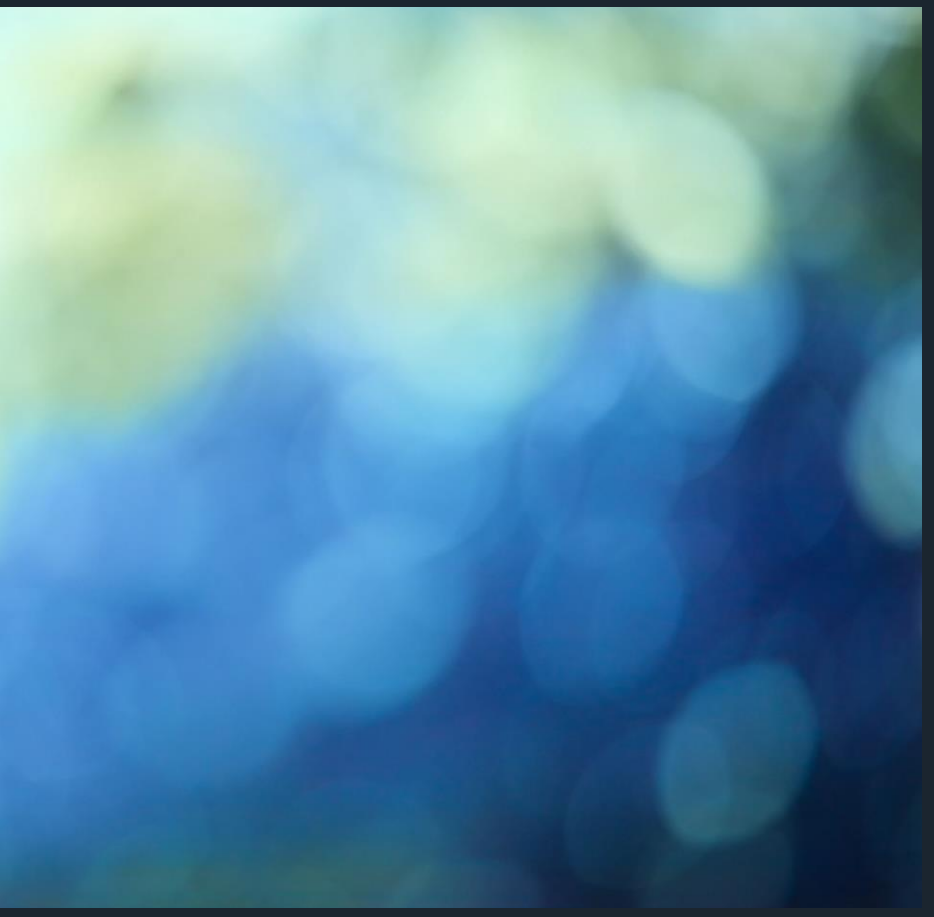

ETHICAL PRINCIPLES & INFORMED CONSENT IN ALS RESEARCH

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Outline

1. Ethical principles

What is research and why do we do it?

Who is involved in research?

The development of research ethics

2. Informed consent

Process vs. form

Aspects of informed consent

Tips for successful informed consent

3. Questions

What is research and why do we do it?

***Research* -** A systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. (Webster 2023)

***Clinical Research* –** Research that involves human subjects.

Examples:
Clinical trials- testing treatment options or new devices (i.e. Healey Platform Trial)
Biorepository studies- collecting biological samples (i.e. Target ALS)
Observational studies- collecting general data from participants with the disease (i.e. ALS Natural History)

Why do we conduct research with the ALS community?

1. To better understand ALS as a disease
2. To identify safe and effective treatments for ALS and it's symptoms
3. To develop new diagnostic tools for early detection

All with the goal of improving clinical outcomes for patients with ALS

Who is involved in research?

Scientific community: Clinicians and researchers

Industry: Pharmaceutical companies and laboratories

Government: NIH, FDA, DHHS

Ethics Board: Institutional Review Board (IRB)

And, of course, **patients** and **caregivers**!

Patients **volunteer** to participate in research.

