Implementation Science

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Ethical issues in implementation science: perspectives from a National Heart, Lung, and Blood Institute workshop

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Abstract

Ethical issues arise in the context of implementation science that may differ from those encountered in other research settings. This report, developed out of a workshop convened by the Center for Translation Research and Implementation Science within the United States National Heart, Lung, and Blood Institute, identifies six key themes that are important to the assessment of ethical dimensions of implementation science. First, addressing ethical challenges in implementation science does not require new ethical principles, commitments, or regulations. However, it does require understanding of the specific contexts arising in implementation research related to both study design and the intervention being implemented. Second, implementation research involves many different types of people in research, including patients, clinicians, administrators, the social networks of any of these, and the general population. These individuals play different roles that may entail different ethical considerations, obligations, and vulnerabilities. Third, the appropriateness of and need for informed consent in implementation research is connected to the role of the subject/participant, the nature of the intervention, and the design of the study. Even where traditional "full" consent processes are unnecessary or inappropriate, communication and engagement are critical. Similarly, even when research is exempt and informed consent unnecessary, Data Safety and Monitoring Board oversight of implementation studies may be advisable to ensure quality, address unexpected consequences, and identify overwhelming evidence of benefit. Fourth, implementation science is often explicitly designed to encourage specific behaviors and discourage others. There is a need for clarity regarding when efforts at behavioral change enhance or threaten autonomy and how to protect participants whose autonomy is threatened. Fifth, there is significant overlap between implementation science and quality improvement, and the ideal regulatory oversight structure for implementation science remains unclear. It is critical to encourage learning and growth while assuring appropriate protections. Sixth, implementation research takes place across a range of social and cultural contexts. Engagement

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and collaboration with stakeholders in designing and executing implementation trials and studies- especially when vulnerabilities exist- is essential. Attention to these themes will help ensure that implementation science fulfills its goal of advancing the practice of health care within a sound ethical framework.

Contributions to the literature

- Implementation science can raise ethical challenges that are distinct from other forms of clinical research and quality improvement.
- Implementation science does not require new ethical principles or commitments, but it does require understanding of specific contexts related to study design and interventions being implemented.
- This report, developed from an NHLBI-sponsored workshop, identifies six key areas that are important to assessing ethical dimensions of implementation science.
- This framework can facilitate assessment of individual studies, identify areas for further empirical evaluation, and clarify opportunities for development of consensus around oversight.

Background

In recent years, there has been growing recognition of the gap between the high-quality health care that should be available to people living in the United States and the care patients routinely receive. While clinical research has identified effective treatments and preventive interventions for many diseases, translating evidence into practice often lags far behind [1]. Diffusion of effective interventions into clinical practice often takes years, and numerous interventions are never successfully implemented. It has historically been estimated to take, on average, 17 years for new evidence-based findings to reach clinical practice, and newer estimates have not changed significantly [2, 3]. There are complexities related to how time lags are measured and multiple steps at which delays can occur [4]. It is clear, however, that implementation of evidence-based practices can be difficult, that accelerating implementation requires its own evidence base, and that implementation science addresses an important gap. As illustrated in the context of the coronavirus pandemic, implementing an effective vaccine on a population level poses substantial challenges that differ from initial development, discovery, and testing [5, 6]. This disease and its vaccine are relatively new; effective interventions for conditions such as diabetes and hypertension have existed for many years but are still sub-optimally utilized.

Implementation science can be broadly defined as the scientific field dedicated to developing generalizable knowledge "to promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings" [7]. The National Institutes of Health (NIH) and other federal agencies have recognized the essential role implementation science plays in the translational research pipeline [8, 9]. As such, major funders of research have begun to invest in research in this domain, training opportunities and curricula to develop scholars in this field, and efforts to integrate implementation science into quality improvement and outcomes research as part of learning health systems [10, 11].

With the rise of implementation science as a research field has come the growing recognition of associated ethical challenges that warrant attention [12–14]. Existing frameworks for clinical research ethics, and biomedical ethics in general, have predominantly focused on research evaluating new treatments and devices. Because implementation research generally evaluates how best to introduce interventions for which evidence of efficacy and potentially effectiveness already exists into ongoing clinical care and public health practice, many of the key ethical concerns of traditional research ethics may be less salient. For example, there are fewer unknown medical risks or invasive assessments in most implementation science studies. In contrast, considerations related to demarcating clinical care from research and providing opportunities to decline participation may become more complex. To clarify the range of ethical challenges in implementation science and to identify a practical path forward for addressing them, the Center for Translation Research and Implementation Science (CTRIS) within the NIH National Heart, Lung, and Blood Institute (NHLBI) convened a workshop in December 2020 to bring together experts in ethics and implementation science. During the workshop, key stakeholders gave short presentations on selected topics followed by iterative discussion among the workshop panel. The idea for this workshop grew out of a prior NHLBI-supported meeting that highlighted the lack of alignment between current approaches to research ethics and the goals and real-world context of implementation science [15].

