Protection of Human Subjects

ICS 491

Reminder - For Final Project Checkin #1 on Sep. 26, be prepared to discuss:

- General project idea
- Specific datasets you will use or recruitment strategy
- How your project goes beyond prior work

I will provide feedback in class for other students to learn. (Roughly 2.5-3 minutes for each student's discussion)

Milestone #3: Methods Figure

There are two purposes of a Methods Figure:

1. Effectively communicate the steps you will follow and the data sources you will use to address your research objectives

2. Be visually appealing, informative, and easy to understand, allowing the reader to grasp the essence of your research approach at a glance

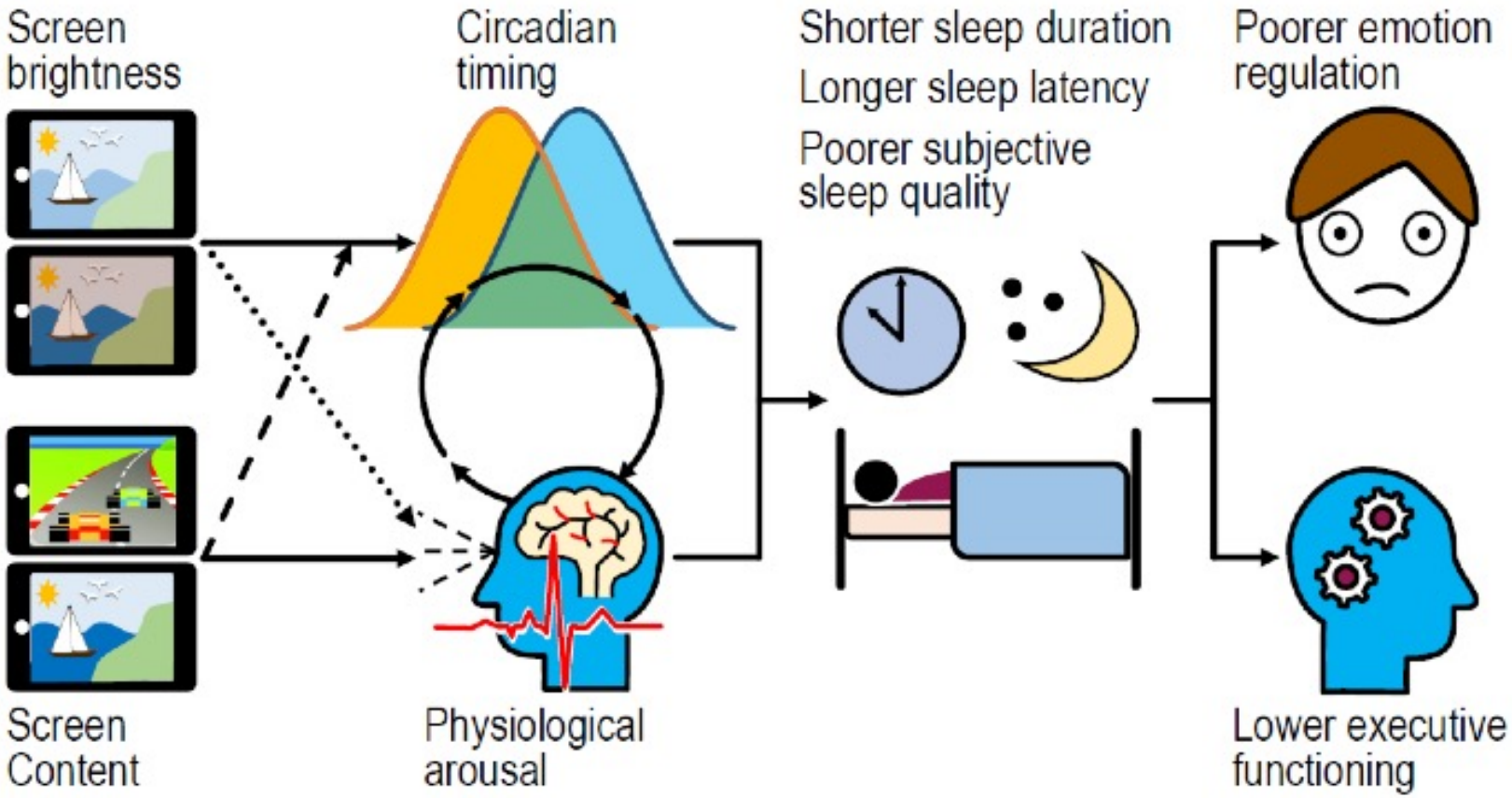
Milestone #3: Methods Figure

How to create a Methods Figure:

