

Navigating Clinician-Researchers' Duties in Decentralized Clinical Trials

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Article abstract

Decentralized clinical trials (DCTs) are clinical trials in which some or all trial-related procedures take place outside traditional clinical trial sites. Digital technologies have played an important role in enabling the remote conduct of clinical trials, and it is anticipated that many clinical trials will adopt full or hybrid decentralized models. While DCTs present many benefits and opportunities to streamline and improve the conduct of clinical trials, there are also several challenges in their implementation. These include privacy and confidentiality risks, challenges in trial oversight and monitoring, digital literacy, and participant compliance. To address these challenges, it is essential to clarify the ethico-legal duties of clinician-researchers, who are responsible for the overall conduct of clinical trials. This article analyzes these duties and identifies key factors needed to support the adoption of DCTs while safeguarding participants' health, safety, and well-being.



ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Navigating Clinician-Researchers' Duties in Decentralized Clinical Trials

Dimitri Patrinos^{a,b}, Ma'n H. Zawati^a

Résumé

Les essais cliniques décentralisés (ECD) sont des essais cliniques dans lesquels certaines ou toutes les procédures liées à l'essai se déroulent en dehors des sites d'essais cliniques traditionnels. Les technologies numériques ont joué un rôle important dans la mise en place d'essais cliniques à distance et il est prévu que de nombreux essais cliniques adoptent des modèles décentralisés complets ou hybrides. Si les ECD présentent de nombreux avantages et opportunités pour rationaliser et améliorer la conduite des essais cliniques, leur mise en œuvre pose également plusieurs défis. Il s'agit notamment des risques liés à la vie privée et à la confidentialité, des défis liés à la supervision et au suivi des essais, ainsi que de la culture numérique et de la conformité des participants. Pour relever ces défis, il est essentiel de clarifier les obligations éthiques et juridiques des cliniciens-chercheurs, qui sont responsables de la conduite globale des essais cliniques. Cet article analyse ces obligations et identifie les facteurs clés qui devront être pris en compte pour faciliter l'adoption des ECD tout en garantissant la protection de la santé, de la sécurité et du bien-être des participants.

Mots-clés

devoirs des cliniciens, essais cliniques décentralisés, consentement éclairé, confidentialité et respect de la vie privée, surveillance à distance

Abstract

Decentralized clinical trials (DCTs) are clinical trials in which some or all trial-related procedures take place outside traditional clinical trial sites. Digital technologies have played an important role in enabling the remote conduct of clinical trials, and it is anticipated that many clinical trials will adopt full or hybrid decentralized models. While DCTs present many benefits and opportunities to streamline and improve the conduct of clinical trials, there are also several challenges in their implementation. These include privacy and confidentiality risks, challenges in trial oversight and monitoring, digital literacy, and participant compliance. To address these challenges, it is essential to clarify the ethico-legal duties of clinician-researchers, who are responsible for the overall conduct of clinical trials. This article analyzes these duties and identifies key factors needed to support the adoption of DCTs while safeguarding participants' health, safety, and well-being.

Keywords

clinician duties, decentralized clinical trials, informed consent, privacy and confidentiality, remote monitoring

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INTRODUCTION

Since the COVID-19 pandemic, the integration of technology into healthcare has increased dramatically. Faced with a rapidly spreading virus and the need for physical distancing, healthcare institutions across the globe adopted technologies to adapt to the key challenge of the pandemic to continue patient care while adhering to public health guidelines. For instance, telehealth involving the remote provision of healthcare services has experienced an unprecedented surge in use (1,2). Patients and healthcare providers alike adopted video consultations, online symptom checkers, and remote monitoring devices to ensure continuity of care when minimizing in-person contact. Furthermore, digital tools played a crucial role in contact tracing efforts, enabling the identification and tracking of potential COVID-19 exposures (3).

