DEPARTMENT OF PSYCHIATRY
INDIANA UNIVERSITY
School of Medicine

Clinical Research Studies… What do I need to know?

To find out more about clinical research studies, you can go online:

www.clinicaltrials.gov

www.fda.gov

www.centerwatch.com

Benefits of research:

- *Access to cutting-edge medication and therapies*
- *Thorough clinical assessment and closely monitored treatment*
- *Contribute to a better understanding of the condition*

What is a clinical research study?

- Clinical research is any research that involves people
- A clinical research study is done to determine how well an intervention actually works
- Interventions may include medications and/or non-medication therapies
- Information may be collected through interviews, questionnaires, blood tests, or other procedures

What is a placebo?

- Inactive substance that looks just like the real study medication
- Also called a "sugar pill"

Will I be a "guinea pig"?

- No
- Some treatments being studied are already used by doctors in the community, but with only limited proof of how helpful they are
- Clinical research involving even a small risk to a person is only allowed if the potential benefit is greater than the risk

What are some common types of medication studies?

- Prospective, open-label - everyone receives medication
- Randomized controlled trial - assignment by chance to either the medication being studied or a control (often placebo)

Who can participate?

- Each person is carefully evaluated to see if he or she can participate
- This evaluation might include diagnosis, review of treatment history, and a physical exam

You can also visit www.clinicalresearch.medicine.iu.edu for more information on research studies.

Some good questions to ask:

- *What kind of study is this?*
- *Why are you doing this study?*
- *What will I have to do?*
- *What are the side effects?*
- *Is the treatment available outside of the study?*

"Research is completely voluntary and you can change your mind at any time"

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What is informed consent?

- The informed consent form explains risks, benefits, and your rights regarding the research
- The form lists the study procedures so you know what to expect
- Everything in the form will be discussed with you

Who's watching out for me?

- The IRB (Institutional Review Board) must approve each study - their primary concern is you!
- Every effort is made to keep your information confidential
- The risks must be as low as possible and well worth any potential benefits

Remember that you can always ask questions if there is anything that you do not understand

Will this cost me anything?

- Not usually
- Study related visits, medication, and tests are often provided free of charge
- Sometimes there is reimbursement for travel, parking costs, and your time

What happens after the study?

- After the study is completed, the study doctor or study staff often provide recommendations for future care

What are the drawbacks?

- The medication or therapy being studied might not work or might cause side effects
- Being in a study takes time; there may be frequent visits to the clinic

Is research voluntary? Can I change my mind?

- Yes
- Research is completely voluntary and you can change your mind at any time
- You should let the research team know you are leaving and why; they might be able to provide instructions (e.g., on how to stop the medication) and/or recommendations for future care
- There are also alternatives to being in a study that can be discussed

Are there special considerations for children?

- Yes
- For children to participate in research, a parent or guardian must complete an informed consent form
- If the child is capable, a special child assent form is used so that he or she can be part of the decision making process