# Fundamentals for Obtaining Informed Consent

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# Why obtain consent for research?

- **Regulatory Requirements**
  - Office of Human Research Protection, General Requirements for Informed Consent (45 CFR Part 46)
  - FDA Requirements, Protection of Human Subjects (21 CFR 50.20)
  - IRB policies
- **Ethical Rationale**
    - *Belmont Report (1979); Declaration of Helsinki (rev. 2008)*
  - Demonstrates respect for persons
  - Establishes trust between researcher and participant
  - Demonstrates honesty and transparency

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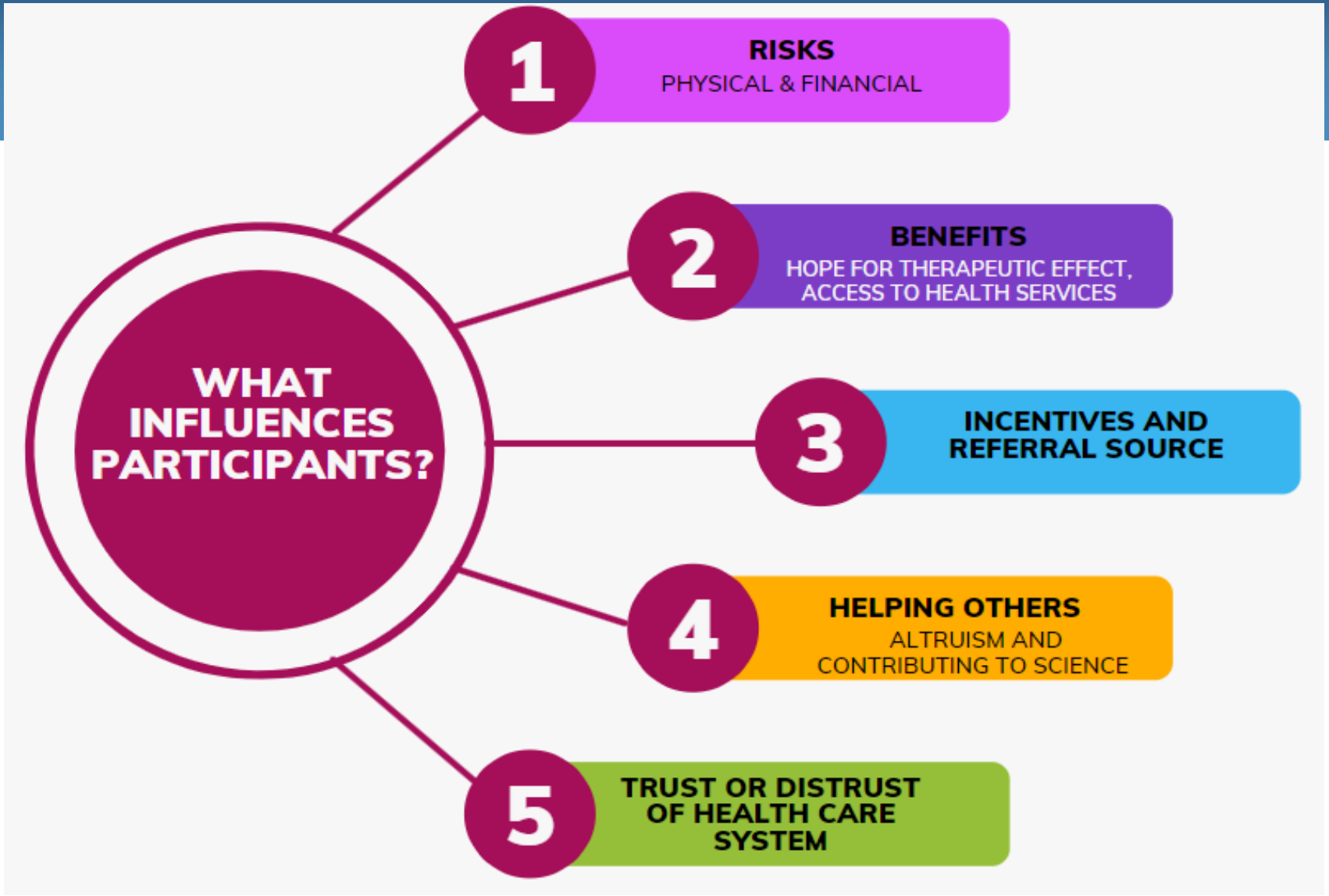
WHAT INFLUENCES PARTICIPANTS?
1
RISKS
PHYSICAL & FINANCIAL
2
BENEFITS
HOPE FOR THERAPEUTIC EFFECT, ACCESS TO HEALTH SERVICES
3
INCENTIVES AND REFERRAL SOURCE
4
HELPING OTHERS
ALTRUISM AND CONTRIBUTING TO SCIENCE
5
TRUST OR DISTRUST OF HEALTH CARE SYSTEM

