



Review Article

Consent Challenges in Emergency Department Research Involving Incapacitated Patients

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ABSTRACT

Emergency research often involves patients who cannot consent because the condition under study -- cardiac arrest, severe brain injury, refractory status epilepticus -- impairs capacity, and there is often no time to locate a surrogate before treatment must begin.

This review examines the three main mechanisms used to enroll such patients: surrogate or legally authorized representative consent, deferred consent obtained retrospectively, and exception from informed consent (EFIC) supported by community consultation.

Recent work shows each mechanism carries a distinct residual cost: surrogate consent asks decision-makers to judge under acute distress, deferred consent risks retrospective refusal, and EFIC community consultation has not kept pace with newer digital outreach methods.

We also consider the enrolling clinician, who simultaneously treats the patient and implements a protocol the patient never affirmatively joined.

We conclude that no pathway fully closes the gap between what consent is meant to protect and what emergency research requires, and that prompt disclosure after the fact does more ethical work than the choice of mechanism itself.

Keywords: informed consent; emergency research; exception from informed consent; surrogate consent; research ethics

Citation: Pedersen E, Novak C and Larsen L (2025) Consent Challenges in Emergency Department Research Involving Incapacitated Patients. *Bioethics*. 1(1):01-06.

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Article History: Received 28 November 2024 | Accepted 03 March 2025 | Published 08 June 2025

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INTRODUCTION

Emergency medicine research occupies an uncomfortable place in research ethics: the conditions

that make a trial scientifically and clinically urgent -- cardiac arrest, severe traumatic brain injury, refractory status epilepticus -- are the same conditions that strip patients of the capacity to consent to being studied at

all. A patient in cardiogenic shock cannot weigh the risks of a novel resuscitation drug against its potential benefit, and there is frequently no time to locate a surrogate before the intervention has to be given or withheld. Waiting for consent, in these cases, is not a neutral default; it is itself a decision to withhold the intervention under study, with its own consequences for the patient in front of the clinician [1]. Ordinary research ethics, built around a competent adult reading a consent form before enrollment, was never designed for this setting, and regulators in multiple jurisdictions have had to construct narrow, heavily conditioned exceptions to make emergency research possible at all.

In the United States this exception has a name -- exception from informed consent (EFIC) -- and a specific regulatory history dating to FDA and HHS rules issued in the 1990s that permit enrollment without consent from the patient or a surrogate, provided a defined set of safeguards are met: the condition is life-threatening, available treatments are unproven or unsatisfactory, obtaining consent is not feasible, the research could not practicably be carried out without the waiver, and the community in which the trial will occur has been consulted and informed in advance [2]. Decades after the rule was written, the debate it generates has not settled; a 2026 workshop convened specifically to address the "edge cases" the original framework did not anticipate found that clinicians, ethicists, and community representatives still disagree about where its boundaries should sit [3]. This review surveys the main consent mechanisms used in emergency department research on incapacitated patients -- surrogate and legally authorized representative (LAR) consent, deferred consent, and EFIC -- along with the community consultation requirement that accompanies EFIC, and the empirical and normative literature assessing whether these mechanisms actually deliver on their ethical promises.

SURROGATE AND LEGALLY AUTHORIZED REPRESENTATIVE CONSENT

The first and most widely used mechanism is surrogate consent: when a patient lacks capacity but a spouse, adult child, or other legally authorized representative is present or reachable, that person may consent on the patient's behalf. U.S. federal guidance treats LAR consent as functionally equivalent to the patient's own informed consent, provided the surrogate is authorized under applicable state law to make treatment decisions for the patient [4]. This equivalence is doing a great deal of ethical work for a fairly thin legal fiction: a surrogate is asked, often in a hallway or waiting room, under acute emotional distress, to absorb a research protocol's risks and benefits and decide on behalf of someone they may not have discussed research participation with, ever.

Guidance from HHS's Office for Human Research

Protections and from CIOMS's international ethical guidelines converges on the same substituted-judgment standard: a surrogate should decide as the patient would have decided, not simply as the surrogate believes best, though both bodies acknowledge this standard is difficult to operationalize when no prior conversation about research participation ever took place [5,6]. NIH guidance on questionable capacity flags a related problem specific to the emergency setting: capacity itself is not binary, and a patient who is confused, sedated, or intermittently lucid may fall into a gray zone where neither full self-consent nor full surrogate substitution cleanly applies [7]. Broader guidance on research with adults who lack capacity more generally reinforces the same point: consent status can fluctuate over the course of a single emergency admission, and institutional policies designed around a single consent determination at enrollment often have no clear procedure for what to do when a patient's capacity partially returns mid-study [8]. Table 1 summarizes how the three main consent pathways discussed in this review compare on timing, who authorizes enrollment, and their principal ethical vulnerability.

Table 1. Consent pathways used in emergency department research involving incapacitated patients, compared by timing, authorizer, and principal ethical vulnerability.

