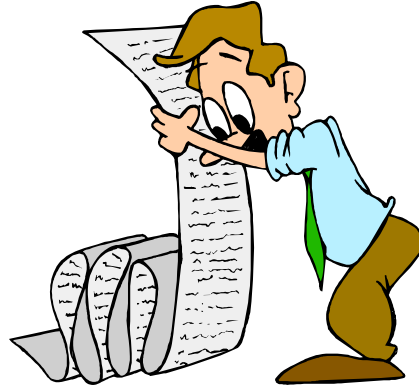A CARNEGIE-DESIGNATED TIER ONE
PUBLIC RESEARCH UNIVERSITY

Presented by:

Office of Research Policies, Compliance, and Committees

On behalf of:

The UH Committee for the Protection of Human Subjects (CPHS)

Human Subjects - History

- Protections for human subjects in research developed as a reaction to a long history of abuses

- 18th/19th century – physicians used selves, slaves, and others to perform human experiments (example – Edward Jenner tested smallpox vaccinations on his son and neighborhood children)

Human Subjects - History

- Nazi War Crimes (Nuremberg Doctor's Trial)
  - Nuremberg Code: 10 key points; the first and foremost being: *"The voluntary consent of the human subject is absolutely essential."*

- U.S. issues leading up to the establishment of first federal regulations for human subjects research:
  - Tuskegee Syphilis Study (1932-1972)
  - Henry Beecher Paper – 1966 – 22 unethical studies published in peer-reviewed journals
  - Milgram Experiments – 1974
  - Belmont Report – 1978-79

Belmont Report

- Respect for persons (autonomy) – dignity/freedom

- Beneficence – risk/benefit ratio

- Justice – equitable selection/distribution

But I Only Want to Hand out a Survey, or have Users Test my Phone App. How do These Apply to My Research?

- The current regulations were put in place to cover ALL research involving human subjects. While not all research is inherently risky, some of these key underlying considerations still apply (ex: respect for persons, confidentiality)

Research Ethics is a Constantly Evolving Field

- Genetic Research

- Social Science Research (ex: Oral Histories)

- International Research

- Deception Research

- Social Media Research

- Internet/Smartphone-based research

- New risks (as well as new benefits) are inherent in all new research fields – the regulations take some time to catch up!

- In the mean time, IRBs are working through the challenges of assessing ethical boundaries and ensuring adequate protections for subjects.

CPHS

- The Institutional Review Board for University of Houston is the Committee for the Protection of Human Subjects (CPHS)
  - CPHS 1
  - CPHS 2 (primarily CLASS)

- The CPHS is responsible for safeguarding of the rights and welfare of all persons participating in research projects, whether funded or non-funded.

- Reviews are done in accordance with *45 CFR 46 ("The Common Rule,") and the ethical principles established by the Belmont Report.

- Other regulations may apply (FDA, FERPA)

*including subparts B, C, D

When Does my Work need to be Reviewed by CPHS?

- **Simple test:**

  Both answers must be "yes:"

  – Am I conducting research?

  – Are human subjects involved?

What is Research?

RESEARCH is defined as "a systematic investigation, including research development, testing and evaluation, <u>designed to develop or contribute to generalizable knowledge</u>."

45 CFR 46.103(d)

What is a Human Subject?

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.

45 CFR 46.102(f)

Types of Review

Exempt

Expedited

Full Board

Most (not all) student research falls into an "exempt" category

Note: the term "Exempt" is a bit deceiving!

•This terminology is used in the regulations to mean research that does not have to be reviewed by an convened committee

•It is specific to several categories of low risk research

•It still must undergo review. While the PI chooses the category they feel most accurately represents the research, the CPHS office makes the final category determination during the review process.

Exempt Review Examples: Category 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; **or**

    (iii) the research Involves the use of children as subjects

Exempt Review Examples: Category 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.

Expedited Review

- Just like exempt, "expedited" category studies are specifically outlined in the federal regulations. (i.e. "expedited" is not simply a request for a quick turnaround ☺)

Example:

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- Prospective collection of biological specimens for research purposes by noninvasive means.

How do I access CPHS Information?