"Human subjects"
"Research participants"

SANOFI MERCK gsk BAYER NOVARTIS Abbott Pfizer Johnson & Johnson abbvie Roche

eIRB+

NUREMBURG CODE (1948)

Defines ethical behavior in the conduct of research using human subjects.

DECLARATION OF HELSINKI (1964)

Developed by the World Medical Association, these ethical principles provide guidance to physicians and others involved in human subject research. It is the basis for Good Clinical Practice (GCP), standards adopted by medical associations in various countries.

NATIONAL RESEARCH ACT (1974)

Passed by US Congress in response to the US Public Health Service Syphilis Study at Tuskegee, this Act established the existence of IRBs to review and oversee studies involving human subjects.

These principles have been formally adopted by Northwestern University to:

1. Protect research participants
2. Preserve the integrity of the science

HENRIETTA LACKS (2023)

Henrietta Lacks had cervical cancer.

Cells from her cervical biopsy were taken without her consent to undergo research testing without her knowledge.

Her cells lived and are immortal, became **HeLa cells**

Played a role in developing the polio vaccine and the COVID-19 vaccines

Further proved the importance of informed consent and patient understanding of studies

Henrietta Lacks, ITV/Rex USA

ETHICAL PRINCIPLES IN SUMMARY

- Ethical principles have been created by local, national and international groups to ensure protection of human subjects
- IRBs work to ensure the safety of research patients, their rights, their autonomy and their wellbeing
- The rules that govern research are in place to protect research subject and ensure scientific integrity

Informed Consent

The purpose of informed consent is to ensure patients are provided all the information necessary to make informed choices about participating in research.

Informed Consent Process

Informed Consent Form

It begins with the first contact with the patient, continues through the study, and ends with post-study communication (i.e. sharing results).

Informed Consent Process

The informed consent process is a discussion about key information that is most likely to assist the patient in understanding the research. The process involves:

- Research team, patient, family, caregivers, and other healthcare providers
- Conducted in a quiet, private room
- With adequate time to read the consent form
- And ask questions throughout the process about participating in the research
- Review the study setup, benefits, risks, and alternatives to research
- Clearly state that all research is voluntary, you are not signing away rights when signing a consent
- Review the schedule of events, the protocol, and any optional elements

Informed Consent Form

The informed consent form is a document that contains all the key information about participating in research. The form is:

- Written in the patient's preferred language
- Using language that is easily understood by most people
- With signature lines for patient, researcher completing the informed consent process, and sometimes a legally authorized representative

Participants must be given a copy of the signed informed consent form.

All consent forms are reviewed by and approved by an IRB

What is discussed during the informed consent process?

