Towards Streamlined Consent Processes and Participant Understanding

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Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
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In both settings, data sharing has important implications for the informed consent process and document for participants.

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Informed consent is hard to achieve

- Significant problem not restricted to vulnerable populations
- No standard process by which elements of the informed consent are presented and described
- Documentation of comprehension is not required and rarely obtained
- Few well validated methods for comprehension, even fewer for long-term retention of comprehension
  - Teach back
Required information: consent elements

1. Purpose of the research and procedures;
2. Description of any reasonably foreseeable risks;
3. Benefits associated with participation;
4. Alternatives to participation;
5. Confidentiality assurances;
6. For research involving more than minimal risk, an explanation as to whether any compensation and medical treatments are available if injury occurs;
7. An explanation of whom to contact for answers to 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 (Department of Health and Human Services [DHHS], 2009).

**NPRM**: A statement about whether or not the subject’s data will be used for future research studies if the identifiers are removed.
**NPRM:**

Three additional elements have been added to the other additional elements:

1. Discussion of commercial profit and whether the subject will share in such profit
2. Whether clinically relevant results will be returned to the subject
3. Options for consenting or refusing to consent to be contacted for more information/biospecimens or another research study

Basic elements of informed consent are largely unchanged, with one new element. Additional elements are generally unchanged with three new added elements (§ __.116(b)(7-9))

Note that if the NPRM translates to a Final Rule, the FDA has stated that it will amend its regulations to conform to the Final Rule.
Plain language; 6\textsuperscript{th} grade reading level or lower

Use active voice and short sentences

Formatting to aid comprehension:
- Headlines to organize information
- “Big picture” before the details
- Descriptive headers and subheadings
- Limited use of tables and charts
- Adequate “white space”
- Sufficient contrast between font and background
- Avoidance of text in “all caps”

Tools such as CDC Clear Communication Index may be used to measure successful application of health literacy principles

http://www.cdc.gov/healthcommunication/ClearCommunicationIndex
TEMPLATE ICF LANGUAGE FOR DATA SHARING

**Issues to address in ICF:**

- How data is protected
- How and with whom data may be shared
- Personal information versus personal health information
  - “My data”
  - “Coded data”
  - “Anonymized data”
- Where and with whom data will be shared
- Clinical data (to which participants have a right) versus research data
TEMPLATE ICF LANGUAGE FOR DATA SHARING

INFORMED CONSENT LANGUAGE FOR CONFIDENTIALITY AND DATA SHARING

What information about me will be used in the study?
If you join the study, information about you will be used for the study. This information will be called “your data”. Your data includes personal information that can be used to identify you, such as your name or address. It also includes your birth date and information from your medical record. As part of the study we will get new information about you such as heart rate, blood pressure and results of tests on your blood and other samples. By signing this consent form you agree that ‘Your Data’ can be used as described here.

At any time, you may ask the study doctor to see your personal information and ask to correct it if necessary. In some circumstances, you may not be able to see your study information while the study is ongoing. This is to ensure the reliability of the study. However, the study doctor will share any important medical information if it is relevant to your health during the course of the study.

Who will have access to my information?
The researchers at the study site (the “Site Study Team”) will give Your Data a unique study code number (such as, 123321). This number will be used in place of your name and other information that directly or easily identifies you (for instance, your address or national identification number.) We will call this new data “Your Coded Data”. The Site Study Team will keep the link between “Your Data” and “Your Coded Data”. They will not send the link to SPONSOR. Your Data that identifies you will remain at the study site. It may be checked by the sponsor, the ethic committee or government agencies that approve medicines to check how the study was run. The Site Study Team will send only Your Coded Data to the sponsor.

How will my information be used?
SPONSOR will take steps to ensure that your coded data stays confidential and secure. SPONSOR will protect Your Coded Data in accordance with current law. SPONSOR and those working with SPONSOR will use Your Coded Data for research only. They may:

- What information about me will be used in the study?
- Who may see and use information about you and your health?
- How will my Coded Information be used and protected?
- What other general information about this clinical study is shared?
- Do I have to participate in this study?
- For how long will my data be used?
- Can I change my mind about participating in this study?
Invest in preparation

Available in
- English
- Albanian
- Portuguese
- Arabic
- Italian
- Russian
- Cape Verdean
- Khmer/Cambodian
- Spanish
- French
- Korean
- Chinese
- Greek
- Polish
- Vietnamese

http://catalyst.harvard.edu/services/rsa/
Alternative approaches

- Invest in preparation
- Common presentations and platforms for education and explanations

http://catalyst.harvard.edu/services/rsa/
Alternative approaches

- Invest in Preparation
- Provide flexibility to explore consent materials

http://catalyst.harvard.edu/pdf/regulatory/Sophie_Science_Project.pdf

Developed by Children's Hospital Boston, Cincinnati Children's Hospital Medical Center, and The Children's Hospital of Philadelphia
Alternative approaches

- Allow use of multimedia tools for IC processes
Informed Consent for data sharing: a look forward

Invest in Preparation

Common approach

- Clear definitions, using common terms for common meanings
- Commitment to plain language communication
- Robust, generally available educational platforms, including through social media
- Cultural tailoring of educational materials
- Common informed consent templates
- Interactive, multimedia IC platforms

Role of eConsents

Research and data needed
Questions and Discussion