Informed Consent-Requirements and Documenting

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AMAZING! THE INSCRIPTION APPEARS TO BE AN ANCIENT CONSENT FORM FOR AN EXPERIMENTAL MUMMIFICATION PROCESS!
Outline

- Informed Consent (IC)
  - General requirements
  - Eight basic elements
  - Six additional elements (when necessary)
- IC Documentation Requirements
- Stanford IC Template
  - Selected sections
- IC Form Review Observations
- Questions
Informed Consent

- Researcher discloses relevant information
- Subject has opportunity to ask ?’s
- Subject volunteers
- Must meet all requirements to be legally effective
Informed Consent

- Consent form is a record of:
  - Information conveyed
  - Subject’s willingness to participate
  - Proof that consent was sought/obtained

Not intended to limit the authority of a physician to provide emergency care
General Requirements

- Information must be in language **understandable** to the subject

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General Requirements

• May not include **exculpatory** language

• **Cannot waive/appear to waive** subject’s rights or liability for negligence from the agents of the study

Not allowed:

> “You waive any possibility of compensation for injuries that you may receive as a result of participation in this research”

Template Language:

> “You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care.”
Elements of Informed Consent

45 CFR 46.116(a)(b)
21 CFR 50.25(a)(b)

• Consists of 8 required and 6 additional “when appropriate” elements

• Except for provisions (waivers and alterations) certain information is required to be provided to the participant or their LAR

LAR = legally authorized representative
8 Required Elements of Informed Consent

1. Study involves research; study description

- Research acknowledgement
- Purpose of the study
- Expected duration of subject’s participation
- Procedures (description)
- Specify which procedures are experimental
2. Reasonably foreseeable risks and discomforts

- What are the risks (physical, psychological, social)?
- Are the estimates of the harm or benefits reasonable?
- Is the nature and magnitude of risk distinguished with as much clarity as possible?

**foreseeable**
Risks that reasonably can or should be anticipated
3. Benefits

- What are the *reasonably expected* benefits?
- Most consent forms contain language: 
  WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY
- Benefits to “*others*” as well (e.g., society)

For example, access to a drug or device that the participant would not normally have that might benefit them
4. Disclosure of alternative procedures/treatments

…that might be advantageous to the subject

Could include “there are no known alternatives” or “an alternative would be not to participate”
5. Confidentiality of records

• The extent that confidentiality of the data will be maintained (if at all)
• Who knows/needs to know
• Who has access to info

For example, the FDA may inspect records
6. Compensation and treatment for injury

- For research involving more than minimal risk/research related injuries
- Explanation of compensation or medical treatment provided, if any
- If there is a risk that some of the treatment may not be covered by insurance
- Payment responsibilities
- Where further info may be obtained
7. Contact Information

Whom to contact for:

- **Questions** about the research
- Subject’s **rights**
- **Research-related** injury, complaints, or other issues
8. Voluntary Participation

- Refusal to participate will involve **no penalty or loss of benefits** to which the subject is otherwise entitled.

- Informed consent is an **ongoing process**; subject can withdraw at any time.
Additional elements of Informed Consent

“When appropriate, one or more of the following elements of information shall also be provided”

45 CFR 46.116(b)
21 CFR 50.25(b)
Additional “When Necessary” Elements

1. Risks are currently unforeseeable
2. Investigators may terminate participation
3. Additional costs
4. Consequences of subject’s withdrawal
5. Significant new findings
6. Number of subjects participating
Documentation of Consent

Along with the elements of consent, there are regulations surrounding signatory requirements.

The IRB may waive the requirement for documentation, in certain circumstances - 46.117(c).

Must always use the most current and approved consent form in order for it to be legally effective.
- Must be **signed and dated** by the subject/LAR
- Copy **must be given** to the person signing the form
- Subject **must be given adequate time to read** it before signing it
- Short form consent process – used when dealing with subjects whose primary language is not English
Statements from actual consent forms

- “we will insert 3 catheters, one in each arm…”
- “The investigator may terminate the procedures and/or the subjects at any time”
- (translational error, English to Chinese) “double-blind” to “blind in both eyes”
Stanford Consent Form Template

- Contains all aspects of the regulatory requirements
- Includes HIPAA and California Bill of Rights as prescribed by law
- Can be modified to reflect your research, but all elements and requirements must still be included
Stanford Consent Form

Introduction
Purpose of the study
Duration of study
Procedures
Participant responsibilities
Withdrawal from study
Possible risks, discomforts and inconveniences

Potential Benefits
Alternatives
Participant Rights
Confidentiality
Financial Considerations
Compensation
Contact Information
Experimental Bill of Rights

Research Compliance Office
Purpose of the Study

• Answers the question for the subject:
  – “Why is this research being done?”
  – and “Why are you being asked?”

• Acknowledgement that study involves research

• Participation is not part of therapy, and is voluntary

• Information on how many people would be in the study can be located here
• The purpose of this study is:

- To see if the new type of dye we use for MRIs can get better images of your blood vessels than that done with the previous dye.

- To do a comparative analysis of two distinct formulations of a contrast agent in order to determine which provides better characterization of the circulatory system.
Duration of the Study

- How much actual time the subject will be actively and physically participating
- How long the actual research will take
• This study is expected to involve approximately 10 hours of your child's time in total, across 2-3 days

• You will take part in this study from the time you sign this consent form until you are discharged from the hospital.

