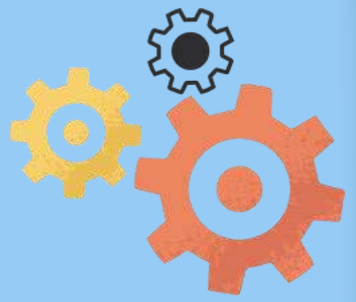
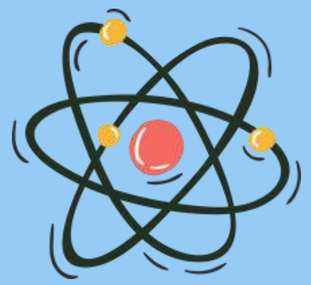
Hello! Young scientist!



Welcome to Bioethics training for Research

By WAYS LAB



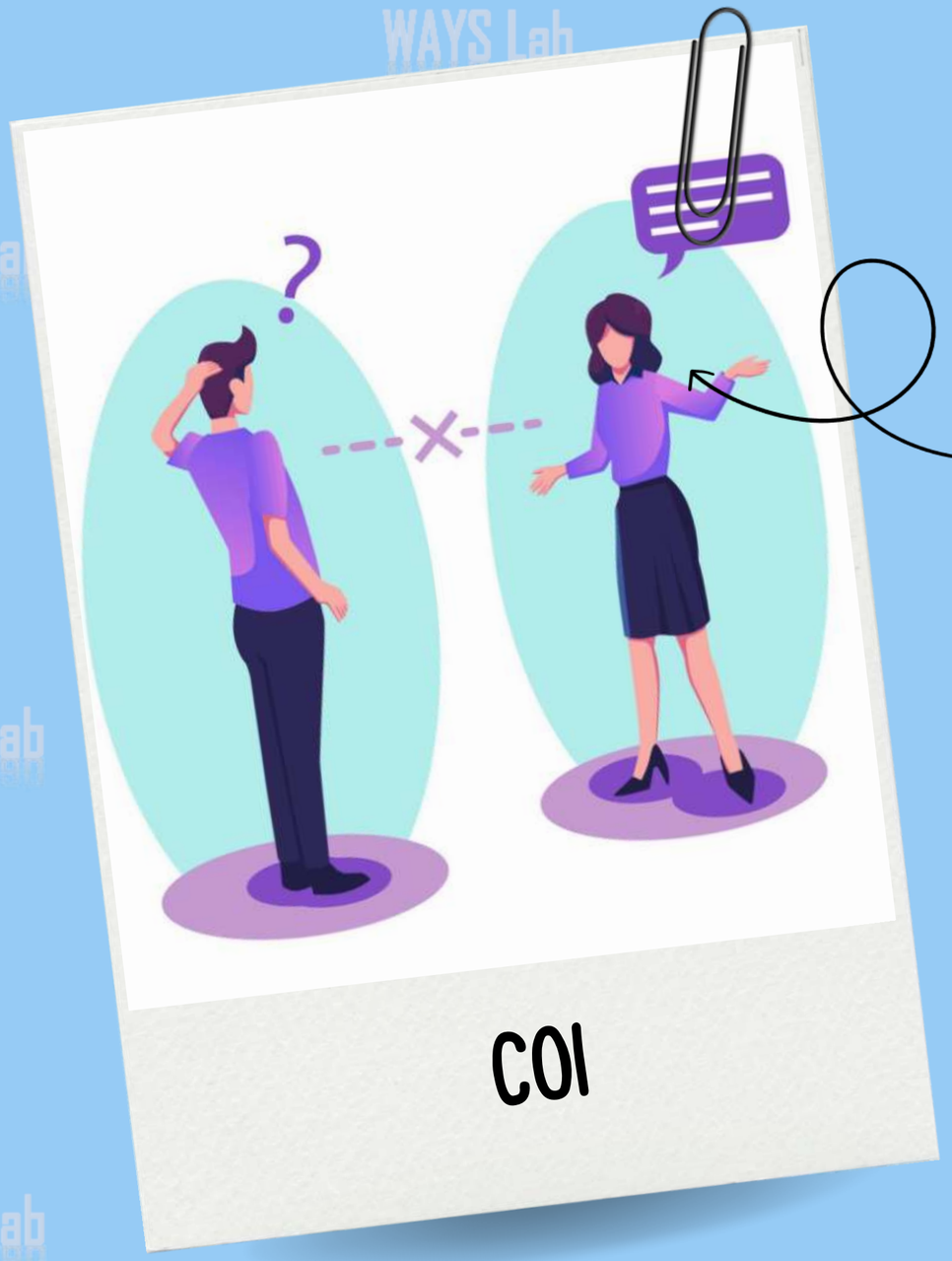
Protection of human subjects

Why?
From who?
How?

Contents

Conflict of Interest

The term conflict of interest (COI)
refers to situations
in which financial/non-financial,
individual/industrial considerations may
affect a researcher's objectivity in
meeting duties or responsibilities.



Individual

The researcher has a personal, financial or other interest- which may affect the design, conduct and reporting of research

Institutional

The institution or official acting with authority has a financial or other interest- which may affect the objectivity of research

Examples

Individual

- Hiring or supervising closely related friends/ family members
- Board member for outside commercial company or organization
- Accepting gifts, discounts, favors or services from a participant.

Institutional

- Research involving a competitor or supplier of the institution
- Supporting projects pertaining to a particular department
- Bypassing inspections/ responsibilities to contend for rankings

Financial

A relationship that has the potential to result in financial gain for the individual/ institution.

