CTN WEB SEMINAR SERIES:
A FORUM TO EXCHANGE RESEARCH KNOWLEDGE

Celebrating 20 Years of
Research-Practice Partnerships

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FEATURE TOPIC: INFORMED CONSENT

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October 14, 2020 at 1:00 pm ET
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Tailoring Informed Consent for Substance Use Disorder Research

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Disclaimer

The opinions expressed are those of the presenters and do not necessarily reflect the policy of the U.S. Department of Health and Human Services

Importance of Informed Consent

Why is Informed Consent Important for Research?

Purpose is to help people make *informed* decisions about whether to participate

- **Ethical ideals:**
  - Individuals decide for themselves according to their own values and opinions (autonomy)
    - Voluntariness
    - Informed Consent
  - Those whose autonomy is compromised should be protected
    - Attention to undue influence and coercion
    - Additional protections

Autonomy and Substance Use Disorders

Can one's autonomy be impaired when dealing with a substance use disorder? Consider when deciding about protections:

- Protection through empowering those with full autonomy (i.e., providing necessary information for decision)
- Additional protections when necessary
- Avoiding coercion and undue influence

Consider the context around potential participants' circumstances

The Important Question

How do you make sure prospective participants (or their LAR's) have a fair chance of

getting AND understanding

the information they need to make a decision about whether to be in a study?

Meaningful Informed Consent

New Informed Consent Requirements in the Revised Common Rule

Focus on the information needs of prospective participants, including:

- Information that **a reasonable person** would want to have in order to make an **informed decision about participation**
- Information presented in **sufficient detail** and **organized and presented** in a way that **facilitates understanding of why one might or might not want to participate**

46.116(a)(4) & §46.116(a)(5)(ii)

If you were asked to participate in a research study:

What information would you need to make an informed decision about participation and how should this information be presented?

The Importance of Providing Context

- Decisions affecting one's health are complex
- Substance use treatment may impact more than health
- People are unfamiliar with concepts about research

Give Information in Ways that Make Sense

Examples:

- Why do researchers need to study the intervention? (Why can't it just be given to people?)
- What are researchers looking for? (If they think there may be some good, why don't they just give it?)
- What are the risks? (What are they worried about?)
- Why am I asked to participate? Why does it matter to me?

Avoid Using Vague Terms

- Don’t just say “*we are trying to find out if drug X is effective*”
- Instead, be specific, give details about what you mean, e.g.,

  “*We want to find out if drug X might decrease chances of relapse over time*”

Explain Important Terms to Avoid Confusion

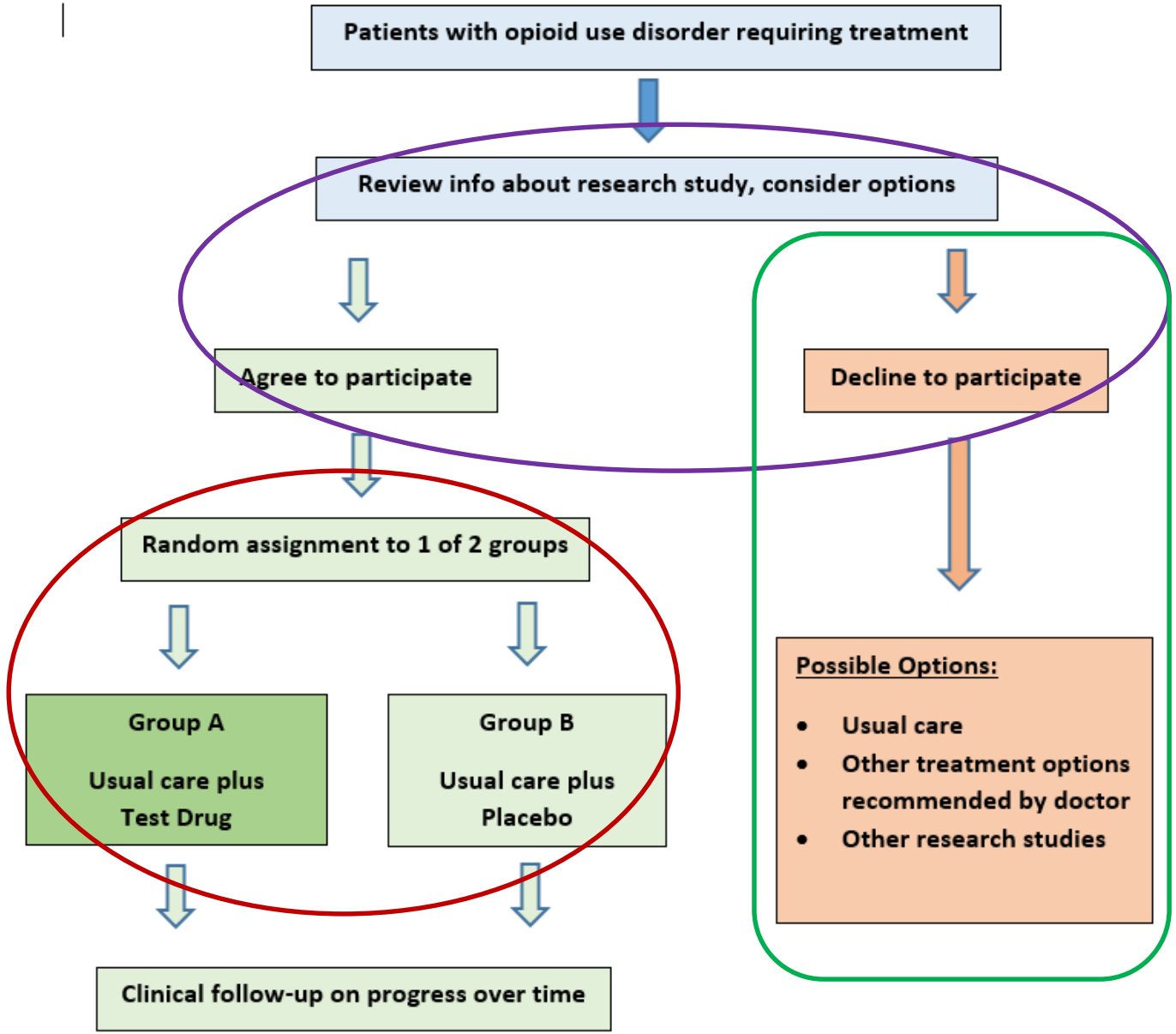
"Randomization means you will be assigned to a group randomly, like the flip of a coin"