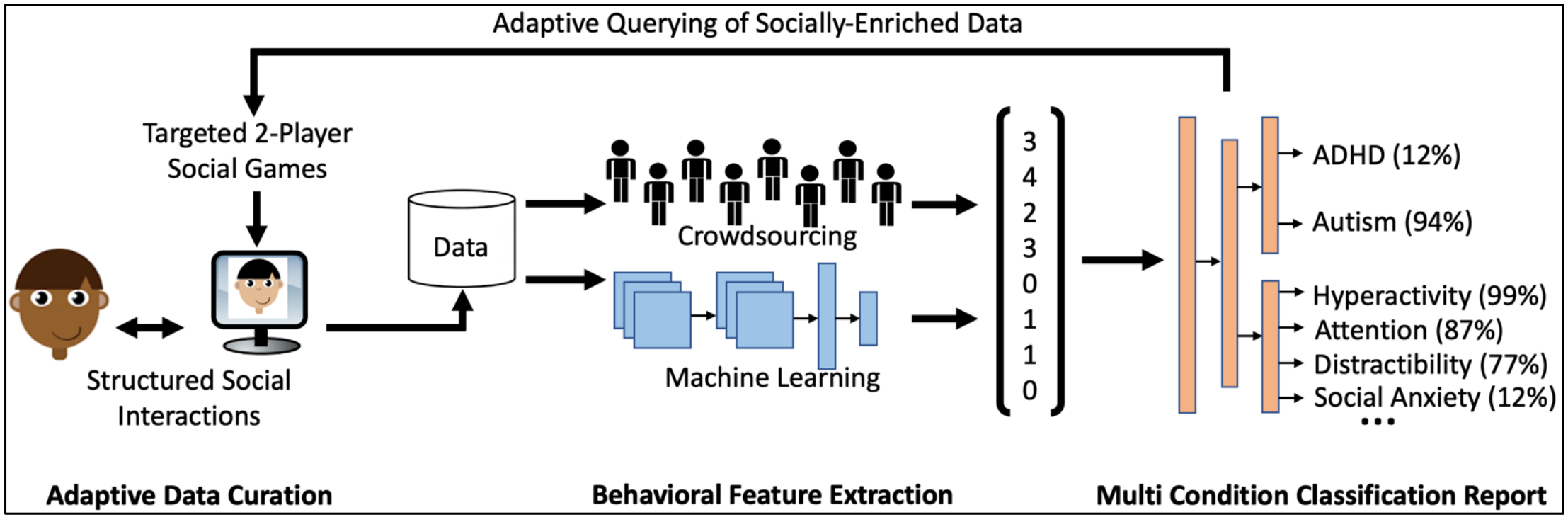
1. Microsoft PowerPoint
2. Google Slides
3. Adobe Photoshop
4. …

Milestone #3: Methods Figure Examples

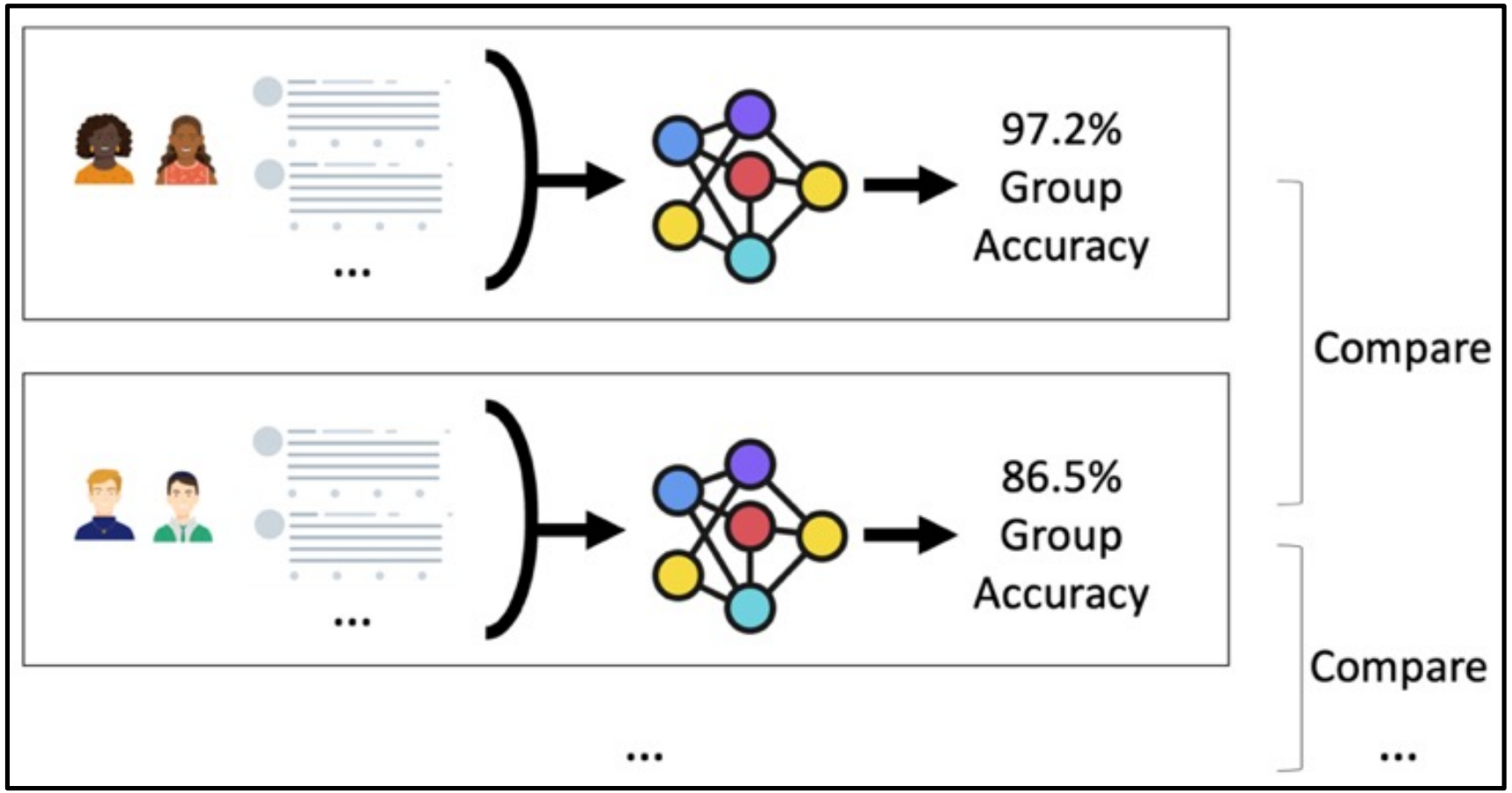
Figure 1. Conceptual model: Pathways through which screen media influences sleep in school age children with a set bedtime