• All of the study images will be obtained while you are on the catheterization table.
Procedures

• What will be done to the participant?
• What they should expect?
• Additional considerations for:
  – MRI
  – Pregnancies
  – Tissue banking
  – Genetic Testing
  – Gene Transfer
Financial Considerations

• MUST disclose who is paying for what

“Participation in this study is not a substitute for health insurance.”

“You and/or your health insurance must pay for those services and care that you require during this study for routine medical care.”

“You will be responsible for any co-payments and/or deductibles as required by your insurance.”
There are **2 choices** in the template language:

- **Option 1**: Use this language for Industry Sponsored Projects
- **Option 2**: Use this language for Non-Industry Sponsored Projects, including:
  - projects with federal funding (i.e., NIH funding)
  - Stanford department funding
  - gift funding
  - medical scholars funding
  - projects with no funding
Informed Consent Review
Observations

• Signatures/Dates

**Missing** from HIPAA section or by Person Obtaining Consent

Approval dates and expiration dates **omitted, incomplete or inaccurate**

**Changing the dates** to match the panel meeting date
• Consent Text –
  - Using **draft consent form** instead of final version
  - Using **earlier versions** (not updated)
  - **Altered text** - Altered approved consent forms (sections, phrases or words crossed out/replaced)
Once consent form is approved...

At the time of your visit, approximately 9 mL of blood (2 tablespoons) will be drawn from a vein in your arm.

Mary Smith
Subject or Authorized Representative

Date

March 31, 2004
Best Practice

• Always print approved ICF from eProtocol
  – Accept tracked changes prior to printing

• If there are date or text errors on the approved form, submit a modification to the IRB

• Verify completeness of signatures and dates at time of consent
Questions?
# Basic Elements of Informed Consent (ICF) : Location in ICF Template (SECTION HEADER)

<table>
<thead>
<tr>
<th>#</th>
<th>Basic Elements of Informed Consent (ICF) :</th>
<th>Location in ICF Template (SECTION HEADER)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Study involves research: a)Explanation of the purpose of study b)Expected duration for subject’s participation c)Study procedures (experimental procedures)</td>
<td>PURPOSE OF RESEARCH DURATION OF STUDY INVOLVEMENT PROCEDURES</td>
</tr>
<tr>
<td>2</td>
<td>Reasonably foreseeable risks to subject</td>
<td>POSSIBLE RISKS, DISCOMFORTS, &amp; INCONVENIENCES</td>
</tr>
<tr>
<td>3</td>
<td>Benefits</td>
<td>POTENTIAL BENEFITS</td>
</tr>
<tr>
<td>4</td>
<td>Alternative procedures or treatment</td>
<td>ALTERNATIVES</td>
</tr>
<tr>
<td>5</td>
<td>Confidentiality of records</td>
<td>CONFIDENTIALITY</td>
</tr>
<tr>
<td>6</td>
<td>Compensation and treatment for injury</td>
<td>COMPENSATION FOR RESEARCH-RELATED INJURY</td>
</tr>
<tr>
<td>7</td>
<td>Contact information</td>
<td>CONTACT INFORMATION</td>
</tr>
<tr>
<td>8</td>
<td>Voluntary participation: Refusal to participate or termination of participation will not result in penalty or loss of benefits to which subject is otherwise entitled.</td>
<td>PURPOSE OF RESEARCH</td>
</tr>
</tbody>
</table>

# Additional Elements of Informed Consent (ICF) (when appropriate) Location in ICF Template (SECTION HEADER)

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<tr>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Statement that the particular treatment or procedure may involve unforeseeable risks to the subject (or embryo or fetus, if the subject is or may become pregnant)</td>
<td>POSSIBLE RISKS, DISCOMFORTS, &amp; INCONVENIENCES</td>
</tr>
<tr>
<td>2</td>
<td>Anticipated circumstances when the investigator may terminate the subject’s participation without regard to the subject’s consent</td>
<td>WITHDRAWAL FROM STUDY</td>
</tr>
<tr>
<td>3</td>
<td>Additional costs to the subject that may result from research participation</td>
<td>FINANCIAL CONSIDERATIONS</td>
</tr>
<tr>
<td>4</td>
<td>Consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject</td>
<td>WITHDRAWAL FROM STUDY</td>
</tr>
<tr>
<td>5</td>
<td>Statement that significant new findings developed during the research which may relate to subject’s willingness to continue participation will be provided to the subject</td>
<td>PARTICIPANT’S RIGHTS</td>
</tr>
<tr>
<td>6</td>
<td>Approximate number of subjects involved in the study</td>
<td>PURPOSE OF RESEARCH</td>
</tr>
</tbody>
</table>
Resources

Human Subject Research Consent:

• OHRP/DHHS - 45 CFR 46.116 – General Requirements
• OHRP/DHHS - 45 CFR 46.117 – Documentation of informed consent
• FDA – 21 CFR 50.25 – Elements of informed consent
• FDA – 21 CFR 50.27 – Documentation of informed consent
• CA Health and Safety Code, Sections 24170-24179.5 – Protection of Human Subjects in Medical Experimentation
• CA Health and Safety Code, Sections 24173 (d) – ICF Attestation
• RCO: GUI-C41 – General Requirements for Informed Consent

https://spectrum.stanford.edu/resources-and-services/study-support-services/regulatory-support.html

http://cancer.stanford.edu/trials/admin/

http://humansubjects.stanford.edu/research/medical/med_consent.html (medical consent)

http://humansubjects.stanford.edu/research/nonmedical/nm_consent.html (non-medical)

http://humansubjects.stanford.edu/research/medical/sf_consent.html (sf - short form)