Tangible: can be seen & measured easily

Non-Financial

Personal relationships or research in pursuit of tenure or need for producing data in support of ongoing hypothesis

School COI

Let us listen to this conversation between a schoolteacher and a student

Teacher - Ms Little

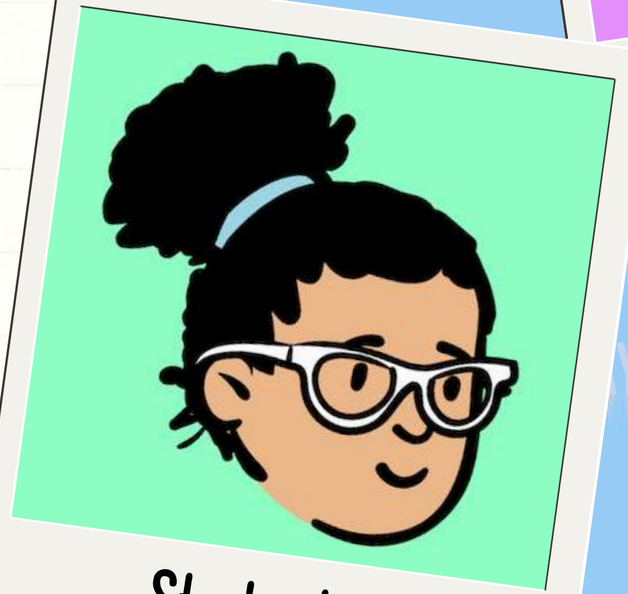
Student - Connie

https://drive.google.com/file/d/1Z2QqZitFZe-54EdUX5OtgoLeV6iy_ekN/view?usp=sharing

Research COI

Let us listen to this conversation between a school guidance counselor and a student researcher !

Counselor - Ms Proviso



Student - Ree

https://drive.google.com/file/d/1AYd7JOrEd6OjRyX2WjNOsBR5YicurXDa/view?usp=sharing

The potential bias due to COIs may affect the following:

choice of research design & statistical methods

Data collection, analysis and interpretation and results

Vendor selection in the purchase of equipments

Decisions about the choice of personnel to conduct the study

Recruitment and consenting of research subjects

Decisions about enrollment and inclusion/exclusion criteria

Solutions

1 Disclosure

2 Review

3 Management

Disclosure

1 PHS regulation

Investigator must disclose significant financial interests (SFI) at the time of proposal submission.

2 NSF Policy

Applicants must disclose significant financial interests (SFI), eliminated and managed prior to expenditure of funds.

3 FDA regulation

Applicants submitting marketing applications (& conducted clinical study) must disclose the financial interests.

Management

1 **Management plans**
as decided by the institutions or standard COI management

2 **Informed consent**
encouraging voluntary and objective decisions

3 **Controls:**
Blinding, Divestiture, Third-party data analysis

What is Research

A human subject is a living individual about whom an investigator (you) conducting research:

1. obtains information/biospecimens through interaction/intervention and uses/studies/analyzes (or)
2. obtains/uses/studies/analyzes or generates indentifiable private information/biospecimens

Research

https://www.youtube.com/watch?_time_continue=1&v=mVObUQpz468&embeds_referring_euri=https%3A%2F%2Fhubblecontent.osi.office.net%2F&source_ve_path=MzY4NDIsMjM4NTE

Who is a human subject?

Living ?

Deceased?

What doesn't count as research ?

- Scholarly/ journalistic activities (oral history, journalism, biography, literary criticism, legal research, historical scholarship
- public health surveillance activities
- Some activities that involve interactions with humans and data gathering that are designed for quality improvement.

- Authorized intelligence, homeland security, defense/ national security missions
- Collection and Analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law/ court order/ criminal investigative purposes

No !!!

Communication or interpersonal contact with participants.
Interviews/ surveys and participant observation.

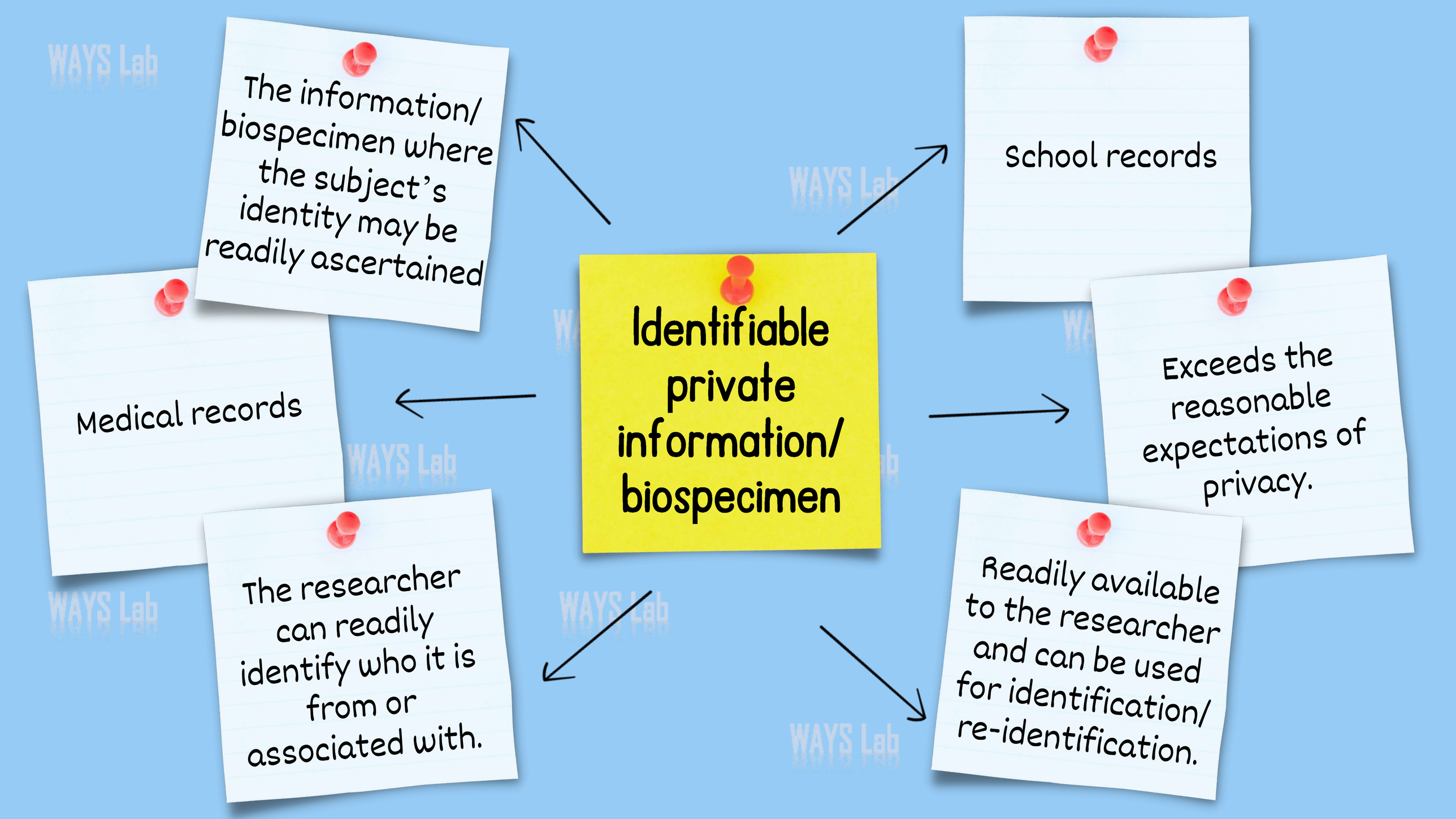
Yes !!!