In addition to the clinical setting, technological innovations have been increasingly employed in research settings (4). The pandemic presented many challenges to clinical research, such as reduction of face-to-face study visits and delays in data collection and reporting (5). These constraints resulted in many research institutions suspending nearly all in-person interactions (6). Clinical trials were greatly affected by the pandemic, with sharp declines in participant enrollment and significant difficulties in conducting study procedures (7,8). Many sponsors, institutions, and contract research organizations (CROs) either delayed clinical trial initiation, suspended enrollment, or terminated their clinical trials altogether (9). Clinical trials are a fundamental tool in evaluating the safety and efficacy of new drugs, medical devices, and health system interventions in human participants (6). Given the need to continue clinical trials during the pandemic, a paradigm shift was required in their design and execution.

Digital technologies have featured prominently in this shift. Research teams and institutions began to conduct clinical trials remotely, in part or in full, using digital health technologies (DHTs) and other tools to facilitate research without physical contact between participants and the research team. Generally referred to as decentralized clinical trials (DCTs), these trials use digital tools and remote monitoring to allow participants to engage in trial activities from their homes, reducing the need for in-person

visits. Activities that can be done remotely in DCTs include informed consent procedures, participant monitoring, home study visits, and sending investigational products, such as medications and wearable health devices, to participants' homes (10).

DCTs are not a recent phenomenon. The use of decentralization in clinical trials dates back to the 1980s, when mail-based methods began to be used for randomized clinical trials (11). In 2011, Pfizer conducted the first fully decentralized clinical trial, the REMOTE trial (12). REMOTE was a randomized, placebo-controlled, Phase 4 clinical trial that assessed the safety and efficacy of Detrol LA, a treatment for overactive bladder (12). The study included adult women in the United States who had experienced symptoms of overactive bladder for at least 3 months and had regular Internet access (12). It employed web-based digital technologies throughout the study cycle, from recruitment and informed consent to data collection (12). Additionally, study drugs were delivered to participants' homes via courier (12). While the study was terminated early due to inadequate enrolment — only 18 participants were recruited — REMOTE demonstrated the potential for DCTs to be successfully conducted within the framework of regulatory oversight and ethics approval. Furthermore, the lessons learned from REMOTE offered critical insights to help inform the design and development of future DCTs (12).

Despite growing interest in DCTs following REMOTE (13), uptake of decentralization was slow, mainly due to administrative, regulatory, and bureaucratic barriers compounded by high operational costs for both sponsor and site alike (7). Absent regulatory guidance on conducting DCTs also led to resistance in adoption (14). Regulatory bodies responsible for the oversight of clinical trials issued guidelines on the remote conduct of clinical trials to encourage continued trial conduct for those sites able to operationalize labour and resource redistribution outside brick-and-mortar settings (15-17).

Post-pandemic, researchers, institutions, sponsors, governmental institutions, and non-governmental organizations (NGOs) have retained interest in decentralization as a long-term possibility for clinical trials (6,18). In 2020, the Decentralized Trials and Research Alliance (DTRA), a non-governmental, not-for-profit organization in the US, was founded to expand awareness and advocacy surrounding the use of decentralized technologies in clinical trials and research (19). The Multi-Regional Clinical Trials (MRCT) Center, a policy and research centre associated with Brigham and Women's Hospital and Harvard University dedicated to promoting safe and ethical clinical trials, also works to address issues in the oversight and conduct of DCTs (20). In 2021, the Ministry of Economy, Innovation and Energy in Quebec, Canada, funded a large-scale, multi-institutional initiative to develop a digital platform for conducting fully remote clinical trials without the need for any in-person visits (21).

Although the use of DCTs is growing, they raise several challenges that require attention. For one, they raise important ethical issues, such as informed consent, participant safety, and privacy and confidentiality (10). There are also regulatory factors, such as compliance with privacy legislation and clinical trials regulations, that must be considered in DCTs (10,22). A growing body of literature has addressed the ethical and regulatory considerations raised by DCTs (10). However, there is one issue regarding DCTs that has yet to be fully explored: the nature and scope of clinician-researchers' duties.

Clinician-researchers are responsible for the overall conduct of a clinical trial (23). It is therefore important to clarify how their duties are engaged when the clinical trial is decentralized. Several of the challenges presented in DCTs may necessitate changes to the traditional way that trials are conducted in order for clinician-researchers to fulfill their duties. For instance, while all research requires the implementation of measures to protect participants' privacy and confidentiality, the use of digital devices in DCTs, such as wearables or mobile applications, may require additional safeguards or protections (24).

