Consent, Quality and Key Information

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The duty and responsibility for asserting the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.

Nuremberg Code, 1949
What does “good” look like?

What exactly are our standards?

How do we address the different needs of individuals?

Do these considerations apply differently to so-called vulnerable populations?
(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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What have we learned?
Anyone’s understanding of the information in a consent form will be inversely related to its length and the proportional to the time they have to consider it.

The ways that research differs from care is often not apparent to participants (and sometimes researchers?).
The regulations say little about process, and we have been inattentive to this.

The notion of *emphasis* has been almost entirely lacking.

Researchers have a vested interest in the outcome of consent.
Preconditions for Informed Consent

- Disclosure of **necessary** information
- **Understanding/Capacity**
- Voluntariness or free choice

- Able to evidence a choice
- Demonstrate factual understanding of the information
- Manipulate information rationally
- Appreciate the nature of the decision and its consequences compared to other options
Participant-side factors requiring attention

- Poor education and literacy, poor health literacy, poor scientific literacy
- The spectrum of impaired decision-making
- Urgency, captivity, desperation, limited access to care
Participant-side factors requiring attention

- Lack of familiarity with the nature of the choice
- False expectations based on a confusion of research and clinical contexts
- Difficulty in understanding research concepts and methods
Vulnerability and Informed Consent

Vulnerability:

• Unable to make full use of the informed consent process to “protect” one’s own rights and welfare

• Especially or uniquely susceptible to risk

• Significantly burdened
Assessing (Capacity to) Consent

• Researchers should be appropriately qualified and trained;

• Investigators should consider/attend to each subject’s consent capacity in all research.

• Formal methods can be used to support or supplement the assessment of consent capacity.

• The choice of the method should be informed by the characteristics of the research, population and setting.

• Safeguards might be necessary at specific time points in the study or throughout the study.
Framing the choice; facilitating comprehension

Informed consent…must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s…understanding of the reasons why one might or might not want to participate in the research.
Framing the choice; facilitating comprehension

• The informed consent must begin with a concise and focused presentation of the **key information** that is most likely to assist a prospective subject in understanding **the reasons why one might or might not want to participate** in the research.

• This beginning portion of the informed consent must be organized and presented in a way that facilitates comprehension.

Final Rule, 2017
You can use the form to shape the process
Use the Key Information section to:

• Engage the subject in the initial and ongoing process of making a choice

• Address known deficiencies in the consent process
Key Information

- It is pointless if it is too long or simply redundant with the content of the consent document itself.

- It should be tailored to the nature of the research at hand.

- It should encourage thoughtful interaction around the choice and encourage the participation to translate and personalize the implications of participation.

- It should emphasize aspects of the study experience that are likely to be misconstrued or misunderstood or otherwise difficult to grasp.

- It should be free of bias.

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Consent Enhancement/Accommodation

• Consent enhancements may enable some individuals who “lack consent capacity” to make capable decisions.

• Common-sense approaches:
  • involve individuals trusted by the prospective research participant during the consent process and beyond
  • allow additional time for decision-making,
  • Approve consent materials that support rather than hinder understanding and choice

• Obligations do not end once the consent form is signed
The following outline is meant to serve as a guide to help you learn about this research study and decide whether or not you want to take part.

It does not replace the consent form that you will be asked to read. The consent includes much more information that you’ll need when you make your decision. After we review this outline together, I’ll ask you to read the consent carefully. Ask questions about anything you want me to explain further.
• You may take as much time as you need and seek advice from friends or family before you make your choice.

• Remember, even if you agree to take part in research now, you can change your mind at any time.

• This is a research study—and you do not need to take part in research to receive treatment for your obsessive-compulsive disorder (OCD). There are medications and talk therapies you can choose instead. These options are described in the consent form and will be discussed with you by a study doctor. You should carefully consider these options.

• This purpose of this research is to see if a drug called Excellon is safe and if treats OCD. We do not know if Excellon works. We do not know if it will help you.

• A company called XL makes Excellon, and XL is paying for this research.
• If you take part in the study, you will be receive either Excellon or an inactive pill (a placebo) twice a day, every day for eight (8) weeks. One group of people who take part will get the Excellon and the other half will get the placebo every day for the entire 8 weeks of the study.

• You will not know whether you are in the Excellon group or the placebo group, and you will not be told which you received even after the study is over. Whether you get Excellon or placebo is decided at random, as with the flip of a coin.

• Because Excellon or the placebo treatment may not help you, your OCD may worsen as a result of your taking part in this research. You should carefully consider the consequences of worsening of your symptoms based on your past experience.
• Even if you receive Excellon in the study and it helps you won’t be able to take it when the study is over. This means any benefits from the drug will be time-limited.

• The consent form describes what is known about the risks of Excellon. Read it carefully. The most common risks include headache, nausea, and blurred vision. Excellon has been known to cause a rare but very serious liver problem. This is described in detail in the consent.

• Because Excellon has only been given to about 500 people before, there may be other serious and common side effects that are not known.

• In this study, you will have a physical and psychiatric exam, and we will do blood tests and an EKG to make sure you can safely take part in this study. The results of these tests will be shared with you. If you are eligible, we will slowly reduce the dose of any medication you are currently taking now and then stop it.
• You will spend the first 2 days in the hospital at which time you take doses of the study medication and have blood drawn over the course of 4 hours on each day. Blood will be drawn from a small plastic tube in a vein in your arm. It will be left in place while you are in the hospital.

• After discharge, you will be asked to take the study medication twice each day, and visit the clinic each week for eight (8) weeks where you will be interviewed by a psychiatrist and a research assistant.

• If your OCD gets worse during the study, you may be taken out of the study and provided with standard care.

• After the study, we will stop the Excellon and provide you will 3 months of standard treatment at the clinic at no cost to you. After the first month of treatment, you or your insurance will be responsible for the cost of medication.
See one
Do one
Teach One
Quality improvement?

• How well did the consent discussion prepare you to make your choice about participation?

• How well did the consent discussion prepare you for what you experienced during your study participation?

• What was missed? What would have been helpful?