Procedures through which data are generated or measured.
Modification of the participant or their environment for research.

The common rule (2018) provides robust set of protections for human research subjects and defines key terms!

Identifiability

- Information about someone's behavior in a place where they would reasonably expect that no one is recording them.
- Information someone shares for a specific purpose that they reasonably expect will stay private and not be made public.


Identifiable private information/ biospecimen
The information/ biospecimen where the subject's identity may be readily ascertained
School records
Medical records
Exceeds the reasonable expectations of privacy.
The researcher can readily identify who it is from or associated with.
Readily available to the researcher and can be used for identification/ re-identification.

Generalizability

- To generalize is to derive general conclusions from particulars.
- Research intended to contribute to a body of knowledge (such as, the function of culture, expression of gender, or political views of marginalized community members).
- Results of the research are easily replicable.

What is the difference between Generalizability & Identifiability? Let's discuss some examples!

WAYS Lab

Protection by law

1 FERPA

Family education rights and privacy act (FERPA) protects the privacy of school records.

Can only be released with express written permission

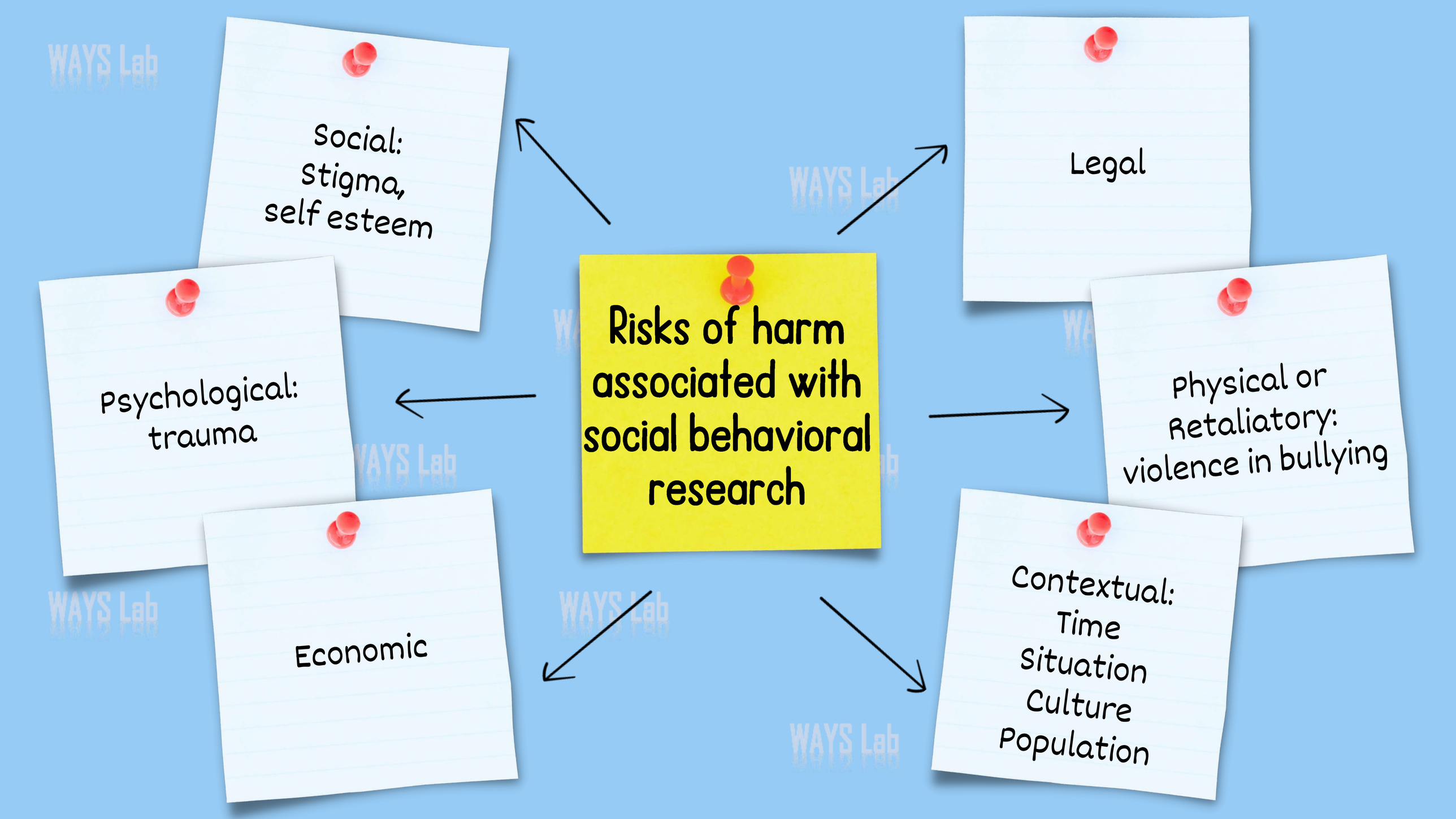
2 HIPAA

Health insurance portability and accountability act (HIPAA) protects private health information.

Risk Assessment

Challenging task to identify and evaluate risks of harm associated with participation in research. Potential harms in social & behavioral science may be more ambiguous and less predictable such as individual reactions to certain events/ questions.