UNIVERSITY of HOUSTON | RESEARCH

http://www.uh.edu/research/

Compliance ➡ Human Subjects/CPHS

How do I access RAMP?

http://www.research.uh.edu

Link from main page

RAMP
Research Administration Management Portal

Exempt/Expedited Information

- Exempt and Expedited criteria – full list:

http://www.uh.edu/research/compliance/irb-cphs/categories/

Criteria for IRB/CPHS Approval

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may reasonably be expected to result
- Selection of subjects is equitable
- Informed consent will be sought and documented appropriately
- Adequate provisions for monitoring data
- Adequate provisions to protect privacy/confidentiality
- Protections in place to minimize coercion or undue influence, and additional protections for vulnerable populations

Filling out the Application

- Title
  - Concise description of project
- Research Reason
  - Funding/degree fulfillment - check all that apply
- Key Personnel
  - List all who are involved with the research, including thesis/dissertation members, anyone involved in recruitment, consent, procedures, and/or data analysis

Filling out the Application

- Research Hypothesis
  - State specific hypotheses/research questions

- Importance
  - Broad application to science

- Subject population
  - Type and age - different subject types and ages require specific protections

- Number of Participants
  - Reasonably anticipated number. Provide a maximum number (accounting for withdrawals) and monitor enrollment; increase with a revision as needed.

Inclusion/Exclusion

- Inclusion Criteria
  - Clearly defined criteria for those you will target for data collection

- Exclusion Criteria
  - Clearly defined criteria for those who will be excluded from data collection

- Justification
  - Provide justification for the criteria you have defined. Why are certain individuals excluded? Does this group target the question asked?

- Determination
  - How will you determine that these criteria are met?

Does the Research Involve the Following?

- [   ] Interview
- [   ] Clinical Studies
- [   ] Survey/Questionnaire
- [   ] Behavioral Observation
- [   ] Study of Existing Data
- [   ] Study of Human Biological Specimens
- [   ] Deception
- [   ] Waiver of Consent
- [   ] Venipuncture
- [   ] Data Analyses Only
- [   ] Other (specify) (ex: focus group, phone app)

Filling out the Application

- Location of Research – Choices:
  - Choices are:
    - UH - for study of existing data, data analysis, on-campus participation
    - "Other" - for any locations the research will take place off-campus. If subjects will have control over the location of their participation, indicate this and state that privacy will be participant-determined.
    - If "Other" is selected, sometimes a letter of approval/cooperation from the specified site is required (ex: setting up a survey table inside GameStop).

- Research Study Design
  - Describe the research methods to be employed and the variables to be studied. Include a description of the data collection techniques and your plan to analyze data.

- Tasks
  - This should include all proposed tasks subjects will be asked to complete. Include whether or not you will audio record or track participants, or otherwise access sensitive data.

Recruitment

- Fully describe this process. Provide a detailed description detailing how your participants will find out about your study. Attach copies of all flyers, letters, verbal scripts, or electronic messages used for recruitment.

- If a computer app, be clear if app is only available to those who are participating in the research, or if available to the public without the requirement to participate in the research

- If non-English speaking participants will be included in the study, provide copies of all relevant documents in the appropriate language.

- Written recruitment materials must include the following statement, "This project has been reviewed and approved by the University of Houston Committees for the Protection of Human Subjects (713)743-9240."

Informed Consent

- Informed consent is an educational process that takes place between the investigator and the prospective subject.

- Informed consent must be presented in a manner that allows a subject to voluntarily agree to participate.

- It is generally recommended that consent forms be written to a 6th grade reading level.

- The written document must include all elements established in the regulations as well as any institutional elements.

- **Templates on website

Informed Consent - Children

- There are additional regulations that provide additional protections for children (in Texas, those <18). 45 CFR 46, Subpart D

- Most research in children requires both parental permission AND child assent

- Some kinds of research in children cannot be exempt, as it would be for adults (ex: surveys)

- Contact the CPHS office

Informed Consent

- Appendix A – Waiver of Documentation of Informed Consent
  - The only record linking the subject and the research would be the consent form document and the principal risk would be potential harm resulting from a breach of confidentiality.
  - The research presents no more than minimal risk of harm to subjects and involves no procedures for with written consent is required.
  - Still requires cover letter! **(Very common for survey/online research)**

- Appendix B -Waiver of Informed Consent
  - The research involves no more than minimal risk to the subjects.
  - The waiver will not adversely affect the rights and welfare of the subjects.
  - The research could not practicably be carried out without the waiver. **(Common for research on archival data)**
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Filling out the Application