# *DISCLAIMER*

**Each study is unique.**

**Always refer to the overseeing IRB, and local (institutional) requirements to determine applicable policies or guidance for obtaining and documenting informed consent.**

**Always follow the consent process, as detailed in IRB- approved protocol.**

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# Key components of informed consent

| Basic Components | Additional Components |
|---|---|
| Study involves research, purpose and description of procedures | Additional costs |
| Risks | Consequences of withdrawal |
| Benefits | Termination of participation by the investigator |
| Alternatives to research | Approx. number of participants in study |
| Participation voluntary, can withdraw at any time | Significant new findings will be provided |
| Extent of confidentiality | Remuneration (compensation) |
| Medical treatments available in event of injury | Request for Waivers |
| Contact information /receive copy | |

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# Institutional Requirements

- Individuals may obtain informed consent from participants only if they are delegated by PI and IRB-approved to do so.

**Delegation of Responsibilities Log**

| Investigator Name: | Protocol: | Site Number: |
|---|---|---|
| | | |

List staff to whom the Principal Investigator (PI) has delegated significant study-related duties.

| Name | Responsibilities* | Initials | Signature | Start Date | End Date | PI Initials/Date |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

By initialing above, I, the PI, declare that during the conduct of the above study, I have delegated the following study-related activities:

| *Responsibilities Legend | | |
|---|---|---|
| 1. Administer Consent | 6. Randomize Subjects | 11. Complete Study Forms |
| 2. Screen Subjects | 7. Dispense Study Drug | 12. Provide Discharge Instructions |
| 3. Obtain Medical History | 8. Drug Accountability | 13. Make Follow-up Phone Calls |
| 4. Perform Physical Exam | 9. Assess Adverse Events | 14. Query Management |
| 5. Determine Eligibility | 10. Complete Source Documents | 15. |

Signature of Principal Investigator: _____ Date: _____

Version 4.0 - 2012-03-14

Page _____
Check if final page of log: ☐

# Before you get started

**Circumstances that promote voluntariness**

- **When**: BEFORE any research procedures
- **Where**: Consider environment (Private, quiet area)
- **How**: Avoid technical language

- Be sensitive to culture, literacy, and timing of disease diagnosis
- Prevent misunderstanding
  - Teach back method

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# Presentation of Information

- Use plain language
- Formatting or framing of document to promote comprehension
  - Ex: grouping side effects by expected frequency can help (most common→ least common), rather than full list
  - Visuals: schematics, photos if applicable
- Know your audience and what concerns them
- Be specific

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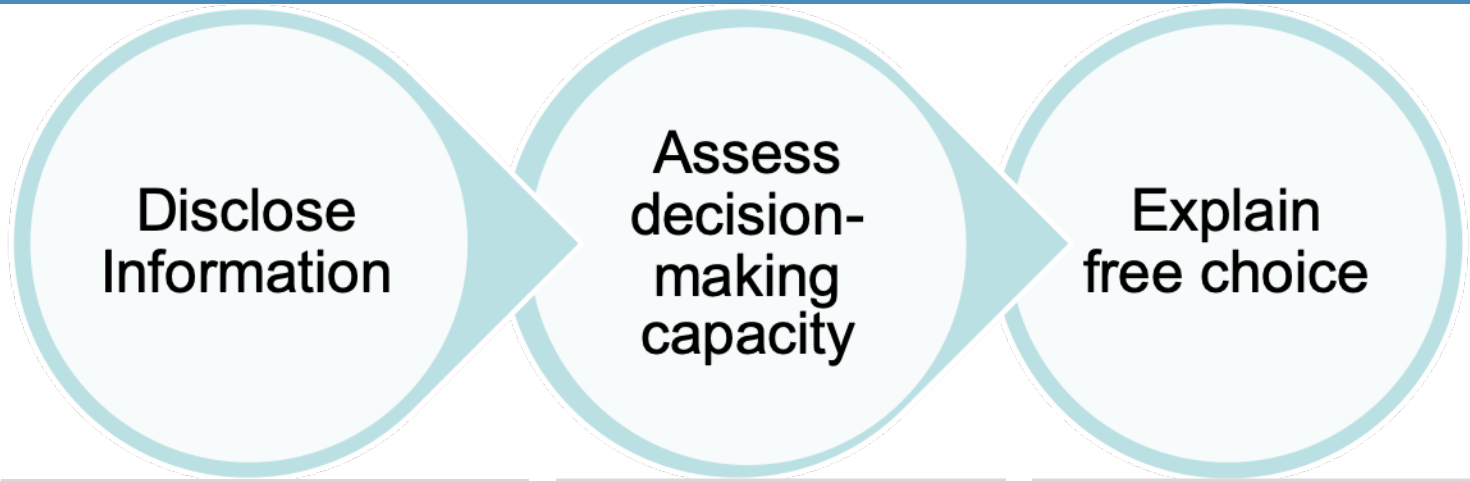
# Key Steps in Consent Process