Insufficient understanding of the scope and content of clinician-researchers' duties in DCTs may prevent DCTs from realizing their full potential. Maintaining high standards of care, improving trial efficiency, and protecting patient safety all depend on clinician-researchers' understanding of the nature and extent of their responsibilities. Better-defined roles can help facilitate efficient use of DCT technologies while still ensuring regulatory compliance and ethical integrity. This article aims to address the existing gap in the literature by analyzing the scope of clinician-researcher duties within the DCT setting.

It is important to note here there is variation in the degree to which different components of a clinical trial are decentralized. Some DCTs may adopt a fully decentralized model, whereas others may employ a hybrid approach, with both decentralized and in-person elements. Different forms of decentralization can include electronic consent, remote recruitment through social media, virtual visits with members of the research team, and the use of digital devices for data collection (20). The use of digital devices, however, is not unique to DCTs; indeed, many in-person clinical trials are using digital devices as part of their protocols. Nevertheless, given their important role in enabling decentralization, our focus in this article will be on the use of digital devices in DCTs, particularly for informed consent and data collection and storage purposes.

In Section I, we outline some of the potential benefits and opportunities of DCTs, as described in the literature. In Section II, we discuss the key challenges raised by the use of DCTs, specifically privacy and confidentiality, safety monitoring, digital literacy, and participant compliance. While many of these challenges are already present in traditional in-person trials, decentralization can change the scope and nature of these challenges.

In Section III, we turn to the ethical and legal duties of clinician-researchers in the conduct of clinical trials. We consider the ethical duties of clinician-researchers as outlined in both Canadian and international research ethics guidelines, including the Declaration of Helsinki, Canada's Tri-Council Policy Statement (TCPS2), and the Guidelines for Good Clinical Practice (GCP), the latter of which establishes guidelines and best practice principles specific to clinical trials. In discussing the legal duties of clinician-researchers, we focus on Canadian law, which encompasses both the common law used by the Anglo-Canadian

provinces and the civil law used in the province of Quebec. Under both legal traditions, clinicians have legal and ethical duties, and these are largely similar between the two systems. We consider the unique position of clinician-researchers, whose ethico-legal duties encompass both clinical care and research but which have differing primary goals.

Subsequently, in Section IV we present key points to consider for DCTs, focusing on four specific clinician-researcher duties: to obtain informed consent from participants (the duty to inform); to maintain participant confidentiality (professional secrecy); to provide detailed instructions to participants concerning the completion of study procedures (the duty to instruct); and to maintain regular channels of communication with participants (the duty to follow up). While many other duties are relevant to the conduct of DCTs, we have chosen to focus on these four because, in our view, they are crucial to ensuring the integrity of DCTs and the protection of the rights and welfare of participants.

I. POTENTIAL BENEFITS AND OPPORTUNITIES OF DCTS

DCTs promise to be an important addition to the clinical trial ecosystem, providing many potential benefits, such as increasing flexibility in study participation, increasing diversity of study populations, and improving recruitment and retention of participants. Indeed, traditional clinical trials often face problems of insufficient patient recruitment, limited participant diversity, low participant retention, high costs, and other logistical challenges (25). By transferring the completion of study procedures from clinical sites to participants' homes, DCTs present an opportunity to address these challenges.

Nevertheless, there is limited empirical data on the purported benefits of DCTs (26). Furthermore, many of the purported benefits raise concurrent burdens and risks. Sugarman and Vayena (26), for instance, cite the example of remote monitoring, noting that while it may enhance data collection efficiency in some contexts, it can also entail a greater time commitment for some participants compared to traditional clinical trials. Moreover, many of the potential benefits of DCTs also depend on the specific study design (26). Lastly, not all clinical trials are amenable to decentralization, either fully or partially.

One of the purported benefits of DCTs discussed in the literature is their potential to “democratize clinical research” by providing access to individuals who would otherwise have been unable to participate due to geographical factors (27). Geographic accessibility has long been identified as a major access barrier to clinical trials (28). In Canada, 20% of the population lives in rural and remote settings, where travel time to urban healthcare institutions is a significant barrier to clinical trial participation (29). Rural participants also incur additional expenses to participate in trials, such as taking time off work and paying for additional childcare to attend in-person visits (30).