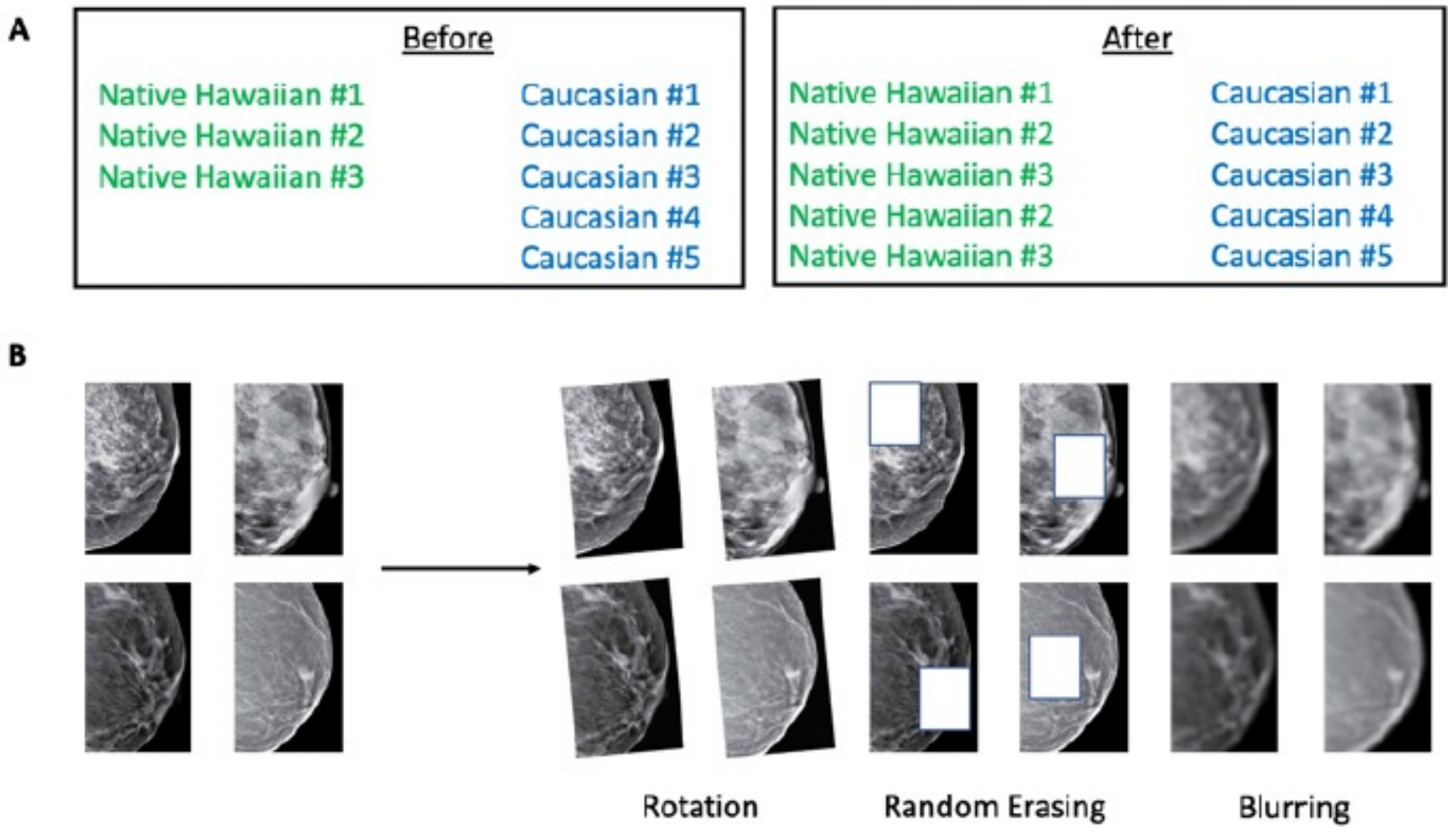
Milestone #3: Methods Figure Examples



Milestone #3: Methods Figure Examples



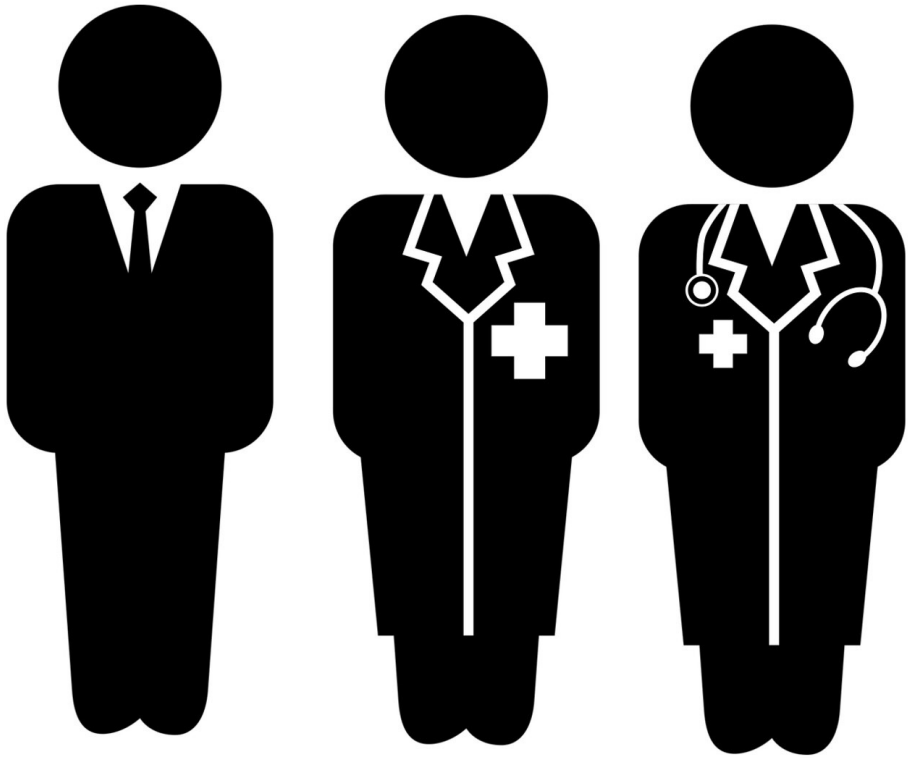
Milestone #3: Methods Figure Examples



Protection of Human Subjects

The IRB

Institutional Review Board (IRB)



IRB Goals

UH Institutional Review Boards (IRBs)

As part of the HRPP, the primary goal of the UH IRBs is to protect the rights and welfare of individuals recruited to participate in research activities conducted under the auspices of the University of Hawai'i.

UH Policies and Procedures

https://research.hawaii.edu/orc/human-studies/resources/