This report distills six key themes from the workshop (Table 1) and identifies a set of practical steps and empirically addressable questions to guide progress. For example, research identifying the impact of various implementation studies on key stakeholders and participants can help

Table 1 Key themes

Underlying Ethical Principles	*Implementation science does not require new ethical principles but requires attention to context*
Heterogeneous Study Populations	*Different types of people play different roles as subjects or participants in research. Healthcare workers, community members, and patients may have fundamentally different relationships to research*
Informed Consent	*Individual informed consent is often not necessary or may be inappropriate, but communication matters and is not limited to formal consent processes*
Autonomy and Behavior Change	*Implementation studies designed to encourage evidence-based behaviors through manipulation of choice architecture require clarity about the extent to which autonomy is threatened or promoted in different contexts*
Social and Cultural Context	*Attention to social and cultural context is essential*
Oversight and Protection	*The ideal oversight structure must promote research while providing appropriate protections*

identify which strategies related to consent and communication maximize both respect and knowledge production, and it can illuminate what behavior modification strategies advance versus undermine autonomy. Exploration of various models of oversight within the federal regulations may help to identify best practices. For example, clarifying the role of data safety and monitoring boards (DSMBs), institutional review boards (IRBs), and other oversight mechanisms in studies exploring efficacious and effective interventions is critical [16]. Systematic efforts to identify areas of consensus and optimal practice are important. In this report, we discuss each of these themes with an eye toward identifying both unanswered questions and practical solutions.

Implementation science does not require new ethical principles but requires attention to context

Implementation science does not generally challenge *principles* of research ethics as outlined in documents such as the Belmont Report, which emphasize respect for persons, beneficence, and justice as cornerstones of ethical research [17]. However, implementation science does represent a different research paradigm in which these principles must be interpreted and applied. Implementation studies, for example, often utilize designs other than individual participant-level randomization, but they often assess outcomes at the individual participant level. System-level interventions and cluster-level assignment introduce practical and scientific constraints related to informed consent, which has historically been a key way in which the Belmont principle of respect for persons is put into practice [18]. Conducting such studies without prospective informed consent (where appropriate) is not a statement that respect for autonomy is irrelevant or unimportant. Rather, it is an acknowledgement that the autonomy interests of patients may have different weight in the context of approved medicines as opposed to experimental ones and a recognition that countervailing ethical considerations related to social value, scientific rigor, and professional responsibility may make it acceptable and necessary to do the study without consent. Implementation studies also typically evaluate interventions whose benefits are known to outweigh risks. This has important implications regarding obligations of beneficence and justice, since patients in general, and disadvantaged groups in particular, may stand to directly benefit from the research, especially when there are disparities in adoption of efficacious interventions. Careful and independent evaluation of risks and benefits of a proposed study remains essential, and existing ethical and regulatory frameworks can accommodate such balancing of competing ethical considerations. Yet the setting is different, and approaching an implementation study as if it were evaluating an experimental drug or device may be inappropriate and counter-productive.

One ethically important feature of implementation science is its critical role in optimizing health system quality and population-level outcomes. Patients, clinicians, health care administrators, and health policymakers are all participants in the healthcare system, and they have a shared interest in optimizing how the system functions to improve health. In this context, these stakeholders have a special reason or even responsibility to participate in improving the system through implementation research [19]. Similar arguments regarding obligations of participation have been made regarding other types of clinical research as well (especially when risks are low), [20] but it is particularly widely accepted in the context of quality improvement [21]. The fact that implementation science sits at the border between clinical research and quality improvement raises novel challenges, particularly from a regulatory perspective (discussed below). It is important to ensure that any regulatory structure avoids disincentivizing production of generalizable knowledge by overemphasizing an implementation study's risks relative to its benefits.

