Safety and Efficacy in Human Factors Device Studies: Interpreting IDE Exemption 4

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The Regulatory Question: Usability vs Safety and Effectiveness

Human factors and usability studies are critical for evaluating issues that are closely connected to patient safety. Investigators can assess whether users are able to correctly operate a medical device, follow its Instructions for Use (IFU), complete critical tasks, or avoid potentially dangerous user errors. This creates an important regulatory question: When human factors studies evaluate whether a device can be used safely, is the study necessarily being conducted to determine the device's safety of effectiveness?

For the purposes of IDE Exempt 4, perhaps not.

Understanding IDE Exemption 4

Under 21 CFR 812.2(c)(4), an investigation may be exempt from the requirements of 21 CFR Part 812 when it involves *"A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk"*. The operative phrase *"not for the purposes of safety or effectiveness"* is crucial in human factors studies.

What Human Factors and Usability Testing Evaluates

Human factors/usability testing is often intended to evaluate whether representative users can appropriately interact with the device and follow the Instructions for Use (IFU). This includes successful completion of critical tasks, identification of use errors, close calls, difficulties, or areas of confusion. However, the fact that these endpoints have implications for safety does not necessarily mean the investigation is designed to determine the safety or effectiveness of the device itself. This is a critical distinction when determining the applicability of IDE Exemption 4.

FDA Guidance on Human Factors Validation Testing

FDA's "*Applying Human Factors and Usability Engineering to Medical Devices (2016)"* guidance describes human factors validation testing as, *"observation of participant performance of the test tasks and assessment of their understanding of essential information"* and identifying *"use errors and 'close calls' on critical tasks"*.

FDA guidance also provides rationale for human factors studies: *"The results of the human factors validation testing should be analyzed qualitatively to determine if the design of the device (or the labeling or user training) needs to be modified to reduce the use-related risks to acceptable levels"*.

Distinguishing Safe Use from Device Safety and Effectiveness

These objectives are fundamentally different from directly evaluating whether a device produces its intended therapeutic or diagnostic effect, or whether actual clinical use produces adverse effects. Evaluating whether users can safely interact with the device is not the same regulatory question as determining whether the device itself is safe or effective for its intended clinical purpose.

This guidance and interpretation support characterizing investigations whose endpoints are limited to user performance and comprehension as an evaluation of the device-user interface, labeling, and usability, rather than the direct clinical safety and efficacy. Even though those endpoints may have implications for the safe use of the device.

Accordingly, where the study does not evaluate clinical outcomes, diagnostic performance, adverse effects, or other endpoints intended to establish the device's safety or effectiveness, it is reasonable to conclude that the study is not being conducted for the purpose of determining safety or effectiveness within the meaning of 21 CFR 812.2(c)(4). Rather, its purpose is to evaluate the adequacy of the user interface and IFU and to identify use-related problems that may require modification of the device design, labeling, or training.

A Simulated-Use Study Example

Consider a simulated-use study in which participants interact with a medical device, but the device is not used to diagnose, treat, or clinically intervene in the patients. The study may evaluate items such as:

- Correctly performing critical tasks
- Understanding IFU language
- Recalling safety information after a decay period
- Understanding the user interface
- Potential use error or close calls

These are fundamental questions regarding the device interface, instructions, and use, rather than the device's clinical safety or efficacy.

Looking Beyond "Safety" and "Efficacy" Terminology

This distinction can be easily misunderstood when a protocol references "safety" or "efficacy". The use of these terms alone does not necessarily establish that an investigation is being conducted for the purpose of determining the safety or effectiveness of the device. In such cases, the IRB should look beyond semantics and evaluate the study's endpoints, interventions, procedures, and data collection tools. The goal is to distinguish between evaluating safe interaction with the device, and evaluating the safety or effectiveness of the device itself.

If the study is limited to usability-related outcomes, it may meet this element of IDE Exemption 4 provided the remaining requirements of 21 CFR 812.2(c)(4) are satisfied.

Human Factors Studies Require Individual Assessment

However, FDA's human factors guidance does not establish or imply that all human factors investigations are categorically outside the scope of safety or effectiveness testing. Therefore, the study objectives, endpoints, procedures, and intended use of the resulting data must be considered in making the determination. If the investigation is intended to generate evidence establishing the safety or effectiveness of the device itself, the criterion at 21 CFR 812.2(c)(4) would not be satisfied.

Focus on the Purpose of Endpoints of the Investigation

Human factors studies are indispensable in medical device development for several reasons, not the least of which being that usability and safety are inherently connected. However, that connection should not distill two distinct regulatory questions into one. Evaluating whether users can safely use the device is not synonymous with evaluating whether the device itself is effective or safe. For purposes of IDE Exemption 4, the appropriate analysis should focus on the purpose of the investigation, and what its endpoints are intended to establish.

With any IDE exemption review, the determination should be based on the specific facts of the investigation, rather than how the study is characterized.

As always, if you have questions about IDE exemptions, human factors studies, or any other IRB-related issues, please feel free to contact me at clayton.gillespie@salusirb.com.

References

U.S. Food and Drug Administration. (2026). Code of Federal Regulations Title 21, § 812.2—Applicability. U.S. Department of Health and Human Services. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812/section-812.2

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