The significance of these barriers is demonstrated by the fact that rural patients are disproportionately underrepresented in Canadian clinical trials (31). By removing or minimizing the need for in-person visits, DCTs can help to reduce access barriers for patients who would otherwise have difficulties participating in clinical trials. Furthermore, improving accessibility to clinical trials can help reduce health and socioeconomic disparities between rural or remote populations and their urban counterparts (32). Shifting the completion of study procedures to the participant's location may remove some of these barriers, providing more equitable access to clinical trials (33,34). Moreover, by enabling remote participation, patients can avoid the burden of frequent in-person visits, reducing travel time and associated costs. Indeed, DCTs can reduce trial costs by up to 50% for participants (35).

DCTs have also been noted to potentially improve access to clinical trials for other underrepresented groups. Members of ethnic minorities and women — especially women of colour — are two examples of population groups underrepresented in clinical research (36). This lack of representation is a significant issue, as different people may respond differently to medications or other investigational products. This highlights the need for greater diversity and representation in clinical trials (37). Limited participation in clinical trials thus perpetuates existing health disparities and inequities. By removing the financial, geographic, and other barriers that disproportionately limit the participation of underrepresented groups in clinical research, decentralization may help to foster greater diversity in clinical trial participation (38).

Participant recruitment has long been a challenge in research generally; insufficient recruitment has been the principal cause of both delays in clinical trials and their premature discontinuation (39). Research has also shown that patients often perceive participation in clinical trials as burdensome. Patients have reported feeling burdened by the need for multiple study visits, their duration, and the perceived inconveniences associated with study procedures (40,41).

It has been suggested in the literature that DCTs can help remedy these inconveniences by giving participants more flexibility and autonomy in their completion of study procedures (34). Furthermore, some authors have proposed that the flexibility provided by DCTs fosters a more “patient-centric” approach to clinical trials participation (42). DCTs can give patients the opportunity to play a more active and engaged role in the completion of study procedures and, by extension, their healthcare. This increased engagement can, in turn, help patients improve their health literacy and autonomy (42,43). Furthermore, by leveraging digital technologies, DCTs provide patients with the ability to participate from the comfort of their homes or any other convenient location. This may help to make healthcare a more welcoming environment, as studies have shown that fear is an important barrier to seeking treatment (44).

Nonetheless, it should be noted that, while DCTs may improve accessibility to clinical trials, reduce burdens for participants, and increase participant engagement, decentralization alone is unlikely to fully address the complex, systemic barriers that

hinder equitable participation in clinical trials. Indeed, while Goodson et al (38) acknowledge the aforementioned perceived benefits of DCTs, they note that for certain minority groups, the most significant barriers are more likely rooted in structural racism rather than inconvenience. Technology alone is thus unlikely to remove these barriers (38).

Overall, despite limited empirical support for the benefits of DCTs, several authors have raised the potential to improve the conduct of clinical trials, making them more patient-centric and efficient (45). Nevertheless, while the use of DCTs may, in certain circumstances, be beneficial, these benefits are often accompanied by challenges that may negatively affect the overall feasibility and effectiveness of DCTs. These challenges require careful attention to adequately protect participants' rights, safety, and welfare. We address some of these challenges in the following section. In fact, the safety of participants has been identified as a component of DCTs that requires "increased ethical vigilance" (42).

II. CHALLENGES IN THE ADOPTION OF DCTS

While the literature discusses many of the challenges of decentralizing clinical trials, in this section, we will focus on three challenges and their corresponding duties: privacy and confidentiality; safety monitoring; and digital literacy and participant compliance. The issues of safety monitoring and privacy and confidentiality are by no means unique to DCTs; they pose challenges for all clinical trials. Nonetheless, decentralization may change the scope and nature of these challenges, necessitating different approaches to adequately address them. Furthermore, privacy and confidentiality, safety monitoring, and digital literacy and participant compliance are not the only challenges facing DCTs (10,27,43). We have chosen to focus on these three as they are likely to pose the most challenges for clinician-researchers in the exercise of their ethico-legal duties and, thus, warrant specific consideration.