UH Handbook for Protecting Human Subjects

https://research.hawaii.edu/orc/wp-content/uploads/sites/7/2021/12/GUIDE_601_UH_HSP_Investigators_Manual.pdf

Industry IRBs

ADVARRA

Resources ▾ Services ▾ Technology ▾ Community ▾ About ▾ | Contact Login ▾

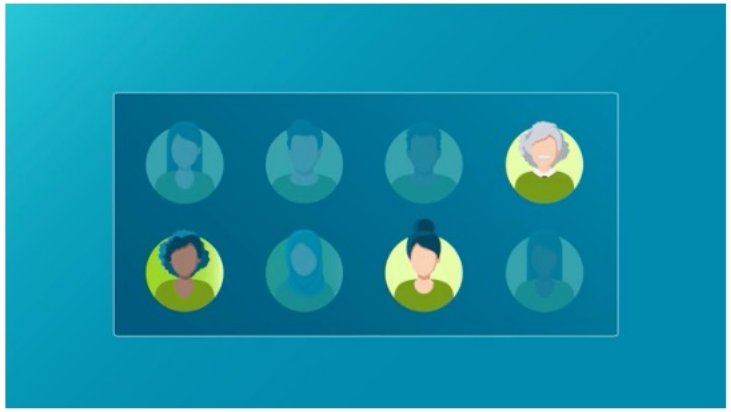
IRB

FAQ Get a Quote

Institutional Review Board (IRB) Services

Solutions to Safeguard Trial Participants

Regardless of your project's scope, therapeutic niche, or number of investigators, Advarra is your partner in the conduct of efficient, responsible research. Objectivity and concern for participant well-being drive all review decisions.