Risks


Risks of harm associated with social behavioral research
Social: Stigma, self esteem
Legal
Psychological: trauma
Physical or Retaliatory: violence in bullying
Economic
Contextual: Time Situation Culture Population

Contextual risks

Youth

vs

Adults

Students

v

Non-students

USA

vs

Another country

Solutions

1 Identify

2 Assess

3 Minimize

Identification

1 Invasion of privacy

- Personal information is accessed or collected without the subject's knowledge or consent. ex: undercover researcher.
- Participation is revealed despite assurances that this would not happen.

2 Breach of confidentiality

- Unauthorized release of data/ unintended disclosure
- Public revelations about sexual orientation
- Information about illegal activities or immigrant status
- No adequate protection of information

3 Study procedures

- Taking part in research can put participants at risk
- Conducting interviews in public
- Focus groups where participants disclose private information.
- Re-traumatization/psycho-logical distress

What are the potential risks in our study ? Long/short term ?

Assessment

Probability of harm

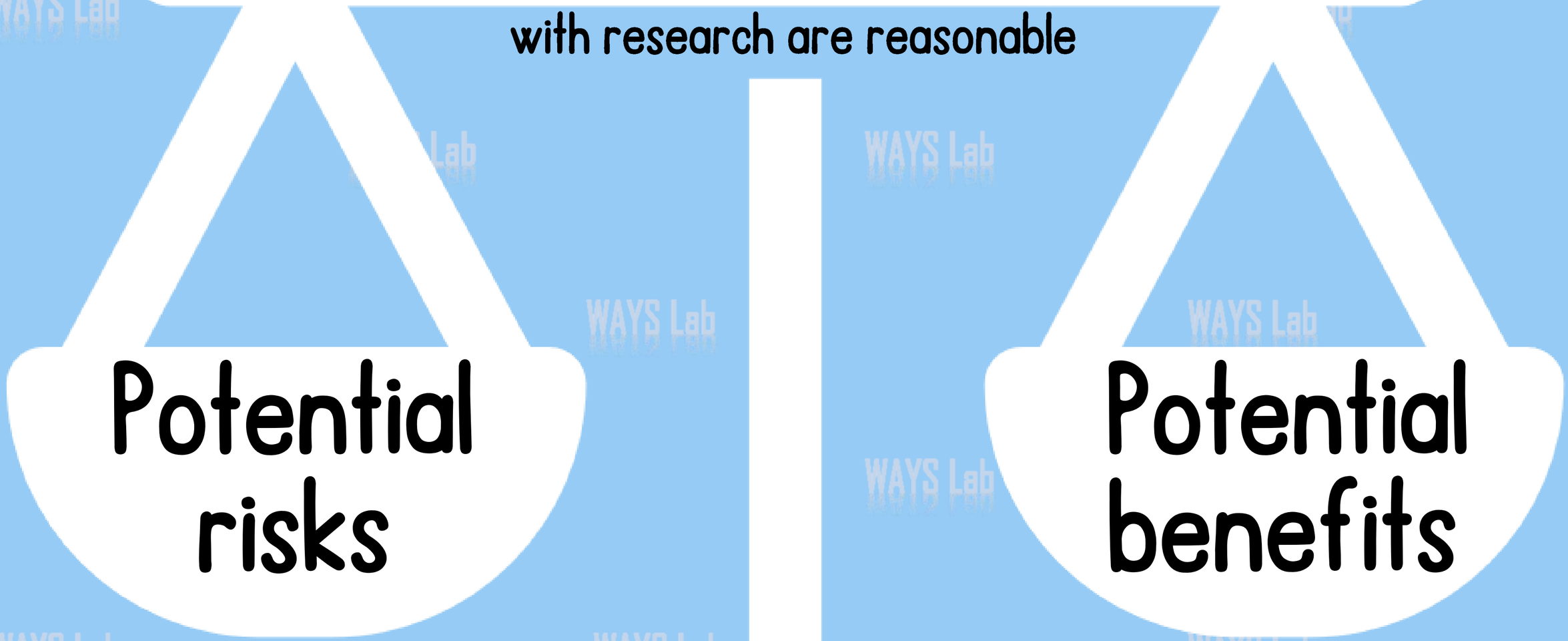
The likelihood that a specific harm might happen. Not all probable harms are equally probable.

Magnitude of harm

The magnitude or severity of harm- should it occur.

What is the probability & magnitude of the risks in our study ?

Ethical principle of beneficence require that risk of harm associated with research are reasonable



What are the potential benefits to participants in our study ?

What are the potential benefits to the community ?