Another reason to avoid making categorical ethical distinctions between implementation science and other research activities is the heterogeneity of implementation science itself. Interventions differ, for example, in whether they are targeted toward clinicians or patients

and whether they are focused on care of individual patients versus system-level practices. Some interventions may profoundly alter patterns of care and individual patients' daily experiences, while others may be imperceptible. Interventions to be implemented and studied also have varying levels of evidentiary support. While interventions should generally not be implemented within routine health care settings if they are not known to be efficacious, efficacy cannot be judged in a vacuum. The real-world effectiveness of an intervention often depends substantially on how an intervention is implemented and the setting in which it is used. The goal of implementation studies is precisely to study the impact, "reach," and sustainability of various implementation strategies on the desired outcome within particular settings. In addition, implementation elements are increasingly incorporated into more traditional efficacy studies and pragmatic trials given the important recognition of the inter-connectedness between efficacy and implementation and profound limitations of efficacy evidence alone [22]. The growth of hybrid implementation-effectiveness studies is a positive and important trend, but it underscores the importance of addressing ethically relevant features of all aspects of a study and the context in which it is performed.

Different research participants play different roles

While the majority of clinical research involves patients as participants, implementation studies commonly involve non-patients. Interventions are often directed toward clinicians, with the behaviors of those individuals as the focus (Table 2). In clinical implementation studies, outcomes may be assessed among health care workers (HCWs), patients, or other populations, all of whom may at times plausibly be considered to be human subjects according to the United States Code of Federal Regulations [23]. Yet, these different populations may have different relationships to the underlying study. This complicates even the choice of whether to describe involved individuals as participants or subjects. For this reason, we use the term "participant" frequently within this manuscript but acknowledge that the term "subject" is more appropriate in instances where individuals being studied do not have a choice about whether to participate.

HCWs introduce an importantly different set of considerations than patients when they are subjects of implementation studies. They are employees and may have little ability to opt out of an intervention. However, employment implies a certain commitment to doing a job well and to making the "system" work by delivering effective patient care. In some cases, HCW's may benefit directly from participating because they are gaining tools to fulfill their responsibilities; HCWs may also have a responsibility as part of their employment to engage in efforts to improve quality of care, even when those efforts do not benefit HCWs. In contrast, patients primarily seek medical care to advance *their* medical interests and generally have the option to receive or not to receive care or particular components of care. The potential for direct benefit may at times be more apparent for patients than HCW, but patients also may have limited obligations to be involved in implementation studies by virtue of being a participant in a healthcare system. In these respects, the role of patient and HCW are highly contextual.

When HCWs are included in studies, implementation science researchers may need to define which activities are "part of the job" and what activities are more independent from employment and primarily research. Use of care protocols or receipt of continuing education, for example, may raise few questions, as they are clearly within the purview of systems to require. Studies of these types of activities typically will not require informed consent. However, studies that involve performing categorically different or new activities (e.g., participation in wellness programs or team-building exercises) may be less straightforward and require more careful consideration of whether consent is necessary and whether HCWs should have the ability to opt-out. Similarly, tracking hand hygiene behavior in the context of a study testing strategies for encouraging hand hygiene raises few concerns, because job performance is routinely monitored, hand hygiene is already expected of all HCWs, and the institution is expected to optimize performance. However, video recording of clinical encounters in the context of a study implementing a new outpatient checklist for medication reconciliation would involve a procedure that is not routinely part of employment, may only be done

Table 2 Implementation science examples

Study	Key Features
Routine use of a decision aid for implantable cardioverter defibrillator implantation	Intervention focused on individual patient care
Reminders for colonoscopy	System-level intervention for individual patient care decisions
Clinical decision support for mechanical ventilation	System-level intervention directed at clinicians
Hand hygiene efforts	System-level intervention directed at all staff

for research purposes, and may introduce vulnerabilities or potential for repercussions that warrant additional protections. All of these activities introduce some level of risk, but not necessarily new risk over and above that inherent in an individual's job. At the most practical level, guidance could be helpful to provide clarity and uniformity regarding the kinds of activities for which acceptance can be considered to be "implied" by taking a job (for which separate consent is not likely necessary) as compared with activities that are more separable or introduce different risks. Separate consent is ethically more important with the latter category. Independent of consent, it would be valuable to develop evidence and guidance regarding what sorts of communication strategies, including transparency about ongoing learning activities, help to advance respect for and trust among HCWs.

