



Major Elements of Informed Consent

Jeremy Sugarman, MD, MPH, MA
Phoebe R. Berman Bioethics Institute
Johns Hopkins University

Ethics and Informed Consent



- **Two senses of consent**
- **The process of consent**
 - **Threshold**
 - **Decision-making capacity**
 - **Voluntariness**
 - **Information**
 - **Disclosure**
 - **Understanding**

Relevant Regulations

45 CFR 46



Part .116 - Requirements for consent

- **Required elements to be disclosed**
- **Conditions for waiver of elements of consent**

Part .117 - Documentation

- **Requirements for documentation of consent**
- **Conditions for waiver of documentation of consent**

Required Elements -1



- **Nature of the proposed intervention:**
 - **purpose of the research**
 - **duration of participation**
 - **procedures to be followed**
 - **procedures which are experimental**
- **Potential risks and benefits**
- **Alternative procedures**
- **Protection of confidentiality**

Required Elements - 2



- **For research involving greater than minimal risk: compensation and treatment, if any, for possible injury**
- **Contact information**
- **Assurance that participation is voluntary**

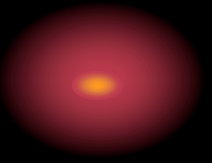
Additional Elements Where Relevant



- **Unforeseeable risks**
- **Termination of participation**
- **Costs to subjects**
- **Consequences of withdrawal**
- **New findings**
- **Number of subjects**

Conditions for Waiver of Required Elements



- 1. Minimal risk;**
 - 2. Would not adversely affect the rights and welfare of the subjects;**
 - 3. Could not be practicably carried out without the waiver; AND**
 - 4. Subjects provided with additional information after participation.**
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Conditions for Waiver of *Written* Consent



1. The only record linking the subject to research would be the consent document, and the principal risk relates to breach of confidentiality;

OR,

2. No more than minimal risk and involves no procedures for which consent is required outside of the research context.