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Industry Protection of Subjects

- Company-dependent
- In general, companies have much more freedom to do whatever they want
- Chain of approvals by higher-ups
- *“If it’s legal, we can do it!”*

Business Ethics Defined

Business ethics are the rules and principles that determine what is morally right and wrong in a business atmosphere. It's the unspoken agreement that a business will conduct itself fairly and within the established rules. Many businesses operate within the proper ethical guidelines, without the need for an outside agency to step in.

However, there are also many instances in which the government has entered into the situation and has forced a company to adhere to more ethical standards. Most of the government regulatory agencies that exist do so, because a company or an entire industry has ranked profits over their workers or the environment.

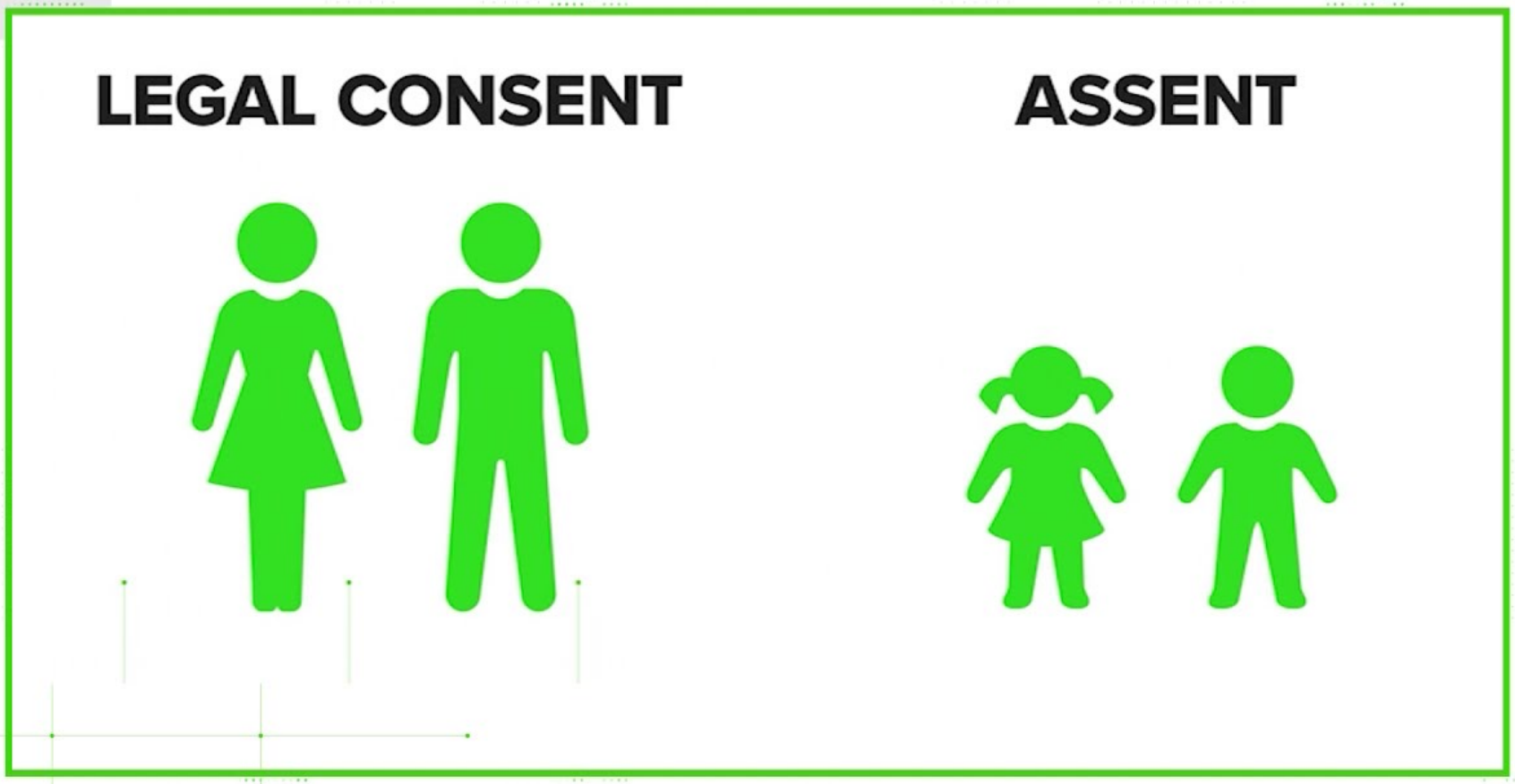
Legal But Not Ethical

There are business practices that are legal but aren't necessarily ethical. Charging $500 for a pill that cost 50 cents is legal, but ethically, it could be questioned, especially if the price point creates a challenge for those who need the medication. Providing miners with required equipment is legally compliant, but if say, the oxygen masks are shoddily made or ventilation equipment is not as up-to-date or maintained as it could be, ethically that could be a problem. Governmental agencies such as the Food and Drug Administration and The Occupational Safety and Health Administration keep businesses within legal and ethical standards.

