

Developing a Consent Document



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Informed Consent Overview



- Must be obtained for each research subject
- Must be obtained prior to initiation of screening procedures or receipt of samples
- Must be tailored to the level of understanding
- If a medical term is used, a lay definition is needed
- Sufficient opportunity must be given for consideration, no coercion

Informed Consent Overview



- What are the types of consent used for research?
- Who will obtain informed consent?
- Who will provide informed consent?
- When and where will consent be obtained?
- Readability/Length
- Sufficient opportunity must be given for consideration, without coercion

Effective Consenting

1. Accurate Information
2. Understanding
3. Voluntariness
4. Decision Making Capacity



Benefits of an Effective Consent Document



- Increases subject adherence to the protocol and the quality of the research.
- Provides the benefit of an additional layer of risk review tailored to the interests of the individual subject.
- Fosters public trust

Informed Consent Document

Basic Elements

- Invitation to take part
- Purpose
- Procedures
- Time Commitment
- Benefits
- Risks and/or Discomforts
- Alternatives
- Study Withdrawal
- Injury Section
- Costs, Compensation, and Reimbursement
- Confidentiality
- New information
- Questions
- Signatures

Informed Consent Document

Additional Elements



Additional Considerations

- Expanded Risks
- Termination
- Additional Costs
- Withdrawal
- Findings
- Population
- CPHS Statement
- Sharing Study Results

Informed Consent Document

Sample Collection/Storage

- Blood and Tissue Sample Collection

Additional Language

Yes/No Check boxes that outline

- What the sample will be collected for (disease/condition/any)
- Timeframe of storage
- Allowance for future studies
- Data for future studies
- Anonymous information –share

Informed Consent Document

Sample Collection/Storage



- Will the results be shared?
- Re-consent Children
- Benefit
- Risks of sharing samples
- Withdrawal of samples/data
- Sponsor owns any use of the results
- Confidentiality-code
- Ownership of the samples
- Anyone working on the study must agree to hold information in confidence

Consent Document Templates

- CPHS Website/iRIS
 - Templates
 - Consent Document Main
 - Sub-study
 - Sample Collection/Storage

Questions

