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**POLICY FORUM**

## Autonomy and Exception from Informed-Consent Research

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The well-recorded historical abuse of biomedical research subjects around the world has led to a lasting distrust of the research system [1]. For this reason, it is usually considered obligatory to acquire informed consent for research studies. The international research community strongly condemns any disregard for proper consenting processes [1]. Because of this requirement, vital emergency medicine (EM) research is hampered by urgent health needs that render patients unable to consent for studies. This has led to a relative dearth of research for emergency treatments.

Aware of the need for EM research and the impossibility of obtaining full informed consent from all patients in emergency situations, the Food and Drug Administration (FDA) developed the Exception From Informed Consent (EFIC) policy in 1996 [2]. EFIC allows research in certain life-threatening situations without the expectation that consent will be obtained prior to beginning study procedures. Several adult EFIC trials have been completed to date, the most famous of which led to the approval of the life-saving automated external defibrillator [3-5]. To safeguard EFIC subjects and respect their autonomy, the FDA requires protective measures not present in nonexempt research studies before and during the EFIC study. Despite these protections, some argue that the EFIC methods and protections have not been studied well enough and that there are no quantifiable outcome measures to demonstrate the efficacy of these FDA protections [6]. Thus, EFIC detractors say, patient autonomy may be at risk.

With the first U.S. pediatric EFIC studies currently underway, EFIC policy has recently been extended to include some of the most vulnerable members of society [7, 8]. Here, we consider whether the extra protective measures required by the FDA successfully alleviate existing concerns about conducting research in the absence of informed consent and examine whether the EFIC policy does, in fact, further compromise the autonomy of ER patients with life-threatening illnesses.

### Regulation of EFIC Research

Informed-consent processes, which allow patients to discuss significant details of their involvement in a study with the research team before consenting to take part, have become standard practice in the United States and other countries. The FDA's exemption from informed-consent policy, by definition, allows research to be conducted on patients who have not been asked for consent, taking away their established right as autonomous individuals to involve themselves, or not, in medical

research. We believe that EFIC policy does not represent a laissez-faire attitude to research and informed consent but that it acknowledges the necessity of EM research and creates a way of conducting such research while respecting the prospective participant as an autonomous subject [2].

The FDA attempts to assuage public concern about violations of individuals' autonomy through the EFIC by employing strict regulations. First, the EFIC may only be used for studying treatments for life-threatening health problems. These are defined by the FDA and include health conditions that pose a significant risk of patient mortality and morbidity. Next, there must be a possibility for direct benefit to the participant—a demand that is absent in traditional drug-versus-placebo studies. EFIC investigators must also carry out public disclosure and community consultation and offer the community opportunities to object and opt out. Through public disclosure, study information is disseminated to the public before, during, and after the research has taken place. It must include contact information for the research team and provide ways for people to object or opt out of the study. Enrolled study subjects must also be given the opportunity to opt out once they or their guardian have been informed about the study. Community consultation engages the community and study team in two-way discussions about the proposed research. It is only when all of these activities are reviewed and approved by local institutional review boards (IRBs) that clinical EFIC research can begin [2].

These EFIC protections do not act as a proxy for or replace informed consent. Instead, they enable investigators to gain important community, cultural, and personal insights about the research and study population that may otherwise be overlooked [9]. Despite the potential benefits, public disclosure and community consultation have been cited as the most difficult aspects of the EFIC process [9, 10]. Current research shows no consensus about what methods qualify as effective community consultation, and, even more importantly, there is no standard definition for what constitutes a complete and adequate community consultation process [9, 11, 12]. In light of this critique, we must agree that community consultation and public disclosure may not in their current forms protect patients in the ER in the way they are intended [6]. Thus, the inclusion of these protections in EFIC policy call for significantly more thought and research.

**Does EFIC Compromise Autonomy of ER Patients?**

This concern, however, distracts from the more fundamental ethical question: do these patients have any autonomy to lose? The gravely ill patients who are brought to emergency rooms, both adult and pediatric, rarely have the capacity for fully autonomous decision making. The physician has little or no time to discuss treatment options with patients or their family members. Patients must trust the doctor to pursue the best course of action without delay. EFIC research into life-threatening conditions may not bring any further loss of autonomy because emergency care already deprives patients of the autonomy they might enjoy in other medical settings. Thus, EFIC research offers a chance to discover the best treatment for life-

threatening situations while reducing a patient's autonomy no more than the emergency encounter does by its very nature.

Patient autonomy should not be the only consideration in EM research. EFIC research accommodates reduced autonomy for the sake of other vital rewards, i.e., knowledge of the best life-saving interventions. Whilst involvement in medical research often carries risks beyond those inherent in clinical care, that claim cannot be made here. Current treatments for life-threatening illnesses are not born of gold-standard investigations but are extrapolated from related conditions, (often less severe), or related populations (e.g., pediatric treatments based on adult-only research). This lack of clinical data confers the same risk on the dying patient enrolled in an EFIC study as on un-enrolled patients. As Chamberlain et al. note,

> As a nation, we are faced with an ethical choice: we can choose to allow every emergency encounter to be an uncontrolled experiment at the hands of the individual physician, and hence fail to advance the science, or we can choose to enroll patients in a systematic manner into rigorously controlled clinical trials with well-regulated treatment arms and safety monitoring aimed at determining the best treatments [13].

EFIC research creates a scientific basis for treatments of life-threatening conditions. Therefore the ethical query is not whether we should proceed with EFIC or not, but why we are not conducting more. The benefit for society, as well as the potential benefit for the patient, must override concerns about reduced autonomy. It is under this premise that EFIC-EM research should continue while increasing awareness of its importance in medical and lay communities.

## Conclusion

The EFIC is a federally mandated process that facilitates investigation of specific, life-threatening medical emergencies without first expecting researchers to obtain the usual informed consent. Many criticize EFIC policy for compromising patients' exercise of autonomy. Extra protections for research subjects in the form of community consultation, public disclosure, ability to opt out, and the possibility of benefit to the patient are unique to research under EFIC. While these protections cannot act as a surrogate for autonomy, they may have a positive impact on the development of research using EFIC methods, but further research on these protections is needed.

If we fully understand the EFIC concept, we must accept that it does not reduce autonomy but merely reflects the already reduced autonomy of patients in the acute emergency setting. Society must also recognize that other ethical considerations might override autonomy when conducting necessary EM research using EFIC. It is then that, despite diminished autonomy of most emergency patients, EFIC studies represent an appropriate ethical path for emergency medicine research.

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