Privacy and confidentiality

Clinician-researchers have a duty to protect the privacy and ensure the confidentiality of participants' personal information. In DCTs, digital technologies are often used to collect data. These increasingly sophisticated technologies can collect a wide range of information, from physiological data (such as heart rate, blood sugar, and respiratory rate) to patient-reported outcomes (PROs) (43,46). For patients, the use of digital technologies can provide greater autonomy and flexibility, avoiding or minimizing the need for in-person visits and giving them more control over their performance study-related procedures (43). For clinician-researchers and institutions, the use of digital technologies can help minimize the costs and time associated with clinical trials (43). The use of digital technologies, however, raises additional cybersecurity risks, such as unauthorized disclosures of confidential information (10,47).

Indeed, clinical trials, whether traditional or decentralized, involve the collection of personal, often sensitive, identifiable information. Personal health information is considered to be among the most sensitive of personal information (48). With the complex data flows inherent in the use of digital technologies, there are increased risks of data security breaches. Hacking and cybersecurity breaches are among the most frequent forms of unauthorized disclosures of health information in the digital era (49). Instances of data exposure in the healthcare industry can result in considerable harm to participants, including "potential discrimination, stigmatization, financial and psychological distress" (50). Although various measures such as deidentification and data encryption can help mitigate these risks (38), the diverse range of digital technologies used in DCTs, combined with the large volumes of data they collect, make it effectively impossible to eliminate all cybersecurity risks (51).

These risks may be heightened by the use of digital technologies that passively collect participants' data. Devices such as wearables or sensors collect data without requiring active input from participants, compared to other types of devices that require active engagement (34). While the vast volumes of data collected by passive-type devices can be beneficial for generating rich datasets for analysis, there is the risk that they may also capture irrelevant data that do not align with the study's purposes. For instance, depending on the devices used, passive data collection — such as audio, video, and location tracking — may occur without the participant's knowledge and consent, raising privacy risks for both participants and for third parties (42,52,53).

Privacy and confidentiality risks associated with the use of digital technologies are typically disclosed in documents such as Privacy Policies and Terms of Use (54). However, research has shown that few people read these documents and instead simply scroll to the bottom of their screens and accept the conditions (55). Moreover, these documents are generally designed to limit liability for software developers, rather than to educate or inform users in making informed decisions. Disclosing the privacy and confidentiality risks associated with digital health technologies will likely be an important component of clinician-researchers' duty to inform participants. We return to this point in Section IV.

Safety monitoring

Safety monitoring refers to the oversight of the progress of the clinical trial, ensuring that it is conducted in accordance with applicable protocols and regulations. Safety monitoring is an integral part of a clinical trial, as it helps to improve "the safety of the participants, the quality of the data and the trial integrity" (56). Importantly, safety monitoring helps ensure that study procedures are consistent and safe for participants throughout the clinical trial (56). It is therefore essential that there be "adequate oversight and monitoring during the trial" so that the safety and well-being of participants are maintained throughout its duration (56).

In traditional clinical trials, on-site visits allow researchers to monitor participants for potential adverse events or other safety issues. However, with limited in-person interactions in DCTs, there will be an increased reliance on participants' use of digital technologies to communicate safety information, which could pose a challenge to effective safety monitoring (57). In a study of the experiences and perspectives of European regulators on DCTs by de Jong et al. (57), respondents reported challenges regarding safety monitoring in DCTs. In particular, respondents stated that proper safety monitoring would typically require "in-person (on-site) visits to perform physical examinations". Furthermore, respondents stated that "timely and uninterrupted access to interpretable safety data" would be vital to facilitate safety monitoring in DCTs.

While safety monitoring is crucial to all clinical trials, the need for effective monitoring is particularly important in DCTs, as participants are responsible for completing most of the study procedures themselves. For instance, there are increased risks of physical harm to participants if they inappropriately or unsafely administer trial medications (11). For this reason, fully decentralized clinical trials are better suited to medications that are easy to use, have well-established safety profiles, and do not require complex medical evaluations, rather than those that are difficult to administer or need detailed medical assessments (58).