Tell people what randomization *means* to them!

- *You cannot choose the group you are in*
- *Assignment is random, not because the group is better for you*
- *You must be okay with being assigned to any of the study groups*
- *If you have a strong preference for a group, you might not want to participate*

Provide Sufficient Information

To make decisions about the options, people need to have information about both options and how they compare



Compare What it Means to be Assigned to One Group Versus Another

If you receive the Test Drug (active) 50% chance	If you receive the Placebo (inactive) 50% chance
You will receive usual care AND the test drug. You will not know it is the active test drug.	You will receive usual care AND the placebo. You will not know it is the inactive placebo.
We do not know whether the test drug will help treat your opioid use disorder. If it is effective, it may reduce your craving for opioid substances, help you manage withdrawal symptoms, and help you stay off of opioids over time.	You will receive no medical benefit from the placebo. You will not benefit from or be harmed by the test drug since you will not be getting it.
If the test drug is not effective, then you will not get any benefits from it. It is possible that the test drug could worsen your opioid use disorder.	A placebo will not make your opioid use disorder worse. You will not benefit from or be harmed by the test drug since you will not be getting it.
Side effects from the test drug include … You may experience these side effects regardless of whether the test drug is effective.	A placebo does not contain any drug. It is an inactive compound that does not have any side effects or treatment effects.

Discuss Common Reasons for Why Someone Might or Might Not Want to Participate

Possible Reasons to Want to Participate	Possible Reasons to Not Want to Participate
• I want to help advance science. I want to help researchers find out if the test drug could help treat people with opioid use disorder. • I want to try the test drug and participating in this study is the only way that I get a chance to try it. • I'd like to be tested for HIV and hepatitis and participation includes testing and free counseling if I test positive.	• I don't want to participate in research. I don't want more uncertainties. • I don't want any chance of getting an unproven treatment. • I'm worried that if I participate someone could find out about my illegal drug use history. • I don't want to be tested for HIV and hepatitis, and the study requires it.

Give Information on Highly Relevant Questions

For example,

- If I participate in this study, can I still participate in another study that may offer an intervention that I prefer?
- During my participation, what happens if important information about the test drug becomes available?
- What happens if, while participating in the study, I relapse or my opioid use disorder gets worse?

