

QUESTIONS TO CONSIDER WHEN DECIDING WHETHER TO PARTICIPATE IN RESEARCH

I. IS THE RESEARCH IMPORTANT?

1. What questions will the research answer?
2. Are these questions important to you?
3. Are these questions important for society?
4. Have these questions been studied before?
5. Is this research needed? If so, why?

II. WHO IS SPONSORING THE RESEARCH?

1. Is the research being sponsored by industry?
 - a. Is the research being conducted to receive special approval for a new therapy?
 - b. Is the research being conducted so that a product can compete with an already existing product that is essentially the same?
2. Is the research being sponsored by a government grant?
 - a. Are the researchers conducting the study in response to a request for proposals sent out by the government?
 - b. Are the researchers conducting the study to answer a question that arose from clinical experiences?
3. Is the research being conducted independently?
 - a. Is the study being conducted to fulfill a research requirement for a student?
 - b. Are appropriate resources available?
4. What measures are being taken to ensure that there are no conflicts of interest?

III. IS THE RESEARCH LIKELY TO ANSWER THE QUESTIONS IT SEEKS TO STUDY?

1. How will the researchers go about answering their questions?
2. Is there enough time for them to achieve their goals?

IV. ARE YOU AN APPROPRIATE SUBJECT?

1. What requirements are there for being a subject?
2. Do you feel you fit all the requirements?

V. HOW IS RECRUITMENT BEING CONDUCTED?

1. How did the researchers get your name?
2. Did you feel comfortable with the recruitment materials? Were you promised too much? Were the goals of the study very, very clear?

3. Was your privacy honored?
4. Were high-pressure tactics used?

VI. WHAT PROCEDURES WILL BE USED?

1. What exactly will be done if you decide to participate?
2. Are the procedures related to the questions of the study?
3. How much time? For how long will the study continue?
4. How much pain?
5. How many other people will participate?
6. Who will actually conduct the research? Are these people qualified?
7. Will there be costs to you?
8. What will be done for research purposes? What is part of routine care?
9. What will happen if you withdraw from the study?
10. Under what circumstances will the researchers request that you withdraw?
11. Are there medical risks if you withdraw from the study?

VII. ARE NEW MEDICINES OR PRODUCTS BEING TESTED?

1. What is the current status of the medicine or product? Has it been approved?
2. Are there any possible risks or side effects?
3. How many people have tried it so far?
4. What has been the experience of others?
5. Would it be possible to talk to someone who has been involved in this research already?
6. When the study is over, will you be able to continue to receive the experimental product or medicine? How much will it cost? What will happen if you cannot continue with the new product or medicine?

VIII. WHAT ARE THE RISKS AND BENEFITS?

1. What risks can occur (both physical and psychological)?
2. What will be done if you experience a negative side effect?
3. What exactly are the benefits to participating (for you and society)?

IX. WHAT ARE THE COSTS AND COMPENSATIONS?

1. Will you be billed for any part of this study?
2. Will you be reimbursed for transportation, lunch, or any other expenses?
3. Will you receive a gift or money for participating?
4. How do you feel about the amount of compensation you will receive?

X. WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

1. How will your privacy be protected?
2. Will others be told that you are participating in the study?

3. Who will know of the results?
4. Will the results be in your medical record?
5. Do you have control over what happens to the information you provide to the study?

XI. DO YOU FEEL COMFORTABLE PARTICIPATING IN THE STUDY?

1. Trust your gut!
2. Do you like the people conducting the study?
3. Do you feel safe?
4. Do you feel you have a free choice about whether or not to participate?
5. Have you consulted with others about participating?
6. Would you like to have an advocate help you decide?

XII. DO YOU FEEL YOU CAN GIVE INFORMED CONSENT?

1. Has the study been approved by an Institutional Review Board (IRB)?
2. Have you been given an Informed Consent Form to sign?
3. Have you been offered a copy of the Informed Consent Form?
4. Who can you call if you have more questions later?

RESPONSIBILITIES OF A RESEARCH SUBJECT

- I. Be informed.
 - II. Don't sign up just to please someone you respect or like.
 - III. Be honest.
 - IV. Ask as many questions as you would like.
 - V. If you have been promised compensation, be sure you receive it.
- Find out about the results of the study.