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Reasons for Not Participating in PCTs: The Comparative Case of Emergency Research under an Exception from Informed Consent (EFIC)

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additional risks and burdens to patients. Pragmatic research, given its central aim of replication in other settings, falls squarely under the purview of the IRB.

Morain and Largent (2023) raise an important question regarding the obligation of the investigator to patient-subjects involved in pragmatic research. How should one consider the responsibility of the PI in a study in which they may never see an individual participant during the course of the research? In thinking about the juxtaposition between QI/A activities and pragmatic research, we see a divergence here. The former is designed to improve patient care locally and with relative immediacy, so the ethical obligations of those conducting the QA/I activity seem fulfilled by the very intent of the activity. Pragmatic research, with its goal of generating new findings, seems to incur more of a duty to engage patient-subjects in some way. We believe keeping track of the data emanating from pragmatic research and sharing findings more broadly is a good start. The investigator might consider developing an effective mechanism to impart new information derived from pragmatic research, such as a publicly accessible research website or newsletters sent to the post-discharge patient community. Efforts such as these extend beyond journal publications, providing news of scientific gain to those who played a critical and not unwitting role in the effort to improve healthcare. We like to think of such activities as not so much obligatory as they are respectful to the patient community and the right thing to do.

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Reasons for Not Participating in PCTs: The Comparative Case of Emergency Research under an Exception from Informed Consent (EFIC)

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We read with great interest Garland, Morain and Sugarman's manuscript on the obligations of clinicians to participate in pragmatic clinical trials (PCTs) (Garland, Morain and Sugarman 2023). We believe a useful comparator is afforded by clinicians' obligations to participate in studies that utilize an exception from the informed consent (EFIC) mechanism. Below, we briefly describe EFIC studies, noting similarities with PCTs and how these similarities shed light on clinicians' moral obligations to participate in both types of studies. Similar to Garland's conclusions, we agree that it is important to properly characterize the set of acceptable

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reasons that clinicians might have against participating in particular PCTs or enrolling patients in specific EFIC studies. We do, however, take issue with their "four quadrant" arrangement of these reasons and offer a simpler categorization that can accommodate both (EFIC studies and PCTs) and better articulates how these reasons for nonparticipation can be justifiable.

The EFIC regulations were instituted in 1996 for the governance of emergency research which involves greater than minimal risk (Feldman, Hey, and Kesselheim 2018). The EFIC mechanism is intended to apply to clinical situations, such as major trauma, cardiac arrest, or other incapacitating circumstances, in which prospective research participants are unable to grant consent. Under the rules, the situation must be life-threatening, requiring immediate intervention, and there must be no standard treatment that could be used instead of an experimental intervention (Macklin and Cowan 2009). In many ways, EFIC studies are similar to PCTs. Both are embedded, to a great extent, in usual care settings. Both generally require at least some level of involvement of ordinary (non-research-focused) clinicians or other healthcare professionals. In both, individual patients are typically enrolled without formal written informed consent. In both situations, clinicians may be expected to participate or enroll patients as the "default". Importantly, concerns about enrolling patients in EFIC studies might look, on the face of it, to be different from objections to "participating" in PCTs. However, in both cases, without explicit informed consent from the patient, it is the clinician who decides whether the patients under their care will be enrolled in the particular study.

Perhaps the key difference between PCTs and EFIC studies lies in the highly fraught nature of the emergency setting where the patient is very often at significant, time-sensitive risk. This is not the case for most PCTs. In our view, this makes the emergency setting particularly helpful and serves to focus on the reasons that clinicians might have for not enrolling. It sharpens our appreciation of how we think about the clinician's obligations to participate in the research study but in a situation where the research is close to practice and there is a consent waiver in place.

Given these similarities and the salient focus of the emergency setting, it seems a clinician tasked with enrollment under EFIC could justifiably object to participation for a number of the reasons offered by Garland. In particular, in relation to preserving the "moral standing" of clinicians as individuals (p12) and their "rapport" and relationship with patients (p13) (Garland et al. 2023), we agree with Garland that we should be wary of getting to a situation where clinicians are just empty vessels doing the bidding of the research design without looking to the fiduciary relationship, clinical judgment or simply the caring intuition that might cause them to be concerned about their own and their patient's participation in certain cases. Many explanatory clinical trials give the researcher discretion to exclude a prospective research participant and are meant to allow some accommodation for the researcher's judgment about patient enrollment in a particular study. Similarly, we see no reason why ordinary clinicians with responsibility for conducting research interventions should not sometimes use their discretion to exclude a particular patient.