Common Rule Requirements of Particular Relevance

Common Rule Requirements of Particular Relevance

- General requirements for informed consent include, among others:
  - Sought under circumstances that provide sufficient opportunity to discuss/consider whether to participate and that minimize the possibility of coercion or undue influence
  - Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- IRB waiver or alteration of consent
- IRB waiver of documentation of consent

Voluntariness

Informed consent must be sought under circumstances that provide sufficient **opportunity to discuss/consider** whether to participate and that **minimize the possibility of coercion or undue influence**

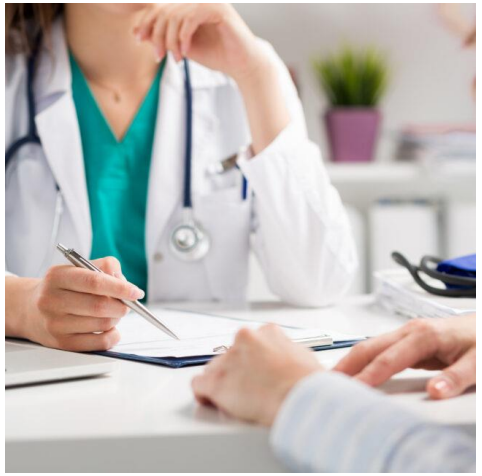
- Consider the circumstances
  - Does subject population have history of mistrust of research?
  - Location, timing, etc. of consent process
  - Avoid coercion and undue influence
- Time for them to ask questions, consider decision, ask others

(46.116(a))

Privacy and Confidentiality: Informed Consent

Informed Consent must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (46.116(b)(5))

- Consider when information might be shared between researchers and clinicians
  - Provide info in consent
  - Be aware of HIPAA requirements



IRB Waiver or Alteration of Informed Consent

i. No more than minimal risk to the subjects;

ii. Could not practicably be carried out without the waiver;

iii. If research involves using identifiable private information or identifiable biospecimens, the IRB must determine that the research could not practicably be carried out without using such [materials] in an identifiable format

iv. Will not adversely affect the rights and welfare of subjects; AND

v. Whenever appropriate, the subjects will be debriefed

(46.116(f)(3))

IRB Waiver of Documentation of Informed Consent

Documentation of informed consent can be waived if:

- Consent form is the only record linking the subject to the research and the principal risk of harm is a breach of confidentiality,
- No more than minimal risk and only involves procedures that don't require consent outside of research, **or**
- Subjects/LARs are members of cultural group in which signing forms is not the norm

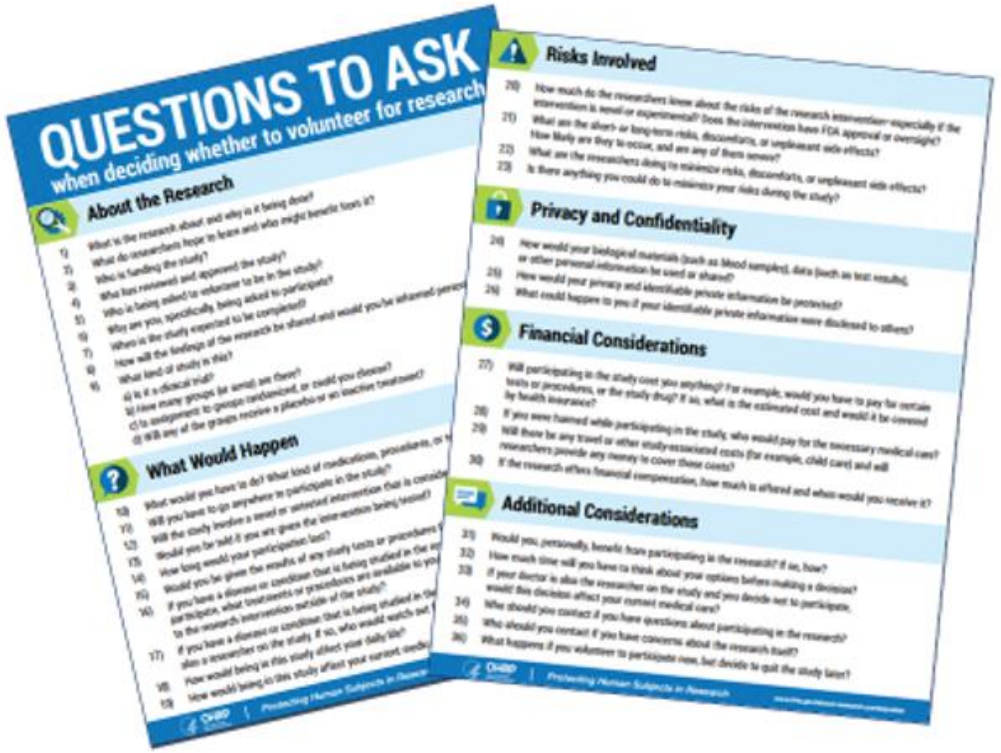
IRB may require investigator to provide subject/LAR with written statement about the research