- This is research
- Purpose of the research
- What will happen to participant
- Benefits, risk, and burden
- Confidentiality
- Conflicts of interest
- Other institutional requirements

- Determining participant's ability to reason and comprehend

- Voluntariness
- Freedom to withdraw
- Agreement

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# Key Information Section

- Provide concise, focused information about why/why not someone would want to participate
- Orient, guide, and assist potential subjects in the decision-making process

- Not required for ALL studies.
- Refer to IRB for guidance.
- 45 CFR 46 Revised “Common Rule”

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**KEY INFORMATION FOR: RANDOMIZED, PLACEBO-CONTROLLED TRIAL TO ASSESS THE SAFETY AND EFFECTIVENESS OF INVESTIGATIONAL E-FLEX IN THE TREATMENT OF ARTHRITIS**

We are asking you to choose whether to take part in a clinical research study that will test the benefits and safety of E-FLEX stiff in patients with Arthritis. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

**WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**
The purpose of this study is to compare the effects, good and/or bad, of E-FLEX with a placebo (an inactive pill). The Food and Drug Administration (FDA) has approved E-FLEX to treat some conditions. FDA has not approved E-FLEX to treat arthritis.

If you are eligible for the study, we will use a computer program to place you in one of the two groups. The group the computer picks is by chance, like a flip of a coin. You will have an equal chance of getting in either group. The test group will take E-FLEX. The placebo group will take an inactive pill. Neither you nor the study staff will know to which pill you get. They both look the same. Participants in both groups will have monthly research study visits for one (1) year. See Appendix A for the study visit schedule.

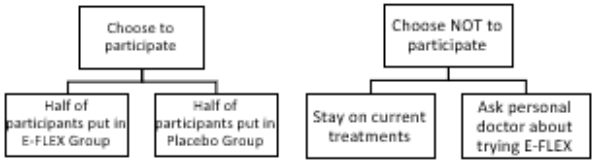
**WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**
Some doctors have noticed an improvement in arthritis on patients taking E-FLEX. While on the study, we will monitor your arthritis. If your arthritis worsens, the study doctor may take you off the study so that your personal doctor may treat you.

The study will provide the E-FLEX or placebo pill, research tests and care at no cost to you. For a complete description of benefits, refer to the Consent Document below.

**WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**
You may decide that you do not want to participate in this study because there is a 50/50 chance of being in the placebo group. If you are in the placebo group, you will take a pill daily for one year that will not help your arthritis. If the study computer places you in the test group, there is no guarantee that E-FLEX will help your arthritis. Research has not been done to confirm whether it will improve arthritis.

You may have side effects while on the study. The most serious effect that has happened in one percent of people who have taken E-FLEX is shortness of breath. The researchers do not know all of the side effects that could happen. Appendix B lists the type and rate of known side effects from taking E-FLEX. For a complete description of risks, refer to the Consent Document below.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer. You can withdraw at any time during the study. The following graph may help you consider your options.