A second, somewhat parallel reason for concern about participation highlighted by EFIC as a comparator, is the potential burden of the research procedures on the ordinary clinician. While Garland and coauthors discuss this objection under non-moral personal objections we believe it more rightly fits under the heading of professional responsibility, and their reflections about how objections of conscience may be justifiable when they are based on professional judgment. Just like PCTs, EFIC studies, even though they are often embedded in standard practice, can involve procedures that are explicitly designed with research purposes in mind and which exist outside of standard clinical practice. While these procedures are needed to accurately assess the effect of the intervention they can impose increased burdens. If these burdens negatively impact the clinicians' ability to care for other patients, by being time-consuming for example, the clinician might rightly object to participating in such a trial based on their responsibilities to other patients. Equally, part of this professional responsibility includes attending to their own abilities and capacities: being too tired, pressured or lacking clinical confidence in a different or novel technique can all also be perfectly acceptable reasons for not being involved in an EFIC study.

These two sets of considerations—which we term patient-oriented considerations and professional responsibility considerations—we think capture the range of justifiable reasons for nonparticipation more simply than the four quadrant arrangement given by Garland. The first of these categories—patient-oriented considerations—captures the idea that concerns about participation or enrollment can legitimately involve judgments about the patient in front of the clinician and any aspects of the context of participation or the clinician-patient relationship which recommend against participation. This enriches and clarifies Garland's (personal) conscientious objection by aligning it directly with

judgements about clinical care and usefully does not require drawing a tricky distinction between moral and non-moral concerns. The judgment of an individual clinician about their patient's participation will draw on experience and values that are resistant to such a distinction.

This first set of patient-oriented considerations picks out the clinicians' responsibility both to know about good care for their patients and maintain a healthy clinician-patient relationship. Respectively this responsibility functions to weakly defend the obligation to participate (good care flows from the responsibility) and to defend an objection against participation (part of the responsibility is to avoid a breach of rapport or trust). This may seem incoherent, but it shows the importance of clinicians being able to exercise discretion about patient enrollment when a waiver of consent is applied. Participation may yield societal benefits which may flow to a clinician's patients but enrolling that particular patient might be the wrong decision.

All of this is consistent with suggestions made by Miller and Weijer about clinical equipoise. Although various decisions from institutions (clinical community, IRBs) may have judged participation in research to be permissible, this does not make it obligatory (Miller and Weijer 2006). A clinician's judgment is still required to specify the duty of care owed to the particular patient in a particular enrollment situation. To be clear, these kinds of reasons could be inwardly personalized (a matter of pure conscience perhaps) but are much more likely to be outwardly and contextually personalized, looking at the context and relationship between clinician and patient in order to make a judgment about whether the offer of participation should be made.

The second category of considerations, those tied to professional responsibility, rely on a similar set of trade-offs. As professionals working to deliver care to a collection of patients within a healthcare system both in the present and in the future, questions of burden and resourcing matter. Time and effort spent on one patient means less time for others. This category focuses on the professional environment, for example, other patients, the ability of the clinician to deliver time-sensitive care and the burden on the clinician or on the local system. As with patient-oriented considerations, the value of conducting research must be traded-off against the ability of the clinician to function properly as is professionally required in the healthcare system. They must give due regard to their own professional welfare and that of other patients. Sometimes at least, this can provide grounds for nonparticipation.

In sum, we believe the comparison with EFIC studies has been valuable for further elaborating Garland's set of reasons against the obligation to participate in PCTs. First, EFIC's setting highlights the relevance of context, clinician-patient relationship and professional responsibility to justifying acceptable reasons. Second, the comparison has revealed a novel, simpler way of arranging and exploring reasons—into patient-oriented or professional responsibility considerations. This arrangement is better able to articulate what matters in giving reasons than the four quadrants proposed by Garland et al.

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