Safety monitoring using automated data collection may mitigate some of these risks and improve safety monitoring compared to traditional clinical trials, as "continuous monitoring of participants can flag safety issues and adverse events in real-time" (59). This can help research personnel better respond to adverse events when they occur (59). Continuous monitoring through the use of digital devices presents concerns regarding privacy and confidentiality, as discussed earlier. Nor does it necessarily help improve safety monitoring and oversight. Research personnel must therefore remain alert and responsive to potential safety issues. Remote safety monitoring procedures should thus be developed to allow for proper monitoring and responsive action. Furthermore, research personnel should be properly trained on how to identify and respond to potential safety alerts (60). Similarly, in situations where participants are responsible for communicating safety issues themselves, they must be properly trained in how to do so (60). We will return to the importance of participant training when we discuss clinician-researchers' duty to instruct in Section IV.

Digital literacy and participant compliance

DCTs rely heavily on the use of digital technologies. As an increasing number of clinical trials employ decentralized elements, unique technological challenges will likely arise. In Section I, we explored how decentralization may benefit participants, providing them with greater flexibility and autonomy, as well as removing many access barriers. However, the use of digital technologies can also create new access challenges for participants. Issues such as digital literacy, limited technological access, and participant overburdening have the potential to reduce participant engagement and affect data integrity (10). We address each of these issues in this section.

Digital literacy can be defined as "the ability to use information and communication technologies to find, evaluate, create, and communicate information, requiring both cognitive and technical skills" (61). The growing prevalence of digital technologies in everyday life has led to a "digital divide" (62). Limited technological proficiency is particularly common among the elderly and ethnic minorities, who disproportionately lack access to technologies or the Internet at home (63). Consequently, heavy reliance on digital technologies in DCTs may complicate participation for these groups or potentially exclude them altogether, further reinforcing existing disparities and inequities (64). It is therefore crucial for clinician-researchers, institutions, and sponsors to recognize that digital literacy varies across demographic groups. DCTs should not exclude these groups, who may require additional support throughout the study. We will revisit this issue when discussing the duties to follow up and to instruct in Section IV.

In addition to digital literacy and technological access, some studies suggest that DCTs may overburden participants by overwhelming them with different technologies and devices (57,65). Decentralization shifts more responsibility onto participants to complete study procedures that would typically be performed by the study team. This increased responsibility may place undue burden on participants. In their systematic review of methods used to conduct DCTs, Rogers et al. (11) highlight several aspects of DCTs that may overburden participants, including the high volume and complexity of trial activities, the burden of using and charging digital devices, and the emotional weight of responsibility for trial conduct.

As illustrated, the shift toward DCTs requires participants to take a more active role, adhering to remote data collection protocols and assuming responsibility for self-reporting crucial information. However, placing greater responsibility on participants may lead to reduced study engagement, non-compliance, and inaccurate self-reported data. Combined with limited or no in-person contact with the study team, depending on the type of trial, these added responsibilities may exacerbate the compliance challenges already present in traditional clinical trials (41). Indeed, Coyle et al. (13) identify participant overburdening as one of the main barriers to participant adherence to study procedures in DCTs and may affect the results of these studies.

In summary, while DCTs may provide solutions to many of the challenges facing traditional clinical trials, they also raise new challenges. Though many of these challenges are not unique to DCTs, decentralization can change their nature and scope. In this section, we specifically examined the challenges of privacy and confidentiality, oversight and monitoring challenges, and digital literacy. To address these challenges and mitigate the risks they pose to DCTs, in the next section we discuss the roles

and responsibilities of clinician-researchers that are likely to be engaged in DCTs. Based on these duties, we will propose considerations for clinician-researchers to help ensure that the key issues outlined above are effectively managed.

III. ETHICO-LEGAL DUTIES OF CLINICIAN-RESEARCHERS IN CLINICAL TRIALS

Investigators responsible for the conduct of clinical trials are generally required to “be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial” (23). Under Canadian guidelines, a qualified investigator is defined as an individual who is “entitled to provide health care under the laws of the province where that clinical trial site is located.” The investigator is typically a physician, although in dental research dentists can also supervise clinical trials (65). Given that the investigator responsible for the conduct of a clinical trial must be a licensed clinician, we use the term “clinician-researcher” to refer to investigators of clinical trials.