Pathway	Timing relative to enrollment	Who authorizes	Principal ethical vulnerability
Surrogate/LAR consent	Prospective, before enrollment	Legally authorized representative (spouse, adult child, etc.)	Substituted judgment made under acute distress, often with no prior indication of patient wishes
Deferred consent	Retrospective, typically 24-72 hours after enrollment	Patient (if capacity returns) or surrogate, after treatment has begun	Patient already enrolled and treated before any authorization is obtained; authorization may later be refused
Exception from informed consent (EFIC)	No individual consent; community consultation occurs before trial launch	No individual authorizer; community consultation and public disclosure substitute	Community consultation reach may not represent the population actually enrolled

Practical guidance documents from research institutions have tried to operationalize LAR consent with hierarchies of who may serve as a surrogate and requirements to document the basis for the surrogate's authority, but these procedural safeguards do little to resolve the deeper problem that emergency surrogate consent is consent obtained under time pressure, from a person who is also managing acute grief or fear

about the patient's condition [9]. A 2023 review of ethical challenges in research with adults lacking capacity concluded that surrogate consent functions reasonably well for research with modest risk and clear potential benefit to the specific patient, but strains badly when a trial compares two active treatments neither of which is clearly preferable, since the surrogate has little basis for judging equipoise on the patient's behalf [9].

DEFERRED CONSENT

When even a surrogate cannot be located or reached in the window available -- a common scenario in prehospital cardiac arrest or hyperacute stroke research -- some jurisdictions permit deferred consent: the patient is enrolled and treated under the research protocol first, and consent (from the patient, if capacity returns, or from a surrogate) is sought retrospectively, typically within 24 to 72 hours. Early European experience with deferred consent in intensive care research described it as ethically defensible only when interventions carried minimal additional risk beyond standard care and when the deferral period was kept as short as clinically possible [10].

More recent qualitative work complicates that comfortable early framing. A 2025 formative study conducted in Malawi found that patients and family members generally accepted deferred consent in principle, but many were troubled specifically by not having been asked in advance, describing a sense that the research relationship had started without them even if the underlying treatment decision had been sound [11]. A study of deferred consent across two prospective emergency neurocritical care cohorts found that a nontrivial share of patients or families later declined to authorize continued use of their data, even though the initial intervention had already occurred and largely could not be reversed -- illustrating that deferred consent, unlike prospective consent, always carries some risk of enrolling and treating a patient whose eventual decision-maker will not, in retrospect, authorize the research use of their information [12]. Voices in Bioethics has argued that deferred proxy consent, done well, actually strengthens rather than weakens the ethical position of emergency research, because it preserves an opportunity for retrospective authorization that a hard EFIC waiver does not offer at all [13].

A 2022 systematic review and narrative synthesis of stakeholder attitudes toward deferred consent found broad but not universal support among patients, families, clinicians, and ethicists, with the most consistent concern being transparency: stakeholders wanted to know, clearly and promptly, that they or their family member had already been enrolled in a study, and wanted an unambiguous, low-friction path to withdraw if they objected once informed [14]. That finding maps onto a recurring theme across the literature reviewed here: procedural legitimacy in

emergency research consent turns less on which mechanism is used than on how honestly and promptly the fact of enrollment is disclosed once the emergency has passed.

EXCEPTION FROM INFORMED CONSENT AND COMMUNITY CONSULTATION

EFIC removes the surrogate-consent requirement altogether for a narrow category of trials where no surrogate can realistically be found in time and the research addresses a life-threatening condition with no satisfactory existing treatment. In place of individual consent, U.S. regulations substitute a community-level process: community consultation, in which investigators solicit input from the population likely to be enrolled (because they live in the catchment area served by the participating emergency medical services and hospitals), and public disclosure, in which the trial's existence, risks, and an opt-out mechanism are publicized before enrollment begins [2]. The RAMPART trial, a large multicenter study of prehospital seizure treatment, remains one of the most thoroughly documented implementations of this framework and is frequently cited as evidence that EFIC can be operationalized at scale without a collapse in public trust, though the trial's authors were candid that community consultation reached only a fraction of the population later actually enrolled [15].

That gap between consultation reach and eventual enrollment has not closed with time. A 2024 paper on the PreVent and PreVent 2 airway management trials documented how community consultation practices had to be redesigned mid-study during the COVID-19 pandemic, when in-person town halls and public meetings -- the traditional consultation format -- became infeasible, forcing a shift toward online and remote formats whose reach among the actual patient population was harder to verify [16]. Newer trials have leaned further into digital tools: a 2024 study of a pediatric prehospital airway resuscitation trial and a 2026 review of digital technologies for EFIC consultation both describe social media outreach, geotargeted online advertising, and web-based public disclosure portals as increasingly standard, while acknowledging that digital reach still skews toward populations with reliable internet access and away from exactly the lower-resource communities that emergency trials often study [17,18]. A 2026 report on community consultation and public disclosure for a trial of sedative choice in emergency intubation reached a similar conclusion: consultation processes have become more sophisticated without becoming meaningfully more representative, and investigators still lack a validated way to measure whether a given consultation effort actually reflects community sentiment rather than the views of whichever subset of residents happened to respond [19].

Figure 1. Schematic comparison of the three consent pathways discussed in this review across individualized authorization preserved and practical feasibility under time pressure (illustrative, not derived from a single empirical study).

