The Regulatory Trend Towards Health Literacy in Clinical Trials

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Three recent regulatory changes that promote integrating health literacy into clinical trials:

① EU Lay Summary Requirement

① EU GDPR (General Data Protection Regulation)

① US Common Rule Revisions

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GDPR requires plain language for data consent

"When seeking consent, [organizations] should ensure that they use clear and plain language in all cases. This means a message should be easily understandable for the average person and not only for lawyers. [Organizations] cannot use long illegible privacy policies or statements full of legal jargon."

> *"Given that children merit specific protection, any information and communication, where processing is addressed to a child, should be in such a clear and plain language that the child can easily understand."*

Working Party Guidelines:
https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_opinionctrq_a_final_en.pdf

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The revised Common Rule requires research consent to be understandable

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"[M]ust be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's **understanding** of the reasons why one might or might not want to participate."

– Common Rule, Fed Register, Vol 82, No 12, . (Jan. 19, 2017).

Consent must begin with "key information"

"Informed consent must begin with **a concise and focused presentation** of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

This part of the informed consent must be **organized and presented in a way that facilitates comprehension.**"

82 Fed Reg 12 at p. 7265

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But how do you know if something is understandable?

"The reasonable person concept recognizes that it is impossible for researchers to determine what information every individual participant would consider helpful in deciding whether or not to participate."

"Instead, it asks researchers to include what reasonable people in the same or similar circumstances would want to or need to know."

https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

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How will health literacy play a role in this?

- ✓Health literacy helps determine **what a reasonable person would understand**.
  - oWe know a lot more now about what people do and do not understand because of health literacy research and practice.

- ✓**User testing & focus-group testing** should become a standard practice to determine where specific study populations may struggle.