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Basic Concepts for Informed Consent

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When patients are deciding whether to participate in a clinical study, understanding some basic concepts will help them frame their decision process. The following language can be adapted for this purpose:

Free and Voluntary Participation

It's up to you. We can give you information, but joining this study is 100% your decision. If you do not want to join the study, we fully support your decision. If you join the study and later change your mind, we will fully support that decision, too.

Informed Consent

You need information to make your decision. Since joining this study is your decision, you need to know some facts about the study. It's not enough for you to just hear them — you need to understand them and think about how they apply to you.

Clinical Research Is Not Clinical Care

A clinical study is an experiment. When you visit your doctor normally, the purpose is to take care of your health. A clinical study is different — it is a scientific experiment to find out whether an unproven treatment works safely for people with some health condition. The treatment might work safely for you, but that is not the main purpose of the study.

Randomization and Blinding

Neither of us will know if you are getting the unproven treatment. In this clinical study, we are comparing [the unproven treatment] to [a placebo/no treatment/a different treatment]. For the experiment to work, we can't tell you which one you are getting. In fact, we won't know either. The treatment you get will be chosen at random, like flipping a coin. Neither of us will know whether the coin came up heads or tails.

Equipoise

Both treatments seem okay to us. If we knew that [the unproven treatment] is better or worse than [a placebo/no treatment/a different treatment], we would not do this study because we would already know the answer. This means that, if you join the study, you should be okay with either getting or not getting [the unproven treatment].

Risks vs. Benefits

There are risks, but they do not seem unreasonable to us. We do not know whether this study will help you. It might harm you. This study will help us find out

about possible harms. No matter what we think, you have to decide for yourself whether the possible benefits make the risks worth taking for you.

According to Microsoft Word, the explanations above (without the headings) have a Flesch-Kincaid reading grade level of 6.1.

Helping Patients Think through Their Decisions

The following questions can help patients think through their participation decision and engage in a discussion with the investigator:

- How will you decide if you want to join the study?
- What facts are important for your decision?
- Where could we explain things better?
- What do you think about the risks vs. possible benefits?
- What do you like about the study?
- What most worries you about the study?
- What do you think your chances are of getting the unproven treatment?
- How will you feel if you find out later you did not get the unproven treatment?
- How does the clinical study look to you compared to your other healthcare options?

Authors

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