Minimization

1 When the risk is the collection of private data

- Anonymized data
- Safeguarding the identified data from unauthorized users (code-lists)
- Remove direct identifiers
- Passwords, encryption
- Minimize transferring data

2 Certificates of confidentiality

- Issued by NIH
- Prohibits investigators & researchers from compelled disclosure of information
- Permanent & do not expire
- Do not override the requirement to report communicable diseases or suspicion of child abuse

3 When the risk is the consent document

- Applying to IRB for a waiver of the requirement to document consent
- Having verbal consent, cover letter or informational sheet

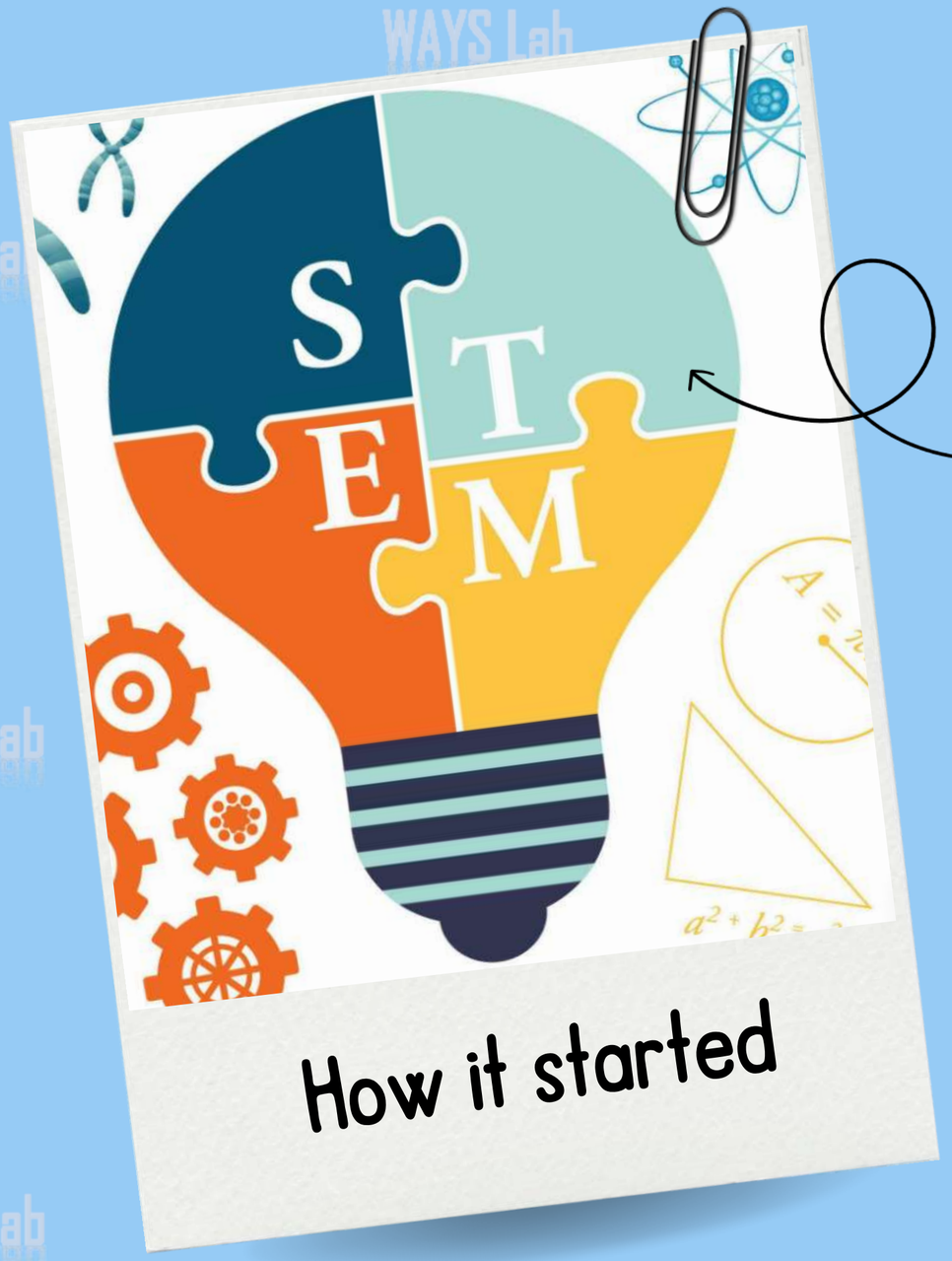
How can we minimize the risks in our study?