While the roles of patient and HCW have different contours, patients may also have limited responsibility to be included in some implementation science studies. To the extent that such obligations exist, they are grounded in being a participant in the healthcare system and having a shared interest in high-quality clinical care that can only be advanced through learning activities that include implementation research regarding evidence-based therapies [20, 24, 25]. These obligations are more likely present and may carry more weight in contexts where research involves minimal or no net risks and where the trajectory of patients' care is not altered. Implementation studies that impact the trajectory of care in important ways (whether through choice of treatment of other processes of care), or that pose risks to patients, are difficult to justify simply as part of clinical care, which is ethically intended to be based primarily on patients' medical interests [26, 27]. Determining the boundaries of these obligations is complex and necessarily involves careful consideration of historic mistreatment and disadvantage, particularly given past patterns of performing research on disadvantaged or marginalized communities without consent. The extent and manner in which the priorities, goals, and activities related to implementation research are made clear to patients is a key factor in these determinations. Organizations, for example, that highlight and communicate in a transparent manner to patients their role as a "learning health system" may be justified in assuming some level of "buy-in" on the part of patients that may not be present when these priorities are less transparent.

Communication is important, even when informed consent is not necessary

A major question in implementation science research has been when or whether there is a need for informed consent. While informed consent is typically expected in most clinical research- consistent with respect for persons- it is not a universal requirement in clinical research. In implementation science, there are often important reasons why it is not needed [28]. For example, federal regulations allow consideration of waivers or alterations of consent when research studies present no more than minimal risks, and implementation science often poses minimal risks because it involves studying the use of evidence-based treatments [23]. Additionally, many implementation studies do not directly impact the experience of healthcare for patients, particularly when they affect a domain in which patients typically are not involved in making decisions. For example, whether clinicians utilize a procedural checklist is not something about which patients expect to make decisions, and what types of reminders clinicians may receive to wash their hands is not typically within the purview of patients. In addition to these ethical reasons that may modulate the need for consent, practical considerations exist. Many implementation science studies can only be carried out at a system or site-level. It may not be possible to seek prospective consent from every patient whose care is affected or to offer an alternative for patients who might refuse enrollment in a study with site-based allocation.

There is not a "one size fits all" answer to the circumstances in which consent is required and when it can be waived in implementation science. Rather, the appropriateness of and need for consent is heavily connected to the particulars: the role of the subject; the nature of the intervention with respect to evidence, the level of burden and risk; the practicality of prospective consent and availability of alternatives; the coherence of the study with the system's stated goals to patients; and the design of the study. Perhaps the most important considerations regarding the need for consent by patients are the extent to which the study impacts the patient's care or trajectory of care- specifically risks, benefits, and burdens- and whether it involves activities that lie within the range of what would otherwise be expected, activities about which patients would typically expect to make decisions, or activities that have been disclosed [29]. The simple act of randomization, for example, should not be the primary deciding factor regarding the need for consent. What matters most is the set of risks entailed and preferences impacted by the intervention or process to which a subject is randomized. Similarly, when subjects are not patients but HCWs or other individuals within the system, the extent to which study activities or interventions expose HCWs to risks and the extent to which they fall within the scope of normal duties are major determinants of the need for consent.

It is also important to recognize that involvement or engagement with research subjects in enrollment decisions is not an all or none process; traditional, written research

consent is not the only way to support autonomy and show respect for persons. For example, use of opt-out mechanisms, assent processes, and post-randomization consent (Zelen consent) can all advance key functions of consent even if they do not meet criteria for traditional "full" consent or do not involve all patients equally. Related, disclosures about ongoing learning commitments of a health system and the types of projects that support that learning in understandable, transparent ways also can demonstrate respect to patients [30]. Ultimately, when research involves no more than minimal risks, U.S. regulations permit both alterations and waivers of consent under certain criteria, though it should be noted that there is not clear consensus on how to determine or to assess the impact of research on the "rights and welfare" of patients. In addition, alterations and waivers are ethically very distinct [31–33]. Alterations to consent may advance important ethical functions in a way that waivers do not. Similarly, communication about studies pre and post enrollment should not be conflated with consent. Even when there are no options for refusing participation, communicating with affected populations about studies in which they may be involved and routine disclosure of general or system-level commitments to research (including processes such as randomization) may serve important goals related to transparency, trust, and respect [18, 34, 35].

Studies designed to change behaviors through manipulation of choice architecture require clarity about the impact on autonomy

A common focus of implementation science is behavior change. Specifically, interventions are often designed to encourage utilization of tools or strategies with demonstrated effectiveness. In recognition that there are numerous reasons for failure to implement or use evidence-based strategies, and that many deviations from evidence-based practice may not be grounded in reasoned objection to those practices, there has been growing interest in and utilization of tools grounded in principles of behavioral economics and decision psychology to improve implementation. Examples may include providing incentives or utilizing other nudge strategies (e.g., changing default options) in order to create a different choice architecture (the way in which decisions are presented, structured, or framed) that encourages evidence-based behavior [36, 37]. These tools can be directed toward HCWs or patients.

