INFORMED CONSENT:

CONCISE PRESENTATION OF KEY INFORMATION

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Federal Regulation Changes

- The final revisions to the Common Rule (Federal Policy for the Protection of Human Subjects) became effective on January 21, 2019.
- All studies approved after January 21, 2019 will be governed by the new rule.
- Existing protocols that are still enrolling subjects are required to revise the consent during a modification or continuing review.
- This is not a local policy, this is a federal requirement

1. 45 CFR 46.111

Revised Common Rule: Federal Register Volume 82, Number 12 (issued, January 19, 2017)

- "The informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the **reasons why one might or might not want to participate** in the research. This part of the informed consent must be organized and presented in a way that **facilitates comprehension**, and provides **sufficient information that a "reasonable person" would want** to have. Informed consent as a whole must present information in sufficient detail relating to the research, and must be **organized and presented** in a way that does **not merely provide lists of isolated facts**."

What is considered “key information”?

1. The fact that consent is being sought for research and that participation is voluntary
2. The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research.
3. The reasonably foreseeable risks or discomforts to the prospective subject
4. The benefits to the prospective subject or to others that may reasonably be expected from the research
5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

What is considered “key information”?

- Information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research.
- There may be additional information that should be provided in the concise summary depending on the nature of the specific research study.
  - *For example, randomization, or if the study involves placebo, or if the study includes an investigational device or drug, that information would likely be considered key information.*
- Information that should already be provided in a consent process. There is no additional information beyond what is already required in the informed consent process.

Presenting Potential Benefits

- If applicable, include a statement that there are no direct benefits, otherwise include an accurate and specific description of potential benefit
- For clinical research, keep in mind the potential for therapeutic misconception - study's primary goal is advancing knowledge and not delivering treatment
- Avoid unclear language

Presenting Potential Risks

- Should refer to the most important risks with regard to ***frequency*** and ***magnitude***
- Avoid exhaustive lists
- Clinical research: include how risks differ from standard of care
- Discomforts and inconveniences, rather than risks, might be key information
  - Large time commitments, cost to participate, special diets

Presenting Potential Risks

- Explain that research = experiment = unknown/untested methods. Research is intended to test hypotheses (it is, after all, an experimental undertaking) that will ideally lead to theories that can be translated to clinical treatment.

- When deciding what risks or side effects to include in the summary, consider whether a potential participant would attach significance to the risk in deciding whether or not to participate.
  - **If applicable**, state that "A complete list of the risks is given in the following pages."

Suggestions for Writing a Concise Summary

- The concise summary should be at the beginning of the consent document and generally should be no longer than one (1) page of content.
- A concise summary should not be created by repeating information verbatim, or directly cutting and pasting sentences from the body of the consent document.
- If the study's procedures and/or risks requires extensive explanation or description, a brief summary or overview of the procedures and/or risks should be given. It should then be explained that the more comprehensive and detailed description will be provided later in the consent document.

