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## What's New in GCP?
## Walden Questions NIH on Consent for Emergency Research

Energy and Commerce Committee Chairman Greg Walden, R-Ore., sent a follow-up letter to the National Institutes of Health (NIH) Nov. 14, questioning NIH-sponsored emergency medical research that is conducted without informed consent.

Walden and Oversight and Investigations subcommittee chair Tim Murphy, R-Pa., sent NIH a letter in June regarding emergency medical research, sponsored by the National Heart, Lung, and Blood Institute (NHLBI). The NIH responded in September.

In the November letter, Walden said the response did not "directly answer the question: What actions will be taken to improve communication with emergency medical service (EMS) providers and site investigators" on such research.

"The answer is of significance to the committee in that NIH not only acknowledges the requirement of EMS responders to either obtain informed consent or provide an opportunity to object to a family member, but that the responders be trained and educated on these requirements, even if in most cases it is likely not feasible to have such communication."

The June inquiry was made on behalf of a constituent whose wife died after cardiac arrest in their home. A few days later, the constituent received a letter from a medical research center informing him that his wife had participated in an out-of-hospital study in which emergency medical service (EMS) personnel administered one of three blinded medications to individuals appearing to be in cardiac arrest. Two were heart-related medications and one was a placebo.

"The constituent later learned that an individual would have to actively opt out of the study in order to not be a participant. Because his wife was unconscious, she could not provide her consent to participate, and was automatically enrolled in the study. The constituent, who was present when his wife went into cardiac arrest, was not given an opportunity to object to his wife's participation in the study before EMS personnel made resuscitation attempts," the June letter said. The constituent also learned that the NIH and the FDA did not require "direct notification of family members" for informed consent in the study. "It was not included in the paramedic training rollout for this fire department… Simply put, they [paramedics] did not obtain your consent because they were not told or trained to obtain your consent," the constituent was told by the local fire chief.

In a September response, Michael Lauer, NIH's deputy director for extramural research, said the NIH "shares your views about the importance of protecting participants involved in research and has a long-standing commitment to ensuring these protections are achieved in the emergency setting."

Lauer noted that, "prior to initiating studies under the Resuscitation Outcomes Consortium [ROC], potentially affected communities are consulted and offered the opportunity to 'opt-out' of participating in the research. ROC researchers work with more than 200 institutional review boards and ethics boards to develop, test and implement community engagement strategies for these emergency research studies."

"However, we are aware that even extensive public consultation processes may miss individuals or groups. Additional research may help to address challenges in obtaining consent from participants' legally authorized representatives (LAR) and notifying family members," the NIH letter said.

Lauer added NHLBI is supporting "research to systematically evaluate multiple sites conducting exception from informed consent (EFIC) studies, including ROC sites. This research focuses on improving community consultation strategies." In addition, a Patient-Centered Outcomes Research Institute study is focusing on participant and LAR perceptions of the enrollment process during emergency research.

"The results of these research activities have the potential to provide a unique perspective from participants and LARs, and to stimulate new approaches to communicating about emergency research between investigators and participants/LARs, and between EMS providers and participants/LARs."

The NIH letter said the agency "recognizes that in an emergency research setting in which a participant is unable to provide consent, an attempt must be made, if feasible, to seek consent from an LAR within a 'therapeutic window.' If obtaining informed consent from a LAR is not feasible, an attempt must be made, if feasible, to contact the participant's family member and provide an opportunity to object to enrolling the participant in the emergency research study."

However, "there is often minimal opportunity for EMS personnel to inform an LAR about a study and seek consent, or to notify family who may be present at the scene and seek objections, but there is no assumption that it is 'never feasible' to complete these responsibilities. For this reason, all ROC protocols contain scripts for LAR communication and family notification. It is essential that all emergency responders are trained to use them, even if determinations may need to be made in particular situations that taking the time to deliver the script is not feasible and would jeopardize the life of the participant."

However, Walden's follow-up letter noted, "The local fire chief overseeing the EMS personnel in the study indicated there was no training at all about soliciting consent from or providing an opportunity to object to patient representatives. Thus, the committee has a reasonable belief that these emergency responders did not receive any training or scripts, which NIH claims were disseminated to the NIH-funded ROC study sites. This further leads the committee to wonder whether there may have been a breakdown in the communication or training process at this study site. NIH did not address how it ensures that EMS responders are receiving proper training in interaction with patient representatives, or what documentation institutional review boards or principal investigators provide to NIH as evidence of proper training. Given what appears to be credible evidence of lack of training and a reasonable assumption of a breakdown, what action is NIH going to take to ensure the proper training and scripts reach EMS responders at ROC study sites?"

Lauer noted, "Considerations regarding the presence of family members during emergency resuscitation research are complex and multifaceted. Family member presence during resuscitation is currently governed by local pre-hospital response policies and procedures." He added that the "few studies that have explicitly examined the association between family presence and resuscitation outcomes have shown mixed results," but that "NIH welcomes research project applications to investigate whether family member presence affects the safety of patients in emergency care settings, and whether it provides comfort to the family."

Walden requested NIH "clarify its comments on the matter of family presence during emergency resuscitation attempts." Walden asked what the agency means by saying it "welcomes research project applications." "What does this mean? Will, or has, the NIH issued any notices or solicitations to welcome such research? If not, why?"

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