- Measurement Instruments
  - List all instruments and how they will contribute
  - Detail the setting for their administration
  - Attach a schedule if complicated

- Time Involved
  - Reasonable estimate

- Include Final Versions of All Instruments

- Include actual links to surveys
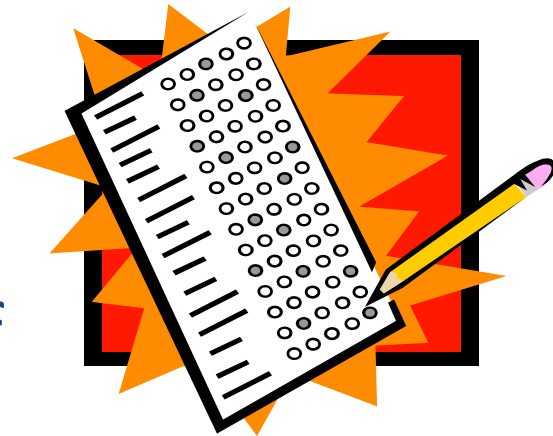
Filling out the Application

- Risks
  - Are the risks adequately thought through and described to potential subjects? Note: for computer science-based research, usually the #1 risk is loss of confidentiality.

- Benefits
  - What are the possible benefits of participation? (Monetary payment is NOT a benefit)

- Inducements
  - Is the amount of compensation or remuneration reasonable? If children or adolescents are involved, who receives the compensation?

Identifying Information – minimum necessary

- Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.?

    - Could any of the participants be identified or contacted based on the data collected?

- If you have consent forms with signatures, contact phone numbers, email addresses, video/audiotape - you will have direct identifiers

- Include justification regarding why identifiers are necessary

- Code if possible

Retaining Study Code Link

- IF coding - will you retain a link between study code numbers and direct identifiers after the data collection is complete?
  - If study code numbers are used and a link between the study codes and direct identifiers will be retained after data collection is complete then "Yes" should be selected
  - Best practice is to strip the data of identifiers as soon as reasonably possible

- Will anyone outside the research team have access to the links or identifiers?
  - Will anyone besides yourself, faculty sponsor (if applicable), or listed key personnel have access to links or identifiers?

Confidentiality vs Anonymity

When filling out the application and the informed consent document, the PI must be clear whether the data is confidential or anonymous. <u>These do not mean the same thing.</u>

- Anonymous means no identifiers are tied to any research subject and the identity of the subject can never be traced back.

- Confidential means you will protect identifiers tied to research subjects.

Data Retention - Students

- Federal regulations require that research data be maintained for a minimum of 3 years after completion of the project (i.e completion of data analysis).

- Describe how you will protect data in all formats. Name an individual/office at UH where data will be maintained

- Data may NOT be maintained solely on private computers/in private homes, or on jump drives

- Full University of Houston data retention policy may be found on CPHS website

Attachments

- Advertisements
- Recruitment scripts
- Letters of Permission
- Informed Consent/Cover Letter/Parental Permission/Assent
- Interview questions
- Survey/Tools
- For computer/app research, screenshots are helpful

Archival Data – Tips and Tricks

- Question 11: Study design
  - Must indicate where the data is coming from – public (meaning anyone can access) or being provided by someone (need letter of cooperation) If you have permissible access to this information due to your employment, this should also be explained.
  - Must indicate exactly what kind of data you will have access to and if any identifiable information is present

- Appendix B – waiver of consent
  1) Greater than minimal risk? Select "no"
  2) Practical without waiver? Select "no" and state "This project consists of data analysis only"
  3) Affect rights/welfare? Select "no" and state "This project consists of data analysis only"
  4) If applicable, will pertinent info be provided to subjects? Select "yes" and state "N/A – This project consists of data analysis only"

Surveys – Tips and Tricks

- ## Question 11: Study design
  - Must indicate if survey will be online or pen and paper.

- ## Question 12: Tasks
  - Provide direct link to survey. If waiving documented consent, the first page should be a cover letter to which subjects must click "I agree" (or similar) before proceeding to survey. This will be checked.