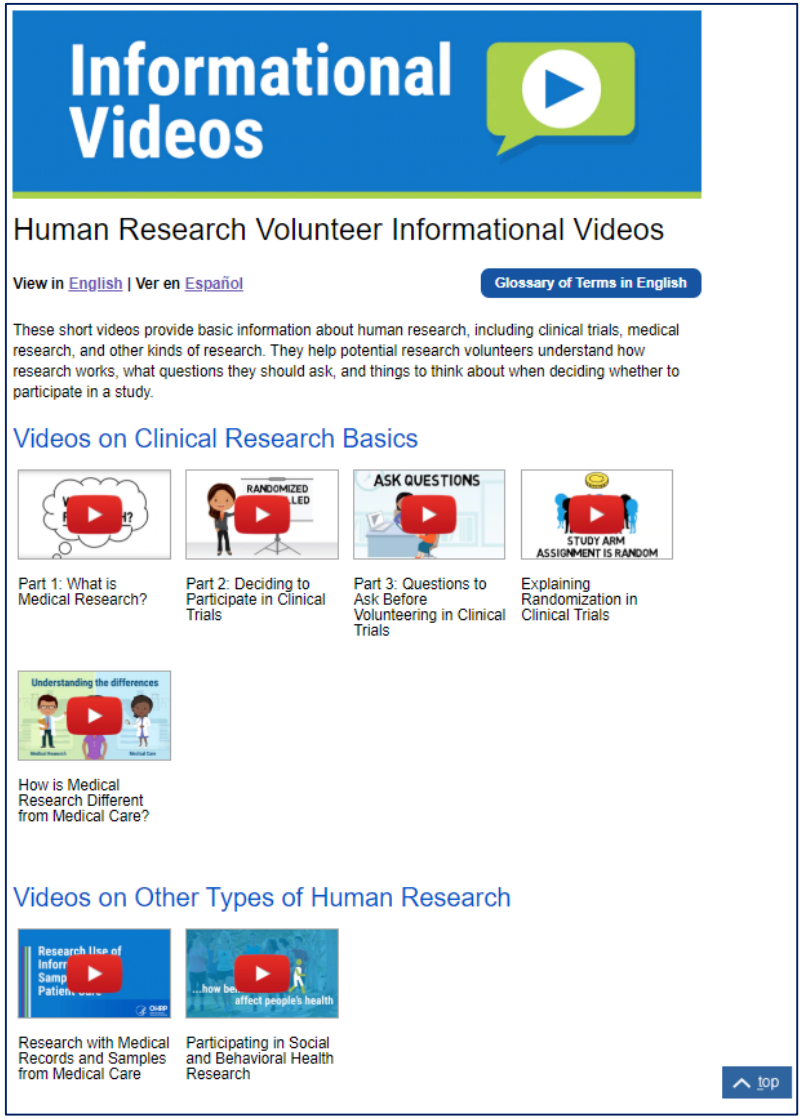
(46.117(c))

www.hhs.gov/About-Research-Participation

Educate prospective participants!

Resources also in Spanish!





Contacts and Resources

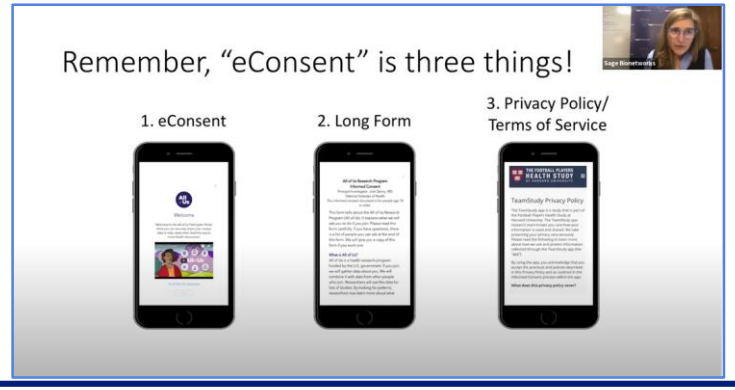
- Contact us or submit your questions to OHRP@hhs.gov
- Visit OHRP website at www.hhs.gov/ohrp
- Bookmark this page for quick reference to OHRP resources on the revised Common Rule: www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html
- Check out OHRP Mini-tutorial on Prisoner Research Requirements at https://www.hhs.gov/ohrp/education-and-outreach/online-education/mini-tutorials/index.html

Luminaries Lecture Series

https://www.hhs.gov/ohrp/education-and-outreach/luminaries-lecture-series/index.html

Ethics & Social Justice in Health Research Involving Vulnerable Adolescents (Celia Fisher)

Use of eConsent in Human Subjects Research (Megan Doerr)



Q&A

CTN Dissemination Library post

Recordings and materials available at http://ctndisseminationlibrary.org/ctntraining.htm

Thanks for your participation.