History & ethics

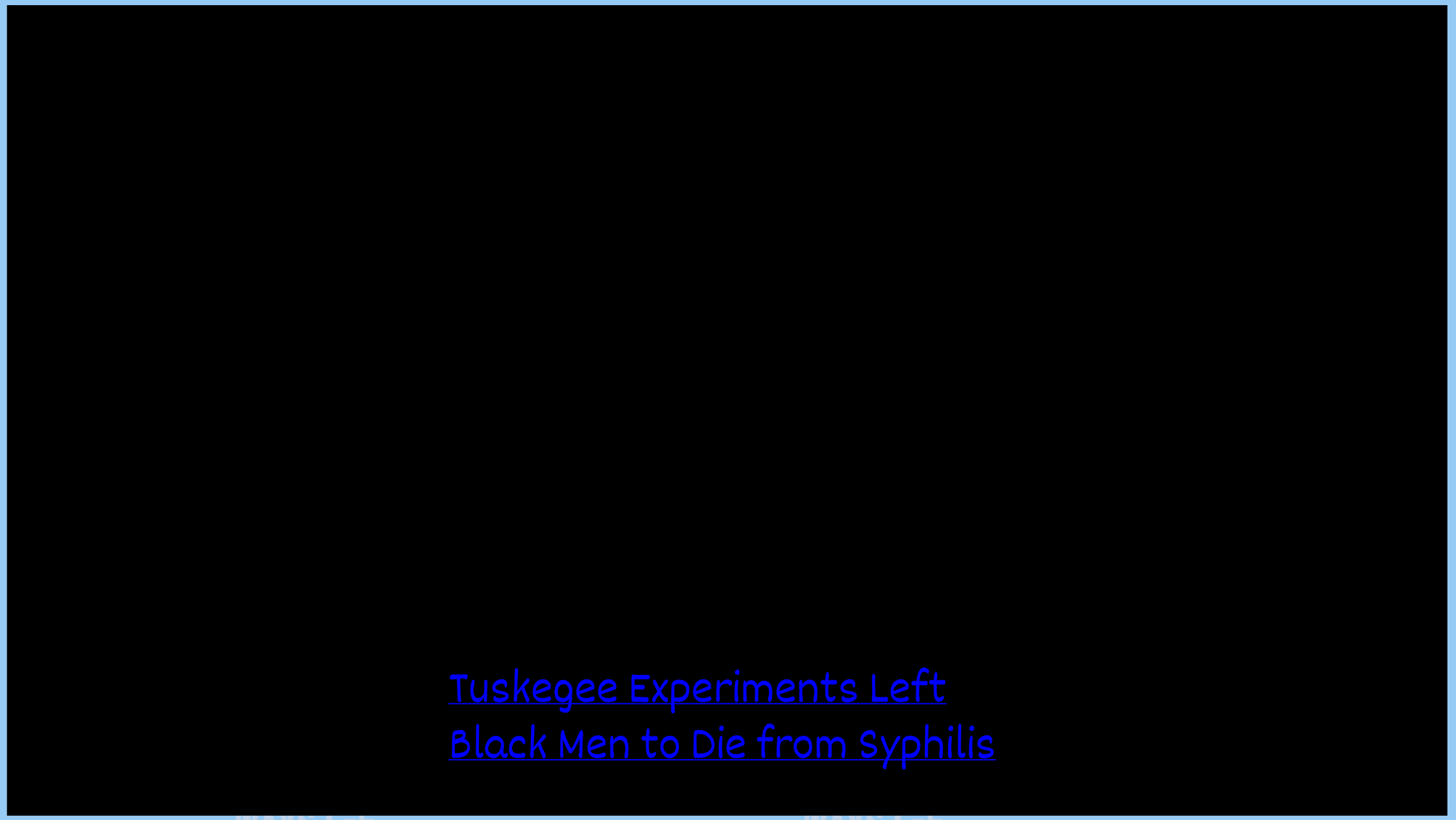
Unethical practices & contemporary abuses in research in the biomedical sciences:

- Experiments conducted by Nazi doctors & scientists on concentration camp prisoners during World War II
- Tuskegee study

led to the creation of codes of research ethics



How it started



Tuskegee Experiments Left
Black Men to Die from Syphilis

Belmont

1 Respect for persons
National commission 1979

- Individuals should be treated as autonomous agents
- Persons with diminished autonomy are entitled to protection

2 Beneficence
National commission 1979

- Making efforts to secure participant's wellbeing
- Acts of kindness or charity that go beyond strict obligation
- Do no harm & maximize possible benefits and minimize possible harms

3 Justice
National commission 1979

- Equitable distribution of benefits and burdens of research
- Injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly

Respect for persons cont.

Autonomy

means that people must be empowered to make decisions concerning their own actions & wellbeing. Individuals must be given the choice to participate or not and they must be provided sufficient information and possess the mental competence to make that choice.