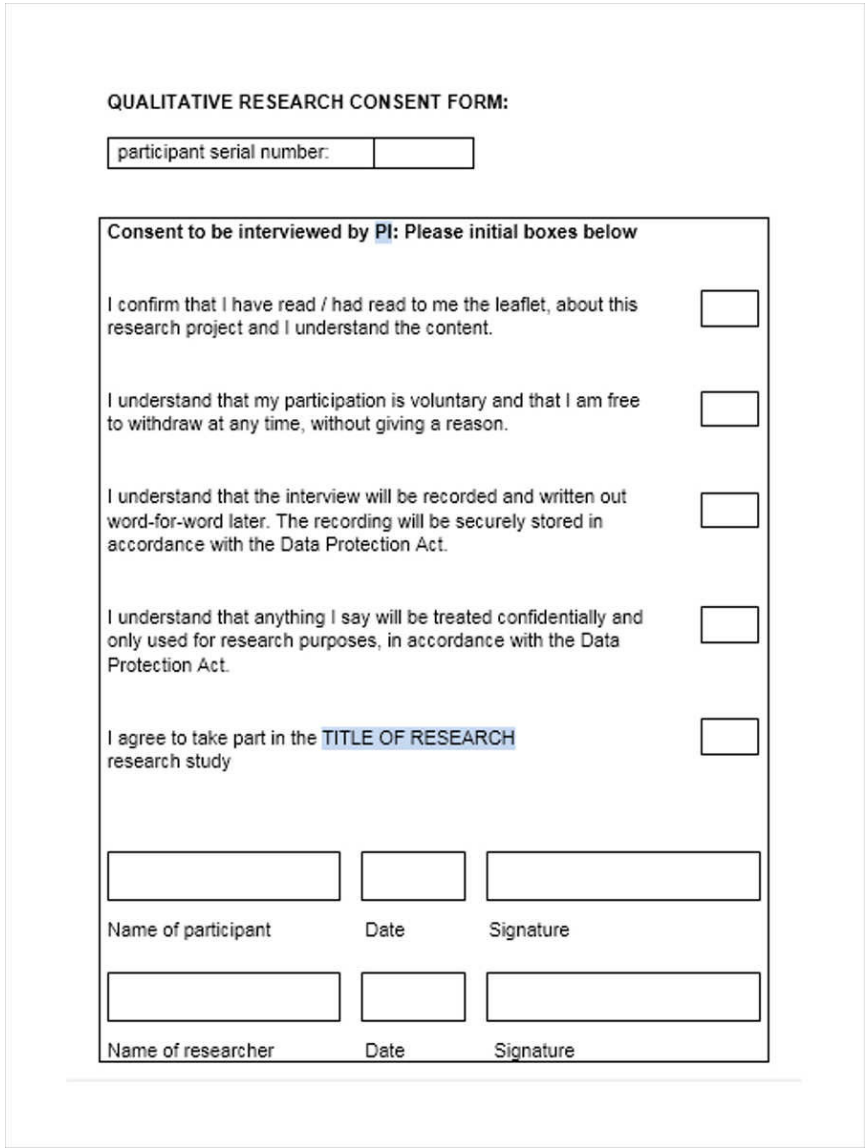
Industry Protection of Subjects

Consent and Assent

Consent vs Assent



Academic Consent Process



QUALITATIVE RESEARCH CONSENT FORM:

participant serial number:	