There has been substantial debate about the ethical acceptability of manipulations of choice architecture, especially the extent to which they are or are not compatible with respect for autonomy [38–40]. Several key considerations may impact the extent to which these manipulations or interventions raise concern. First, there is a spectrum of "control" or influence. As is recognized by the Nuffield Council on Bioethics "Intervention Ladder" and other categorization systems, use of injunctive norms and defaults, for example, involve less control than imposition of penalties for non-adherence and may vary importantly in the extent to which they are transparent [41, 42]. Second, it must be recognized that implementation science studies are typically designed to increase uptake or use of interventions that are known to be effective, many of which have been recommended or expected to be implemented in the settings in which the implementation science project is occurring [43]; these are not interventions to which most people object, and choice architecture to promote their use generally aligns with autonomous wishes rather than contradicting them. In fact, to the extent that strategies facilitate uptake of evidence-based treatments that might otherwise not be utilized and do not contravene well-reasoned decisions that differ, these strategies may well serve to *promote* autonomy by expanding or facilitating use of easily available options [41]. Third, the notion that any choice architecture is neutral may in fact be a myth. All "default" settings represent the choice- whether explicit or not- of some actor or actors to start with. There are numerous constraints or influences on clinicians' actions at baseline (e.g. medication formulary), and some form of choice architecture is often unavoidable. In those cases, the issue is not *whether* a certain choice is promoted but *which* choice is promoted and, in some circumstances, *by whom*.

Implementation strategies testing various forms of choice architecture are important, and ethical evaluation of these strategies is necessary. Key factors include careful oversight, clarification of the values underlying the strategies, assessment of *whose* values are being prioritized and advanced, and attention to the extent to which autonomy is or is not impacted. In addition, evaluation of the experiences of individuals affected by the behavioral intervention, as well as the impact and sustainability of the intervention on key outcomes, are important.

Attention to social and cultural context is essential

Like medical care and clinical research more generally, implementation research takes place across a wide variety of social and cultural contexts. Careful engagement of and collaboration with key stakeholders, particularly marginalized populations, in designing and executing implementation studies- especially when significant vulnerabilities exist- is essential to produce high-quality, ethical research. There are several specific ways in which attention to social and cultural context is particularly important.

First, implementation research has enormous potential to address health disparities and vulnerability through

enhancing delivery and access to evidence-based care for historically disadvantaged populations. However, populations characterized by poor access and poor-quality care may also harbor mistrust of healthcare institutions, clinicians, or research, often for appropriate reasons such as past abuse. Issues related to consent, transparency, and communication may thus take on special salience as the responsibility to demonstrate trustworthiness is heightened. There is a need for greater understanding of the extent to which implementation studies do or do not raise concerns among stakeholders. Related, it is important to develop an evidence base and best practices for effective and authentic communication and engagement regarding both the need for implementation science and its potential to help address disparities. It is especially important to ensure that engagement strategies include populations characterized by vulnerability or disparities.

Second, and closely related, engagement of stakeholder communities impacted by research is both ethically important and practically valuable. At the simplest level, involvement of communities- which may include patients, HCWs, or the broader public in various contexts- can help investigators to operationalize and execute studies in efficient and respectful ways. At a deeper level, robust engagement can be valuable in setting research priorities and developing strategies for recruitment and inclusion that come *from* the impacted community as opposed to being imposed on them. Community-based participatory research and human-centered design methods may be useful in this context, and these approaches are closely aligned with core principles of implementation science- which is rooted in context-sensitivity- in the first place [44]. Recent experience with vaccine rollout for COVID-19 has reinforced the importance of clear communication, robust and longitudinal engagement, commitment to building relationships, and identification of key stakeholders. An important component of any engagement strategy is also the recognition of limitations in health literacy. Many of the communities with whom communication and establishment of trustworthiness is most essential are categorized by substantial gaps in health literacy and numeracy; effective communication must account for and be sensitive to these challenges.

Third, an essential component of implementation research is a commitment to sustainability. Effective engagement of community stakeholders and appreciation of the real social and cultural contexts in which interventions will be implemented is essential to ensuring that key interests are advanced in a sustainable way. This includes, for example, working with facility and program directors, public health agencies, and policy makers. Like informed consent, engagement is not a box to be checked once; it is an ongoing process that requires effort to nurture and sustain.