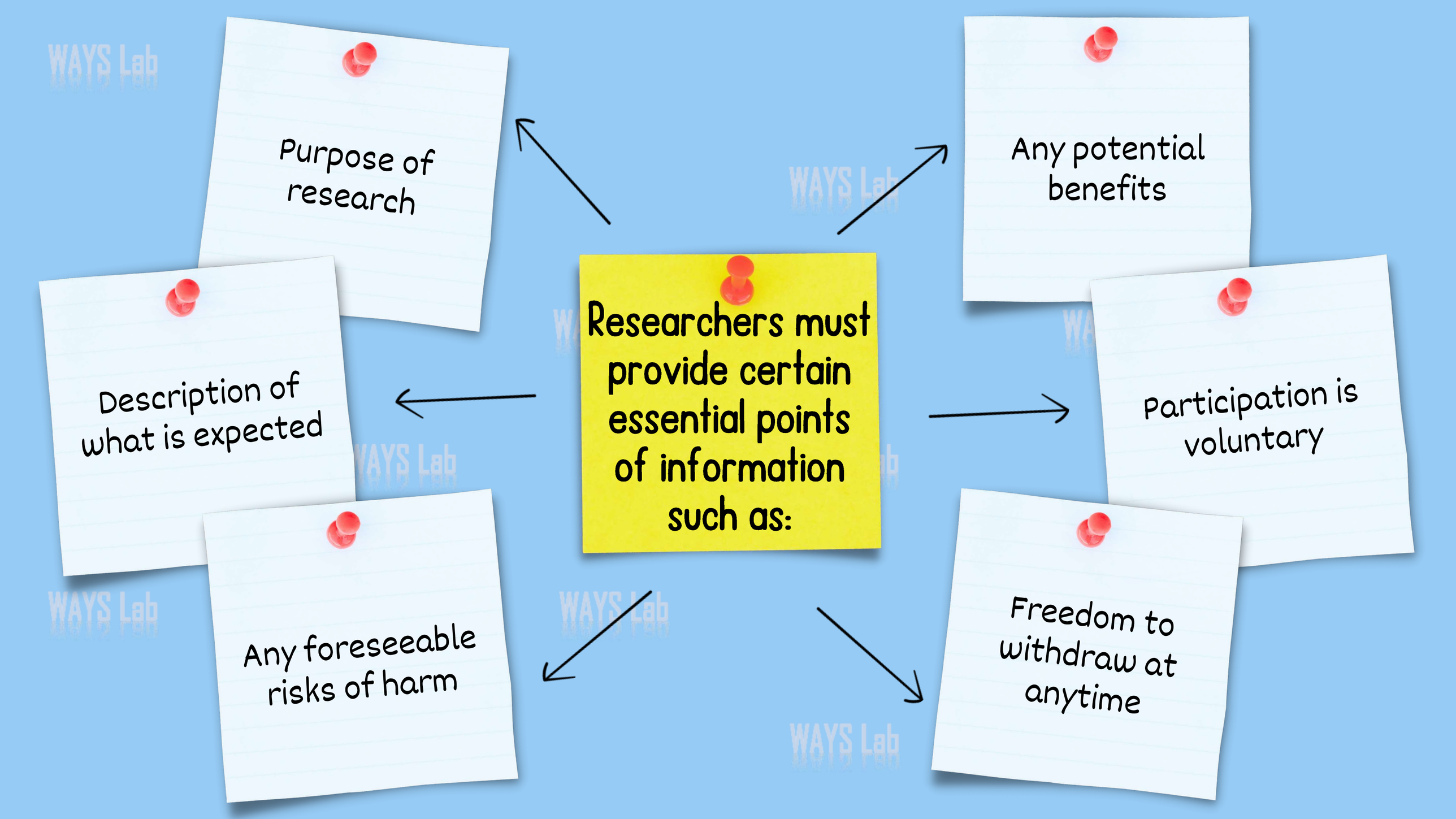
Voluntariness

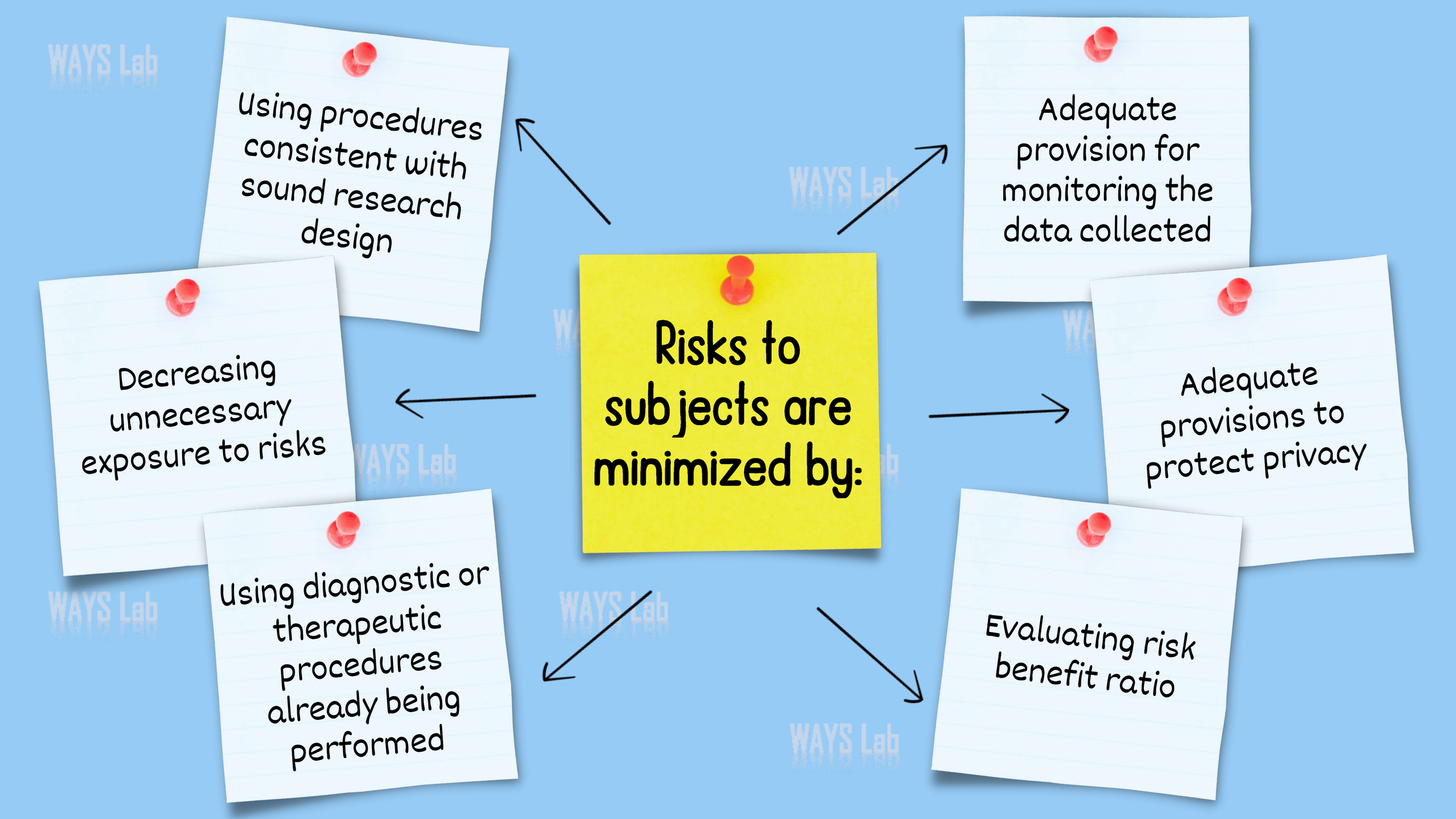
means more than offering people the choice to participate in or withdraw from research. Participants may feel pressured to participate in situations where a relationship with the researcher already exists, where the lines between voluntariness and undue influence may be blurred.