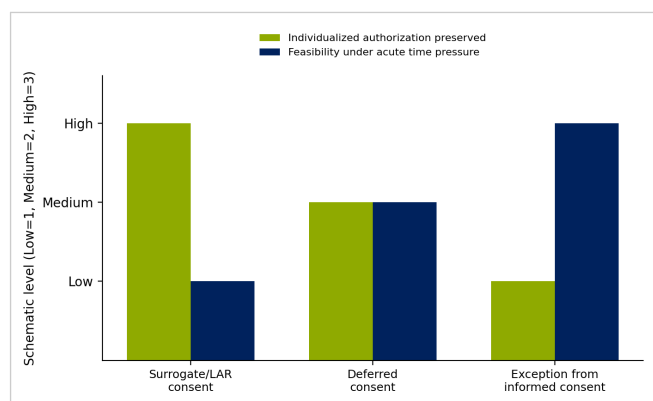


Figure 1 presents a schematic comparison of the three consent pathways discussed in this review across two dimensions that recur throughout the literature: the degree of individualized authorization each pathway preserves, and the practical feasibility of using it under genuine time pressure. The pattern is not a simple trade-off in one direction; EFIC scores lowest on individualized authorization by design, but the pathways do not otherwise sit along one continuous ethical gradient, since deferred consent and full surrogate consent each carry distinct advantages and burdens that do not reduce to a single axis.

THE ROLE OF THE ENROLLING CLINICIAN AND PERSISTENT ETHICAL TENSION

A recent line of work has turned attention away from the consent mechanism itself and toward the person actually implementing it at the bedside. The enrolling clinician under EFIC occupies a genuinely difficult dual role, simultaneously the patient's treating physician and an agent of a research protocol the patient never affirmatively joined, and a 2026 analysis of this role argued that existing guidance gives remarkably little concrete direction on how a clinician should navigate moments where the two roles pull in different directions, for instance, when a family member arrives mid-protocol and asks the clinician to stop [20]. This is not a hypothetical tension: EFIC explicitly permits enrollment to proceed without consent precisely in the population where consent-seeking would be most difficult, which means the clinicians closest to the bedside are also the ones with the least formal decision latitude once a family member does show up and object.

Comparative-effectiveness trials sit at an interesting edge of this framework: because they compare treatments already in clinical use rather than testing an unapproved intervention, some researchers have argued the ethical stakes of proceeding without consent are lower, since neither arm exposes the patient to greater risk than usual care would. A recent analysis of EFIC and waiver-of-consent frameworks

specifically for comparative-effectiveness emergency trials pushed back on this reasoning, noting that even comparative trials embed randomization and data-collection burdens patients never agreed to, and that "no added clinical risk" is not the same as "no ethical cost" [21]. Outside the United States, empirical experience with EFIC-like waivers remains comparatively sparse: a study from Jordan examining exception from consent for emergency biomedical research found that the regulatory infrastructure for community consultation, well established in the U.S. framework, had few local analogues, forcing investigators to adapt safeguards designed for one health system and public-trust environment to a very different one [22]. Long before any of this recent literature, an early and still-cited critique of EFIC described researchers as "struggling with the rule," arguing that the regulation's procedural demands, however well-intentioned, could not fully substitute for what individual consent is meant to protect, and that this gap was a feature investigators would have to keep managing rather than a bug later guidance would eliminate [23].

CONCLUSION

No single consent mechanism reviewed here -- surrogate consent, deferred consent, or exception from informed consent with community consultation -- fully closes the gap between what individual informed consent is meant to protect and what emergency research actually requires to function. Surrogate consent preserves an individualized decision-maker but asks that person to exercise substituted judgment under acute distress and often without any prior indication of the patient's wishes about research. Deferred consent preserves a path to retrospective authorization but always carries some risk of having already enrolled a patient whose eventual decision-maker will decline. EFIC dispenses with individual authorization altogether in favor of a community-level substitute whose representativeness, on the evidence reviewed here, has not kept pace with the sophistication of the outreach methods used to conduct it. What the recent literature adds is less a solution than a clearer picture of where each mechanism's residual ethical cost actually sits, and a growing recognition that prompt, honest disclosure after the fact, whatever consent pathway was used, is doing more of the real ethical work than debates over which formal mechanism to select in advance.

DECLARATIONS

Acknowledgements

The authors are grateful to colleagues in their respective bioethics and clinical ethics departments for helpful discussion during the preparation of this review.

Funding

This review received no external funding.

Conflict of Interest

The authors declare no conflicts of interest relevant to this work.

Author Contributions

Erik Pedersen conceived the review and drafted the initial manuscript. Claire Novak performed the literature synthesis on deferred consent and community consultation and critically revised the manuscript. Lukas Larsen contributed the sections on surrogate consent and the enrolling clinician's role and provided final approval of the submitted version. All authors read and approved the final manuscript.

Ethics Statement

As a literature review synthesizing previously published, publicly available research and policy analysis, this article did not involve new data collection from human participants and did not require institutional ethics committee approval.

Data Availability

No new data were generated or analyzed for this review. All sources discussed are cited in the reference list and are publicly available through their respective publishers.

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