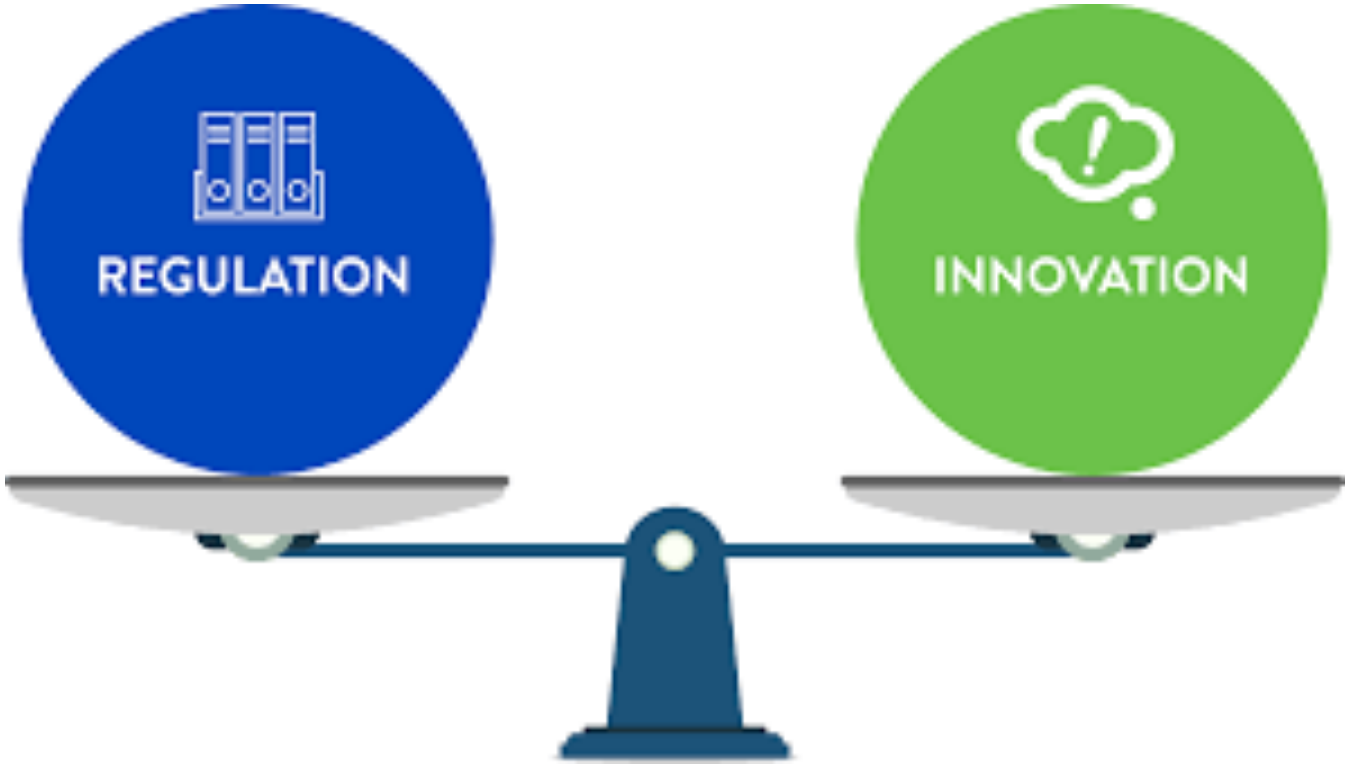
Consent to be interviewed by PI: Please initial boxes below

I confirm that I have read / had read to me the leaflet, about this research project and I understand the content.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason.	
I understand that the interview will be recorded and written out word-for-word later. The recording will be securely stored in accordance with the Data Protection Act.	
I understand that anything I say will be treated confidentially and only used for research purposes, in accordance with the Data Protection Act.	
I agree to take part in the TITLE OF RESEARCH research study	

Name of participant	Date	Signature
Name of researcher	Date	Signature

Industry Consent Process

Discussion question: does less data science regulation (e.g., in industry) promote innovation compared against more data science regulation (e.g., in academia)?



Milestone #4: IRB Questions

- Your assignment will be to answer each question. Each question requires no more than a single sentence, though you are welcome to provide more than 1 sentence per question if you would like.

- If your project involves an already existing dataset, you should describe the process that you would follow if you were to have collected the data. Alternatively, you can describe your plan to collect follow-up data that would enhance the analyses you are performing this semester.

- ***Do not*** write your protocol about the publicly available dataset. Instead, you should describe either the process of collecting that dataset, or a similar dataset that you would collect for a follow-up study.

Why work on an IRB protocol in this class?

- The IRB protocol forces you to think about the Methods section of your project.
- Parts of the protocol related to analysis can be copy-and-pasted into the Methods section of your final paper.
- Other parts can be copy-and-pasted into the Discussion and Future Work section of your final paper.

Final Paper Progress So Far

Introduction	**Milestone #1 (with modifications and revisions based on comments + discussions)**
Related Work	**Milestone #2 (with modifications and revisions based on comments + discussions)**
Methods	**Milestones #3 and 4 (with modifications and revisions based on comments + discussions)**
Results	
Discussion	

Final Paper Progress So Far

Introduction	**Milestone #1 (with modifications and revisions based on comments + discussions)**
Related Work	**Milestone #2 (with modifications and revisions based on comments + discussions)**
Methods	**Milestones #3 and 4 (with modifications and revisions based on comments + discussions)**
Results	**Milestone #5 (with modifications and revisions based on comments + discussions)**
Discussion	

IRB Questions

Proposed Start Date: **Proposed End Date:**

1. **Summary**

a) **Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.**

2. **Purpose**

a) **Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.**

b) **What do the investigators hope to learn from this project?**

3. **Procedures**

a) **Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.**

i) **Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.**

IRB Questions

b) **Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).**

i) **Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**

c) **For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and nonsubjects will be located during the activities.**

d) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section**

e) **Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the tapes/photographs (e.g., shown at scientific meetings, erased, etc.).**

f) **Will the proposed research involve the use of existing data/specimens? If so, check all that apply:**

- ☐ i. **The research involves data from publicly available sources**
- ☐ ii. **That data will be recorded by the investigator in such a manner that subjects cannot be identified.**
- ☐ iii. **Any link to identifying information has been destroyed**
- ☐ iv. **N/A**