Study background

Participation and responsibilities

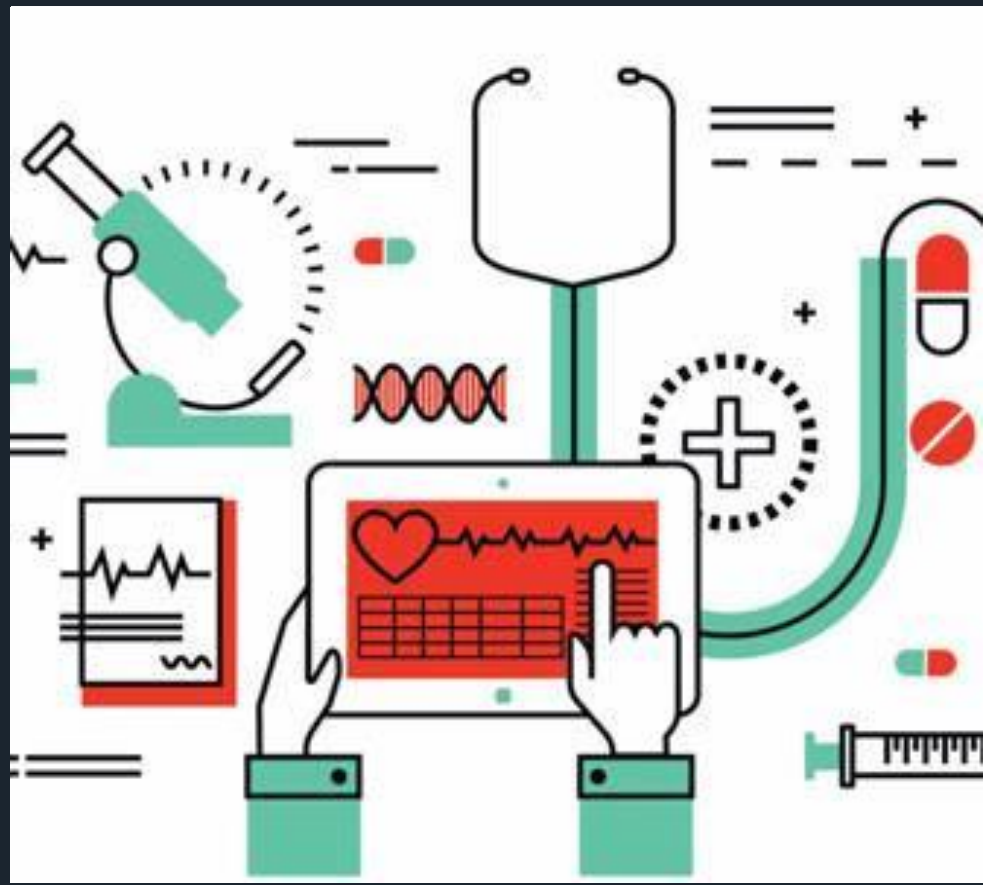
Risks, benefits, alternatives

Data and confidentiality

What is discussed during the informed consent process?

Study background:

- Who is funding the study (i.e. sponsor)
- Who reviews and approves the study (i.e. Institutional Review Board)
- Why you are being asked to participate in the study
- The purpose of the study
- The duration of the study
- Where the study will take place
- Contact information for whom to speak to about study participation and oversight



What is discussed during the informed consent process?

Participation and responsibilities:

- The study design and visit schedule
- A description of the study groups and randomization into those groups (if applicable)
- Defining the placebo and study drug(s) (if applicable)
- A description of the assessments/procedures that will be done during study visits
- The costs of participating in the research
- The responsibilities as a research participant
- Prohibited and allowed medications
- Reporting side effects and new health issues

What is discussed during the informed consent process?

Risks, benefits, alternatives:

- The risks associated with study procedures
- The risks associated with the study intervention (i.e. study drug or device)
- A discussion about reproductive risks for females and males
- A reasonable description of the potential benefits, in-direct and direct, to participating
- How to stop participating and what happens if you choose to do so
- The alternatives to participating
    - Not to participate
    - Other studies
    - FDA-approved medication

What is discussed during the informed consent process?

Data and confidentiality:

- A description of how your research data will be used and by whom
- Where your data will be stored and for how long
- Whether it will be possible to destroy your data if you stop participating
- The steps researchers will take to secure your data
- A list of entities who can view and access your research data
- Specific details about the confidentiality of genetic information

Signing the informed consent form

The informed consent form is not a contract.

Participation in research is voluntary and may be stopped at any time.

Researchers need the informed consent form to document a patient's decision to participate.

Though the signing of the informed consent document is the most visible feature of this process, informed consent begins with recruitment and continues throughout the course of the study.

Tips from a researcher's perspective:

1. Send patient consent form in advance to allow additional time to read and comprehend
2. Re-iterate the duration of the study and study visits (i.e. 2 hours)
3. Walk through what a typical study visit would feel like from participant's perspective
4. Differentiate study results from routine care results
5. Spend additional time explaining different research cohorts (i.e. Regimen A, placebo)
6. Stress the alternatives available…there are always alternatives!
7. Review all restricted medications AND supplements
8. Be realistic about potential benefits; do not establish unrealistic expectations
9. Differentiate between disease progression and research-related injury

Summary

Ethical principles in research

- There are many stakeholders in research
- Milestones in ethical conduct of research: Nuremburg, Helsinki, and National Research Act
- Framework for conducting research that protect human rights

Informed consent

- A process to share information about a study, comprehend participation, and volunteer
- Ongoing process
- Shared responsibility between researchers and participants


QUESTIONS?