Suggestions for Writing a Concise Summary

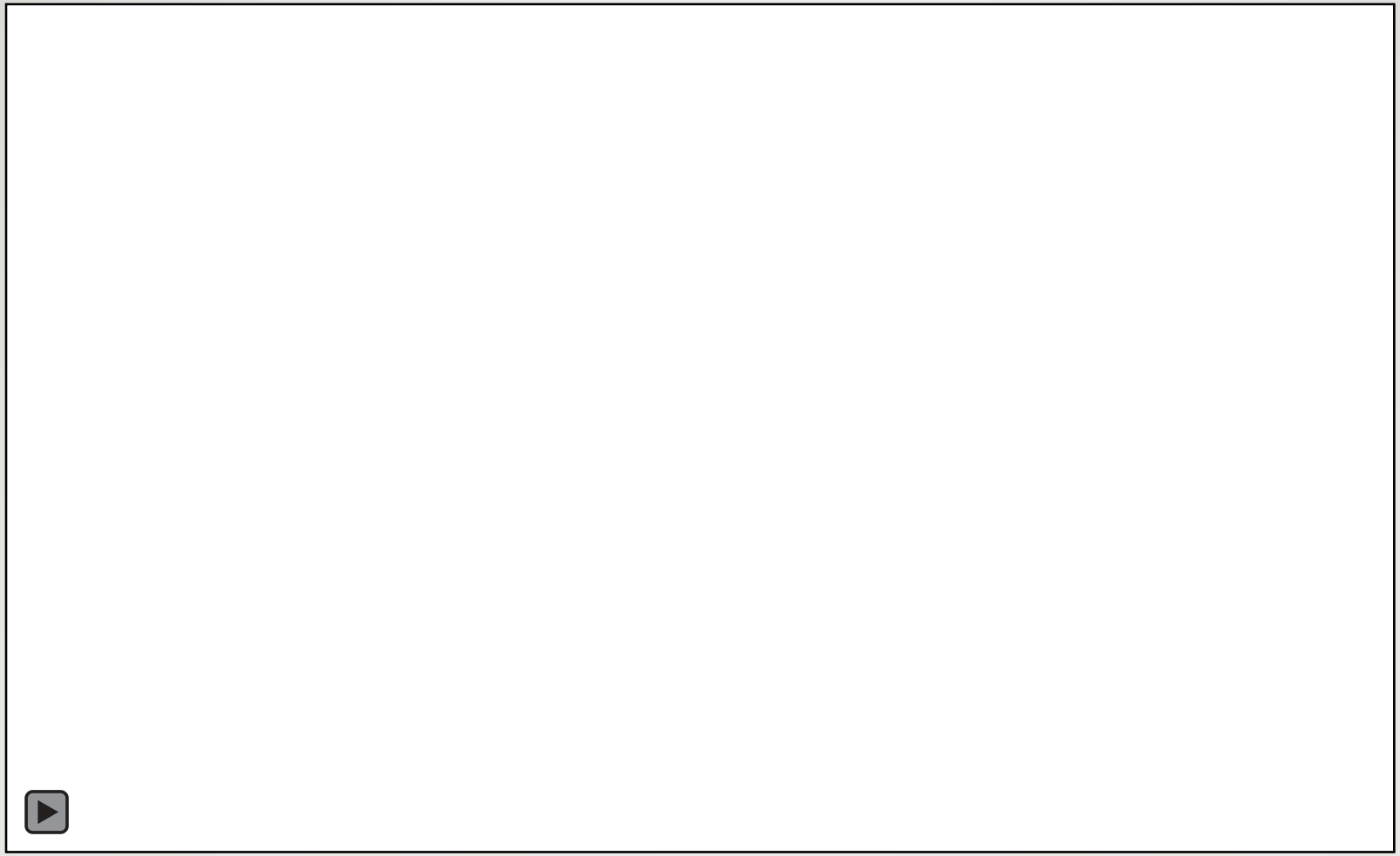
- Use plain, non-technical language.
- Highlight that the person has a choice to make. The consent form should be used as a decision making tool, not a sales pitch.
- Consent forms are recommended to be at an 8th grade reading level to be appropriate for the general population. Use Microsoft Word's readability program to check the reading level

Suggestions for Writing a Concise Summary

HEADINGS

Bolded type

- Keep sentences short and simple.
- Do not use fractions or %. Instead, state “1 out of 10 people will…”
- Use lay language – see plain language dictionary
- Consider using bulleted points to highlight key information.



Why is the PI conducting the research?

This research project is an effort to learn more about how people with autism process information. We know that more than half of people diagnosed with Autism Spectrum Disorder (ASD) have trouble understanding the written word. Others have difficulty following stories, or directions, that are spoken. And yet some of these people can understand ideas or stories in pictures or drawings.

What will happen to me?

In this study we will use a computer to test reading, listening, and looking at pictures — while we watch how your eyes move and how your brain reacts as you process information. We are testing two groups of people — people who have been diagnosed with ASD, and people whose brains have developed in a more typical way.

Why wouldn't a subject want to participate?

The equipment we use won't hurt you. The whole process will take two to three hours. You could get tired or bored. You might get frustrated and upset. You can stop or quit at any time.

Conversational information

Here's some background — understanding even simple sentences requires our brain to make complicated connections. We want to know whether comprehension difficulties in ASD are with the language — that is, the way in which the brain processes words and sentences, OR whether there is something else about the brain's central computing system that may make it more difficult for the brain to make these connections.

Goals of the research

Ultimately, we hope to find ways to improve language comprehension and cognition in autistic individuals so they can better understand the world around them.

Options

The information above is only a brief summary of the study. If you are interested in learning more, it is important to read the following pages for additional detailed information about the study. If you decide to take part in the research, you will be asked to provide written consent at the end of this document.

Why is the PI conducting the research?

The purpose of this research study is to determine the effect of treating depression on how one's body responds to stress. People with known depression and who are willing to seek treatment for their depression are being recruited for this study.

What will happen to me?

If you choose to take part, you will be asked a series of questions about your mental health and asked to complete surveys about your mental and physical health. You will also have your height, weight, blood pressure and waist circumference measured.

After the screening is complete and if you qualify to take part in the study, you will return to the study site on another day to complete a mental stress test as well as additional surveys. You will be asked to complete two challenging mental tasks while your heart rate and blood pressure are measured. You will be videotaped performing these tasks. Once this study visit is completed you will receive twelve weeks of cognitive behavioral therapy for your depression. At the end of the twelve weeks you will undergo another mental stress test.

Why wouldn't I want to participate? Risks to me?

The research study visits will be conducted at UHC and each visit will take anywhere from 1-2 hours. People who are depressed are at a greater risk of hurting or killing themselves. This represents one of the greatest risks of this study. Other risks include strong negative emotions that may arise during therapy and the possibility of loss of confidentiality.

Alternatives

If you choice to not participate, your physician can provide you with other choices on how best to treat your depression including group therapy and medications. If you are interested in learning more about this study, please continue to read below.