The ideal oversight structure should promote research while providing appropriate protections

Implementation science raises challenges regarding appropriate regulatory or oversight structures, in part because it sits at the border between clinical and public health research, quality improvement, and program evaluation. The distinctions can be unclear but have important implications, and ambiguity about oversight can pose challenges. In particular, individuals and institutions may have incentives to categorize implementation science as quality improvement as opposed to research, because the quality improvement designation may allow investigators to avoid the requirement for IRB review and other oversight. This is problematic for at least two reasons. First, it may lead researchers to alter their implementation study designs in ways that reduce scientific rigor to avoid the regulatory burdens posed by IRB oversight without meaningfully reducing risk to participants. Use of strategies such as randomization, for example, may be eschewed in favor of less robust observational designs, leading to suboptimal science with no increase in protection, especially when randomized designs do not increase risks. Second, when studies are considered quality improvement, there may not be a mechanism for independent oversight of potential risks and other human subjects protection issues. To the degree that these activities do threaten autonomy or introduce risk, these issues should be properly weighed and the activities monitored in a way that minimizes potential harm. Many health care providers that conduct quality improvement may lack the necessary structures to ensure appropriate protections. Creative solutions are needed that are flexible to assess activities that sit at the intersection between implementation science and quality improvement, and we encourage institutions to share innovative approaches and models.

While re-design of learning activities to avoid a research designation may reduce the value of the project and obscure the important learning goal without adding protection for patients or subjects, the current oversight process for clinical research may also lack necessary tools. IRBs are typically over-burdened and often unfamiliar with implementation science; standards for other clinical research may not translate well to work designed to encourage uptake of evidence-based approaches. Expectations for consent and communication in implementation studies, as noted above, may be very different, as may considerations related to involvement of staff in research. Oversight challenges can also extend to DSMBs or other committees who are tasked with monitoring studies for safety. There may be a need to incorporate expertise related to system-level impact or economic impact on committees charged with overseeing IS studies, for example. These are not skill sets that

are routinely prioritized in DSMB construction. In addition, approaches to interim analysis and stopping boundaries may differ due to the type of outcome data being collected and timeframe in which those data are available. DSMBs may thus play a more significant role in some implementation studies than they do in others [16]. Their role is highly contextual, and models such as "co-design" may help to tailor approaches to specific studies [45]. While safety monitoring committees such as DSMBs may enhance oversight for many implementation science studies, they are unlikely to be in a position to assume many of the roles traditionally assigned to IRBs.

A closely related priority to oversight is attention to incentives and to potential conflicts of interests. This is an important set of issues for all types of research; however, it has special salience in contexts where there are intentional constructions of choice architecture and alterations or waiver of informed consent. Careful assessment of strategies for communication with relevant stakeholders regarding the rationale for intervention design, choice of intervention, and other considerations is particularly essential.

In summary, there is a clear need to optimize and equip the oversight structure to incentivize learning and growth while assuring appropriate protections, transparency, and trustworthiness. Few effective models of institutional oversight of implementation science are available at present, and development of innovative approaches (ideally involving multiple stakeholders, ensuring appropriate community and patient engagement, and integration with DSMB functions) is an important priority.

Conclusions

The above set of ethical priorities can help to guide implementation science, but three additional steps will be important in moving these priorities forward. First, there are a number of questions that are amenable to empirical investigation and for which robust data can help to ground optimal approaches. For example, evaluation of the impact of various processes for consent and communication for different types of subjects and stakeholders in various study designs may be helpful in determining the extent to which they advance functions of consent and enhance respect. Some formative work has been done to guide approaches, but it would be ideal to assess different strategies within actual implementation studies so that assessments of likely impact are not speculative. Second, deeper understanding of key stakeholders' perspectives on different manipulations of choice architecture would be valuable. Third, efforts should be encouraged to develop consensus standards regarding optimal regulatory and oversight approaches to implementation science and, more specifically, of different categories of implementation science projects. This may be stimulated by the increased, and required, use of single IRBs to oversee multisite projects. However, there is a need for reporting, description, and assessment of institutional mechanisms to provide oversight of studies that straddle the border between quality improvement and research and that promote development of high-quality implementation data. Finally, it will be important to recognize that many clinical trials are increasingly incorporating implementation elements, particularly pragmatic effectiveness trials. This is a significant positive trend. It will be important to apply lessons learned and approaches developed within implementation science to this broader landscape as well.

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