- ## Question 13: Recruitment
  - Be very clear about how you will obtain permission and access to contact subjects and how they will be alerted to the survey opportunity

- ## Appendix A – waiver of documented consent
  - Must be completed and ONE reason chosen (typically no more than minimal risk. Does not require consent outside research context)

Computer Science – unique study design issues

- Online research (chat rooms, social media, etc.)
- mTurk – Amazon
- Unique data types (location (GPS), voice, sensor, access to texts, photos)
- Use of data plan
- Screening of vulnerable populations
- Global recruitment potential
- Subjects upgrade or lend phones
- Most users do not read software licensing agreements
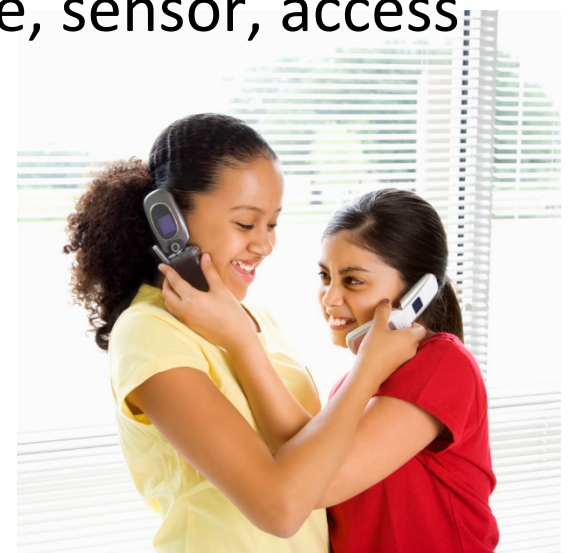
Signatures and Routing

- Student (PI)

- Faculty Supervisor

- Chair OR Dean

Please build time into the submission process to account for required signatures
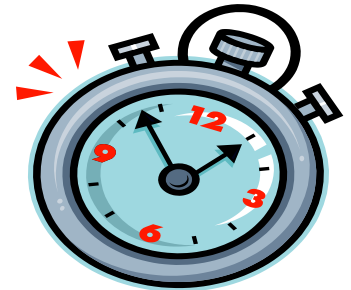
Turnaround times

- Exempt Reviews
  - Reviews are assigned **weekly** (every WEDNESDAY).

- Expedited Reviews
  - Expedited subcommittee meets **twice a month**; determination

- Full Board Reviews
  - Full board meets **once per month**

Feedback is turned around within 7-10 business days

**Secret to quick turnaround – submit a detailed and complete protocol!

CPHS determinations and what they mean to you

- Approved
  - continuing review required
-
- Approved with Stipulations

- Deferred

- Disapproved

Continuing Review

- CPHS must conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year. *Exempt reviews (most surveys and archival data) are approved for 5 years.

- CPHS has the authority to suspend or terminate approved research that is not being conducted in accordance with the committee's requirements, or that has been associated with unexpected serious harm to subjects.

Training Requirements - CITI

- To begin the online course, go to the following website: www.citiprogram.org - select "Register for the Course." After selecting University of Houston as your institution, you will be directed to select a Username and Password.

- There are four options for human subject research training based your affiliation and the focus of your research:

- Group 1: Human Subject Research-Biomedical and Physical Science Research Investigators and Graduate Students

- Group 2: Human Subject Research-Social and Behavioral Research Investigators and Graduate Students

- Group 3: Human Subject Research-UH IRB Members and Staff

- Group 4: Human Subject Research-Undergraduate Students

One Final Tip...

Call or email the CPHS office!

- CPHS@central.uh.edu

- We are happy to work with you and/or your faculty advisor to answer any questions you have specific to your research

- If time allows we can often pre-review protocols prior to their submission to save you as much time as possible on the back end.

CPHS Contacts

- **CPHS Main Line and email address:**

  (713) 743-9204

  CPHS@central.uh.edu

- **CPHS Coordinators:**

  - **Samoya Copeland, CPHS 1 Coordinator**
  - Alicia Vargas, CPHS Program Coordinator

- **Technical Difficulties with RAMP?**

  DOR Research Information Center (RIC)

  access via RAMP (main page: "contact system administrator")

- Jennifer Edge, ORPCC Assistant Director

  jcedge@central.uh.edu

- Kirstin Rochford, ORPCC Director

  kmrochfo@central.uh.edu