**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The person in charge of the study is _____ *{Principal Investigator, PI}*. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: *{PI contact information}*.
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

*Adapted from University of Kentucky Office of Research Integrity*

**Sample Key Information Page**

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# Beginning the Consent Process: Disclose Information

- **Introduction – why are you here?**
  - *"I'd like to talk to you about possibly participating in a research study"*
- **Explain the purpose of the research**
  - *"We are trying to find out if a new drug for your condition could work"*
- **Emphasize experimental, investigational**
  - *"We are trying to learn more about your condition. We hope that by completing this study that we will be able to better understand if **x** can improve **y**"*

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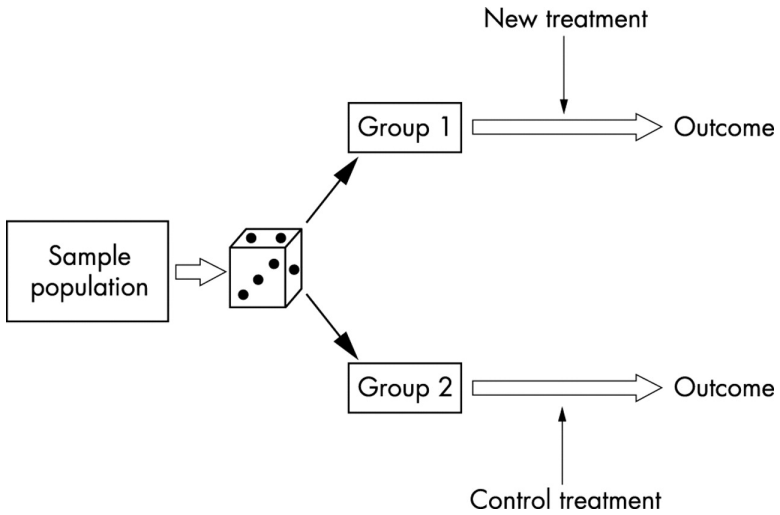
# What will Happen to Participant?

- **Randomization**, controls, placebo, blinding (if applicable)




- **Expectations**
  - *"You will be asked to come in once a month for 6 months…"*

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# Potential Benefits, Risks, and Burden

- **Direct benefits:**
  - Something of health-related, psychosocial, or other value to a participant (not monetary incentive)
    - *"You may learn more about your diabetes..."*
  - Avoid talking about the possible benefit of the 'new treatment'
    - Therapeutic misconception
    - *"There may be no benefit to you at all…"*

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# Benefits, Risks, and Burden

- **Risks**:
  - Drug side effects
  - Anxiety from survey questions
  - Include uncertainty of risks/harms
    - *"Because it's new we don't really know all the possible good/bad things the drug can do"*
  - Include risk of a breach of confidentiality of health information
    - *"Although we protect your private information there is a chance your privacy could be violated"*

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# Benefits, Risks, and Burden

- **Burden**:
  - Time, travel or other requirement (e.g. inconvenience)
    - *"The questionnaire takes about 20 min to complete"*
  - Pain (e.g. muscle biopsy, blood draw)
  - Cost (transportation, time off work)
    - *"You will have to come more often for visits and tests"*

