The meaning of opt-out

In the June issue of Resuscitation, Nelson and colleagues\(^1\) determine attitudes and opinions of persons who, a priori, chose to opt out of an exception from informed consent (EFIC) cardiac arrest research trial. In order to opt out, a “no study” bracelet could be requested that expressed the wearer’s desire to not be included in the trial. A description of the mechanism to opt-out of the study was included within the public notification material developed to fulfil the EFIC requirements and was also described in pre-study community consultation activities. Medics had to ascertain the absence of an opt-out bracelet prior to enrolling a patient into the trial. Individuals who obtained opt-out bracelets were later interviewed to determine factors associated with their opt-out decision. The investigators hoped to characterize persons who opt out of EFIC studies and their concerns, so that future trials could specifically address these issues.

The investigators did a remarkable job fulfilling the requirements for EFIC studies. Community consultation included almost 300 individuals in 13 community presentations. Public notification was extensive, and potentially reached thousands of citizens; press releases were sent to several media outlets with widespread dissemination of study information into the local area by newspapers and radio reports. The IRB mandated that an opt-out option be included in material related to the study. At the end of 18 months, sixty opt-out bracelets were requested by 50 individuals, representing a very small number of community members from potentially thousands who had the opportunity to opt-out.

While most respondents valued emergency research, the majority of those who opted out (91%) did not approve of research enrollment without prospective informed consent. These individuals were concerned about the ethics of EFIC research, and their responses seemed to imply that they prioritized the rights of the individual over the needs of society. Smaller numbers of respondents related previous negative experiences with research, a preference not to be involved in research of any kind, and distrust of government or institutional sponsorship of, or involvement in, research. These same concerns have been found when other community attitudes about research have been gauged.\(^2,3\) A majority of respondents (71%) objected specifically to this cardiac arrest study, often due to misconceptions about the study or confusion that this EFIC trial would interfere with end-of-life preferences. A large number of responses were emotionally charged, inflammatory, or angry, suggesting significant distrust in the medical and scientific enterprise.

It appears that all persons requesting to opt out heard about the study through a media source used in public notification attempts, or by word of mouth. It is not stated whether any opt-out requests came from attendees of community consultation activities. The source of information that is available to inform decision-making by potential patient-subjects makes a difference when considering the meaning of opt-out.

When an individual has the opportunity to receive information, ask questions, and seek clarification, that individual most likely has the tools necessary to make an informed decision about their individual study inclusion or refusal of study participation. The degree of their understanding of complex research concepts may not be great, but understanding of the risks and benefits of the trial are essential for and should be included in this discussion. If these circumstances are met, the refusal to participate is likely informed and therefore expresses the considered opinion of the individual. The criteria for informed refusal may not need to be as stringent as that for informed consent.\(^4\) For example, the risks and benefits of study participation are easier to understand and evaluate than are the concepts of randomization or blinding; understanding the meaning of these research concepts will likely not impact the individual’s overall lack of comfort regarding study participation. However, to consent to be in a study in which the subject may or may not receive an experimental intervention (i.e. randomization) and in which no one knows (i.e. blinding), requires quite a bit of education. In any case, ‘informed’ implies that attempts have been made to be sure the necessary information is available to make a decision to refuse or accept study enrollment based on fact and not emotion.

EFIC is applied when it is not possible to adequately inform prior to study enrollment. If study circumstances require an exception from informed consent, for enrollment, they also do not allow for real time-informed refusal. When the EFIC regulations were developed, extra patient safeguards, including community consultation and public notification, were built in because the seriousness of acting without consent was understood. Community consultation aims for several things, including solicitation and consideration of community concerns about a particular research study, but practically, its major function may be to provide a means of showing respect for the communities involved in research.\(^5,6\) However, when community consultation is well done, informed refusal for participation in the specific study (i.e. opting out) is possible among those who have attended, asked questions, and considered their decisions based on their active interchange with the investigators.

Opt-out that occurs in response to a one way communication effort, such as by public notification, needs to be seen for what it truly is. It is not informed and thus cannot be used as a surrogate for community concerns about the research study or informed refusal. As suggested by Nelson et al., it may be an expression of preconceived ideas based on limited information, or a response to previous
negative experiences. The mandate to include an opt out option for an EFIC study does not signify reservations on the part of the investigator or the IRB; it is an acknowledgement that some may not be comfortable with the proposed research (or with the scientific endeavour in general).

Given that opt out is not a surrogate for informed refusal, and that public notification is a one way communication not meant to address complexities of research, what does opt out really mean? IRBs may mandate the opt out option in EFIC studies, but they do not require an explanation for why persons opt out. While community consultation has the potential to change the way a study is performed, it is not clear if opt out, especially as a result of a public notification, has much impact on the ethical considerations of research decision makers. Do the characteristics and attitudes of those very few potential subjects who opt out of an EFIC trial really matter? Do the reasons subjects opt out make any difference? Is understanding opt out a reasonable means to address the broader issues related to mistrust or misunderstanding of the research endeavour?

The results presented by Nelson et al., suggest that this information has value for investigators who apply EFIC. While we cannot reverse an individual’s prior experiences and perhaps not reverse preconceived opinions and attitudes, we can certainly benefit by understanding what has led to them and how we may attempt to address the concerns surrounding them. If opinions are strongly held but not based on facts, we have an opening for improving our educational efforts and acknowledging our differences of opinion. We need to accept the limited ability of public notification to truly inform, but we need to spend more time determining why people choose to opt out, regardless of how much information was available to them. If strongly held opinions are not at all changed regardless of our best education and convincing, we need to accept that some opinions are irreversible, some people are hostile towards and distrustful of research, and some will remain skeptical regardless of your effort. Opt out should never subvert the process of EFIC research.

Although we may not change the minds of the skeptical minority, listening to concerns of those who opt out, and studying this unique minority, as was done in this research, may enhance trust in the good faith effort of researchers to respect the public, and improve the image of the research enterprise in the minds of those who opt out of research.

**Conflict of interest statement**

The author has no conflict of interest related to this submission.

**References**


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