IRB Questions

4 a. **Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.**

b. **Describe the statistical methods of the research and plans for analysis of the data (i.e. planned statistics, justification of sample size, etc.).**

c. **Alternative Procedures. Describe any alternatives to participating in the research. (e.g., standard of care treatment, etc.). Any standard treatment that is being withheld must be disclosed. This information must be included in the consent form.**

d. **Will subjects be followed after their active participation is complete?** Yes No

If yes, explain why and describe how:

e. **Will subjects have access to the study treatment/procedure after completing the study?** Yes No

If yes, explain why and describe how:

IRB Questions

5. Subject Population

a) How many subjects do you intend to enroll and/or how many subject records do you intend to access?

i. At this site

# of subjects

# of records

ii. At all sites ☐ **N/A**

# of subjects

# of records

b) Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)

i. Identify inclusion criteria.

ii. Identify exclusion criteria.

c) What is the rationale for studying the requested group(s) of participants?

d) If your participants include pregnant women, human fetuses, neonates, children, adults with diminished capacity, and/or prisoners, describe the protocol-specific safeguards used to protect the rights and welfare of this study population:

IRB Questions

e) **Provide a clear compelling rational for excluding women, minorities, or minors, if they are intentionally excluded from the research.** ☐ **N/A**

f) **State if any of the subjects are students, employees, or laboratory personnel. Please explain how subjects will be protected from coercion and undue influence** ☐ **N/A**

g) **Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training). Also, explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).**

IRB Questions

6. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how.**

IRB Questions

c) Planned Recruitment Materials/Methods:

- ☐ N/A
- ☐ Phone Scripts
- ☐ Television ads
- ☐ Letters to prospective subjects
- ☐ Oral Scripts
- ☐ Internet ads/postings
- ☐ Face to face interactions
- ☐ Other (please specify):
- ☐ Flyers/posters
- ☐ Letters to providers/schools/organizations
- ☐ Newspaper ads
- ☐ Radio ads
- ☐ PowerPoint presentations
- ☐ Email
- ☐ UH Subject Pool

*(All advertising must be submitted for review in its final printed/recorded form)

Note: Attach copies of ALL recruitment materials in the Attachment Section

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? Yes No

Total amount (in dollars or equivalent)

b) Form of Compensation:

- ☐ Cash
- ☐ Check
- ☐ Gift card/certificate
- ☐ Other (please specify):
- ☐ Voucher
- ☐ Course/extra credit
- ☐ Reimbursement only

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

d) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.

IRB Questions

8. Risks

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) PI's evaluation of the overall level of Risk. (Please check one: minimal or > minimal.)

- ☐ Minimal (everyday living)
- ☐ > Minimal (greater than everyday living)

b) Describe all known risks or discomforts associated with study procedures whether physical, psychological or social (e.g., pain, stress, invasion of privacy, breach of confidentiality) noting probability and magnitude of potential harm. Specify the risk(s) associated with each research procedure or test.

c) Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).

d) How will subjects be assessed for adverse events?

e) Is there a plan to monitor study data for subject safety? Yes No

If yes, discuss who will monitor the study data and describe the monitoring plan:

IRB Questions

9. Benefits

a) Discuss any potential benefits that would justify involvement of subjects in this study. Compensation is not considered a benefit.

i. Direct benefits to subjects (if applicable)

ii. Indirect benefits to society

b) Explain how the potential benefits justify the potential risks involved in participation in this research.

IRB Questions

10

a) **If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable.**

b) **Explain how you will protect subjects' privacy.**
Note: Privacy refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interest's people want to control:
- **The time and place where they give information.**
- **The nature of the information they give.**
- **The nature of the experiences that are given to them.**
- **Who receives and can use the information.**

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center that is clearly identified as such by signs on the front of the building. Please keep this definition in mind as you respond to this item.

c) **Describe how you will maintain the confidentiality of subjects' information.**
Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.

d) **Who will have access to study records or specimens? (Please identify specific team members by name.)**

IRB Questions

e) **If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?**
NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the IRB application submission. It includes data or specimens collected for research and non-research activities.

f) **How will subjects be asked to provide their permission for release of identifiable data collected as a part of this proposed research (e.g., pictures, recordings, responses to research questions), now or in future? Explain and include appropriate statements in consent materials.**

g) **If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?**

h) **If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.**

i) **Explain why, where, in what format, and for how long data/specimens will be retained.**

IRB Questions

11. Consent Information

11 a & b only apply to applications where no consent document is provided to research subjects.

a) How will subjects be informed of procedures, intent of the study, and potential risks to them?

b) How will subjects be informed they may withdraw at any time without penalty?

See sample consent forms at www.hawaii.edu/researchcompliance/templates

c) Click Add to answer consent process questions and provide the consent forms.

Note: Attach, in the Attachments Section, written and/or verbal instructions the subject will receive.

Class Exercise

- Spend 5-10 minutes thinking through the (1) recruitment, (2) data collection, (3) data labeling, and (4) study design procedures, and (5) protection of human subjects for your project

- We will discuss people's strategies together as a class