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Session Report

Developing Plain Language Informed Consent Forms for Multinational Clinical Trials

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Guidance documents and regulations pertaining to obtaining informed consent from participants in clinical trials have been in place for <60 years. These regulations were developed in part due to atrocities conducted on individuals in the past under the guise of clinical research. Informed consent forms (ICFs) are required for clinical trials and can be found at all phases of clinical trial phases throughout the world. Although ICFs are required documents, medical writers have a responsibility to ensure ICFs are clear, concise, and easy to understand. As a result of the growth of multinational clinical trials and importance of plain language writing, medical writers are on the frontlines of this integration.

WRITING CHALLENGES FOR MULTINATIONAL ICF DOCUMENTS

ICFs have been found to trend toward being lengthy and difficult documents to read and understand. In the United States, the average adult reads at an eighth or ninth grade reading level. However, it is recommended by the United States Department of Health and Human Services that any plain language materials be at a fifth to sixth grade reading level. It is common for sponsors of clinical trials to want ICFs to be written at a sixth to eighth grade reading level. An additional challenge for writers is integrating guidelines from the *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E6 (R2)* and relevant regulatory agencies into the document while maintaining the plain language writing objective.

TWENTY COMMON KEY ELEMENTS TO INCLUDE IN A MULTINATIONAL ICF

Although each country may have a few differing elements to an ICF, the following items illustrate 20 key elements to include in most multinational ICF documents.

Why is This Clinical Trial Being Done?

- Research. Explain to participants what the research means and how what their participation in the study is part of the research.
- Purpose of the trial. Provide a one sentence objective. Is the objective to investigate safety, efficacy, different dose, different route of administration, or a new indication?

What Will Happen During the Clinical Trial?

- Investigational product and random assignment. Provide 1 to 2 sentences describing the investigational product, controls, and probability for random assignment.
- Experimental aspects of the trial. Identify or explain specific parts, tests, or procedures required by the clinical trial protocol that would not be part of a participant's normal care outside of the clinical trial (eg, collecting blood samples for a pharmacokinetic study or to check for specific biomarkers, completing questionnaires or quality of life surveys).
- Trial procedures. Although it can be easy to copy and paste from protocols, it is important for the writer to adjust this to a participant audience. Examples: what will the sample be used for? When will the procedure take place?
- Participant responsibilities. Describe what the participant is required to do to remain in the trial.
- Expected duration. Supply the number of and duration of clinical trial site visits and procedures.
- Approximate number of participants. Explain the expected number of participants who will be enrolled in the clinical trial with them, and which phase of the clinical trial they will participate in.
- Risks, discomforts, and inconveniences. Include adverse events, potential for stopping or changing current treatments and potential effects, and potential unintended disclosure of private information, data, and/or trial-specific procedures. Examples: loud sounds when undergoing magnetic resonance

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imaging, taking time off work or school, and organizing child care.

Are There Any Benefits or Costs to Participate in This Clinical Trial?

- Expected benefits. Explain any direct impacts or benefits to participants, to other patients, or to society at large.
- Alternative procedures or treatments. Present participants with the current standard of care and what options they have besides the clinical trial. For example, there might be a surgery option that is not being offered to patients in the clinical trial.
- Anticipated expenses. Clearly state who will be paying for the clinical trial drugs, visits, and procedures.
- Anticipated compensation or reimbursement. Describe any prorated payments, reimbursements, or vouchers provided by the sponsor to participants for clinical trial–related expenses (eg, transportation, lodging, meals associated with clinical trial site visits). Including this as a benefit can be viewed as coercion.

How Will Participants Be Protected During the Clinical Trial?

- Participation is voluntary. Participants can choose not to join or withdraw at any time, without penalty, from the clinical trial.
- Compensation or treatment for trial-related injuries. Include what form of compensation will be included for clinical trial–related injuries. This cannot include legal language that tells participants the sponsor is not responsible.
- Permission to access participant's medical records. Explain to participants who will be given permission to access their medical records (eg, clinical trial staff, regulatory agencies, and/or ethics committee).
- Confidentiality or protection of participant's information and data. Address how the participant's personal information will be protected.
- Sharing new information that may impact willingness to participate. Disclose to participants how significant new findings identified during the course of the clinical trial (eg, a new treatment option or adverse events), which may impact the participant's willingness to continue to participate, will be provided.
- Individual(s) to contact for trial information and trial-related injury. Include contact for investigator, ethics committee or institutional review board, and emergency contact.
- Reason(s) that trial participation may be terminated. Must give actual information, not just a general statement.

INCORPORATING THE COMMON KEY ELEMENTS INTO A PLAIN LANGUAGE ICF

Including the aforementioned 20 elements will ensure that the ICF incorporates regulatory requirements, but it does not ensure that the document has a plain language focus. Writers who are knowledgeable on their intended audience can weave in the 20 elements with words the audience can identify with. How a document is structured, the flow of the document, incorporating a conversational tone, and having one key message per paragraph helps the reader more easily process information. Key messages that are concise and correctly conveyed provide the readers with a better grasp of the materials.

Additionally, font size and style that reflect the needs of the reader help enhance the writer's message. It is recommended that writers maintain adequate white space by working toward a 50/50 balance between printed and unprinted areas on each page. There are a variety of user readability tools (eg, Suitability Assessment of Materials instrument, Participant Education Materials Assessment Tool) that can be incorporated into the quality control process of a document.

Ultimately, medical writers are on the front lines of helping translate the essential information required in an ICF into plain language for participants to consume. Being able to creatively interlace essential regulatory information with plain language is a growing competence required among medical writers.

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