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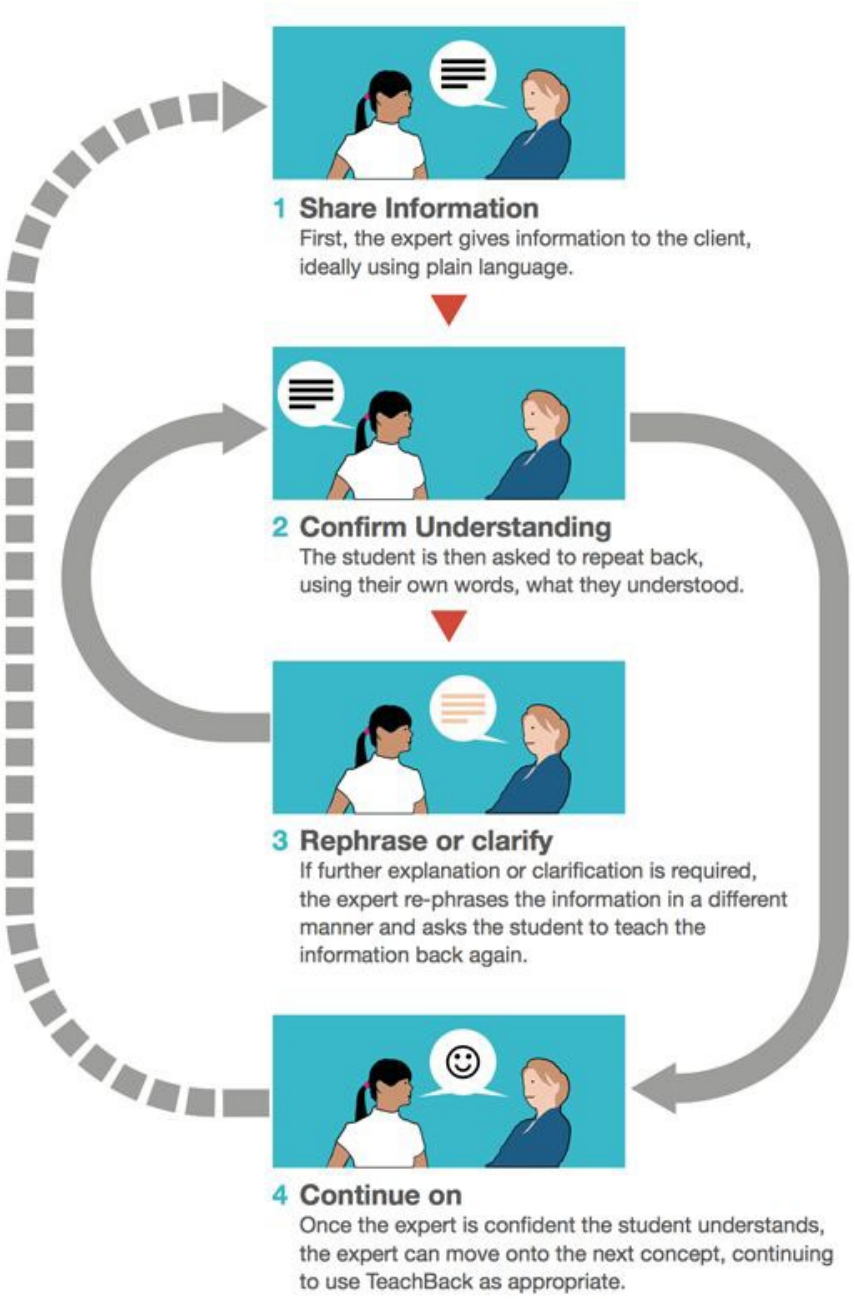
# Technique to Assess Comprehension

- **Teach Back Method**
  - > Ask open ended questions
  - > Ask participant to paraphrase

  *"Can you tell me in your own words…"*



# Ethical Concerns

No Coercion or Undue Influence

Therapeutic Misconception

Determining Decisional Capacity

Language or Cultural Issues

Conflict of Interest

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# Special Considerations: Consent process

- High risk research (e.g. gene therapy, sham surgery)
- Vulnerable participants
  - Serious condition without standard treatment options
  - Impaired decision-making capacity
  - Students
  - Prisoners
  - Children
  - Pregnant women

*Always refer to reviewing IRB's guidance for additional considerations and requirements*

45 CFR 46 Subparts A-D

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# Summary

- Informed consent is a **PROCESS-** not a document
- Obtaining valid consent (or refusal) to participate in research requires knowledge and skills
  - Knowledge of regulations and elements of informed consent
    - Establish process for documentation
  - Communication skills, listening and “translating”
- Adjust for culture, literacy and timing of disease diagnosis

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# Considerations

- **Study and population-specific requirements**
  - > Including required signatures
  - > Additional requirements for FDA-regulated research
- **Consent form versioning**
- **Document translation**
- **Waiver of consent**
- **Waiver of documentation of consent** (written)
- **Broad consent** for the storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens

Review Einstein IRB **Informed Consent Guidelines**

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# Policies

**Einstein IRB:**

- Informed Consent Guidelines
- Short Form Procedure for Enrolling Non-English Speakers

**MMC Policy JC10.1 *"Consents, Informed Consent, and Refusal"***

**Posting Clinical Trial Consent Forms to a Federal Website**

- Research receiving IRB approval on or after January 21, 2019 must post one ICF used to enrolled subjects on ClinicalTrials.gov or regulations.gov

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# Resources

**HHS Office of Human Research Protections**

- General Informed Consent Requirements [Video, 18:38]
- What's New in Informed Consent: Revisions to the Common Rule (2018)
  [Video, 26:50]
- Simplifying Informed Consent [Video, 1:45:38]

**NIH NIMH**

- Elements of Successful Informed Consent [Video, 24:05]

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# Human Subject Research Project Navigation Tool

- Project Management Section > *Participant Consenting*


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# Contact Information

Einstein IRB

irb@einsteinmed.edu

718-430-2237

Office of Human Research Affairs Webpage

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