Consent

A prospective research participant's autonomy is honored through the process of informed consent. The office of human research protections (OHRP 2014) offers these guidelines:

1. disclosing information needed to make an informed decision
2. facilitating the understanding of what has been disclosed
3. promoting the voluntariness of the decision to participate


Researchers must provide certain essential points of information such as:
Purpose of research
Any potential benefits
Description of what is expected
participation is voluntary
Any foreseeable risks of harm
Freedom to withdraw at anytime


Risks to subjects are minimized by:
Using procedures consistent with sound research design
Adequate provision for monitoring the data collected
Decreasing unnecessary exposure to risks
Adequate provisions to protect privacy
Using diagnostic or therapeutic procedures already being performed
Evaluating risk benefit ratio

Informed consent

A process that begins with the recruitment and screening of participants which:

- Provides specific information
- Answers questions to ensure understanding - giving time to consider
- Obtains voluntary agreement of participation
- Documents the process

Informed consent cont.

Broad consent

Consent for unspecified future research using identifiable private information/ biospecimen

Key Information

Concise and focused information presented at the beginning, assisting an individual in understanding the reasons why or why not to participate

Informed consent cont.

Legally authorized representative (LAR)

An individual/judicial/ body authorized under applicable law or recognized by institutional policy as acceptable for providing consent

Vulnerable

subjects in research studies vulnerable to the possibility of coercion or undue influence

Informed consent

Two parts

1 Information

- Provide all the necessary information
- Information about incentives

2 Documentation

- Documentation that the process took place
- Recording the agreement
- Form or Audio Video recording

Informed consent

1 Basic elements

2 Additional

Federal regulations at 45 CFR 46 list specific elements to be provided

Basic elements

Description of any expected benefits- direct or to the community or what you expect to learn

Disclosure of appropriate alternative procedures/ treatments

statement describing the extent of confidentiality of records

Description of any foreseeable risks/ discomforts

For research involving more than minimal risk- treatment available in case of injury or compensation provided

statement that the study is research/ experimental; explanation of purpose, participation, procedures and duration

Explanation of whom to contact for queries

statement explaining voluntary participation or withdrawal from the study

Statement that identifiers might be removed from the information/ biospecimen

Additional elements

Statement of commercializing the profit and sharing

Clinically relevant research results would be disclosed to the subjects

If the research would be involving genome sequencing

The termination of participation by the PI due to anticipated risks without the consent

Approximate number of subjects involved in the study

Statement that the treatment may involve unforeseeable risks to the subject

Any additional costs that may result due to participation

Consequences of a decision to withdraw participation

Significant new findings would/not be provided

Language

1 Exculpatory

You waive any right to sue for injuries that may result because of your participation

Subjects may not be asked to waive any of their legal rights

2 Non-Exculpatory

Your participation is voluntary. If you choose not to participate- now or later- your decision won't affect your relationship with the researcher

Waiver of

1 Consent

- Research involving no more than minimal risk
- Research is impracticable with consent
- Accessing previous records

Waiver of consent may still require documentation and vice versa.

2 Documentation

- Risks associated with breach of confidentiality
- Telephone surveys (Minimal risk and no procedures)
- Cultural obligations- signing forms

Confidentiality

Although privacy and confidentiality are closely related, they are not identical.

It is not always the case that identifiable information provided by research subjects must be protected from disclosure. Some subjects want to be identified and quoted.

Privacy & Confidentiality

Cont.

Privacy

Having the control over what you share about yourself, when you share it, and with whom. It can be personal thoughts, how you act, or anything about your body.

Confidentiality

Taking care of information someone shared with you in a relationship of trust and not sharing it with anyone else.

Privacy in research methods

Observational studies

- Researchers participate in the activities being observed with the knowledge both as participants and as researchers.
- It is a violation, if observed and private identifiable information is gathered about the participant without their knowledge and consent

Focus groups

- In effect, focus group participants relinquish control of the extent, timing, and circumstances of sharing information because other group members may repeat what they say outside the group.

Snowball Sampling

- A recruitment technique where research participants assist researchers in identifying potential subjects.
- If the topic of the research is not sensitive or personal, it may be appropriate. If the topic is sensitive or personal, considerable care should be taken .

Sensitive Topics

Sexual Behavior

Use of Psychotropics

Invasions of privacy can occur if participants are asked questions that they find intrusive. If a survey instrument or an interview script contains questions that individuals are likely to find intrusive, they must be informed about the nature of the questions in advance.

Childhood abuse

Personal topics, Culture

The procedures ensuring confidentiality :

Not collecting identifiable (direct or indirect identifiers) data

Linking identifiable information to unique numbers to create coded data.

Storing encrypted data on secured servers

Reporting data in aggregate in presentations/ journals

Creating Misleading identifiers

Consent forms should explain who will have access and future use of data

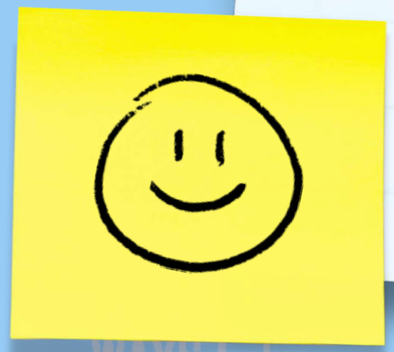
Laws

1. Federal
2. State Reporting
3. International
4. Exempt Research

Certificate of Confidentiality (CoC)

- Certificates of Confidentiality are issued by the (NIH) and (HHS) to protect identifiable research information from compelled disclosure.
- Certificates of Confidentiality protect all copies of information, documents, and biospecimens, that are collected or used by the investigator during the research.
- Do not override the requirement to report child/elder abuse.

Quiz



Conclusion

Thanks!

Any Questions ?