Clinician-researchers are bound by ethico-legal norms applicable to both the provision of medical care and the conduct of research. The primary responsibility of clinician-researchers in clinical trials is to conduct research that both contributes to generalizable knowledge and protects the rights, safety, and welfare of participants (66). The duties of clinician-researchers are defined by their ethical obligations to research participants as well as their legal and deontological duties as members of the medical profession.

In this section, we focus on the duties of clinician-researchers within the research context. Nonetheless, their responsibilities as clinicians also influence their conduct as researchers, particularly regarding their legal obligations. As we will demonstrate, under Canadian law, clinicians’ legal duties in the clinic also extend to research, with courts often imposing stricter standards in the latter context. Many of these duties are also both ethical and legal in nature. The duties to inform and to maintain confidentiality, for instance, stem from both ethical guidelines and the law. It is therefore important to understand how various, often overlapping norms govern clinician-researchers’ conduct in the context of clinical trials. We offer a brief overview of the sources of these duties and some specific obligations imposed on clinician-researchers.

Norms governing conduct of clinician-researchers in clinical trials

Research Ethics Guidelines

Modern research ethics guidelines outline the principles and standards that govern responsible and ethical conduct in research, emphasizing participant welfare and rigorous scientific integrity. Compliance with research ethics guidelines is imperative for researchers, as it safeguards the rights, well-being, and dignity of research participants (67). These guidelines also ensure that research is conducted with integrity, transparency, and accountability, fostering trust within the scientific community and with the public (68). By maintaining the highest ethical standards, researchers not only contribute to scientific advancement but also uphold the fundamental values, such as beneficence, non-maleficence, autonomy, and justice, that guide responsible research conduct (69,70).

Researchers must comply with several research ethics guidelines at both the national and international levels. Nationally, regulatory bodies and funding agencies establish ethical guidelines and frameworks for researchers. Locally, institutions have Research Ethics Boards (REBs) or Institutional Review Boards (IRBs; in the US) to ensure that research is conducted in an ethically responsible manner. In Canada, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is a joint policy of Canada’s three federal research agencies — the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (68). In addition to the general principles governing research involving humans, TCPS2 includes a chapter that is dedicated specifically to clinical trials (Chapter 11) (71). TCPS2 is binding for the researchers receiving funding from the agencies forming the Tri-Council (71).¹ In the United States, most research involving human participants funded by federal agencies is subject to the Common Rule, a set of regulations governing the ethical conduct of research involving human participants (72). FDA regulations apply to clinical investigations that involve the testing of new drugs, biologics, and medical devices (73).

Alongside national guidelines, international research ethics guidelines also establish ethical standards for research. The World Medical Association’s Declaration of Helsinki, first adopted in 1964, has been described as the cornerstone of modern research ethics, serving as the foundation for subsequent research ethics guidelines (74). It outlines the ethical principles and responsibilities of physicians and others involved in medical research with human participants. These principles include respect for autonomy, informed consent, privacy and confidentiality, and research ethics review (75). Similarly, the International Ethical Guidelines for Health-related Research Involving Humans (2016), published by the Council for International Organizations of Medical Sciences (CIOMS), also outline ethical guidelines for research involving human participants. These cover key issues such as study design, informed consent, vulnerability, privacy and confidentiality, data and biological material management, and community engagement (76).

Specifically, regarding clinical trials, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) adopted the Guideline for Good Clinical Practice (GCP), which is an internationally

¹ “As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the Application sections of the articles. Institutions must therefore ensure that research conducted under their auspices complies with this Policy. Researchers are expected, as a condition of funding, to adhere to the TCPS.” (68)

recognized standard for ensuring the ethical and scientific quality of clinical trial design, conduct, recording, and reporting (23). While the ethical guidelines discussed above address research more generally, the ICH-GCP specifically focuses on clinical trials. Among its core principles, the ICH-GCP emphasizes that clinical trials should be “conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki” (23). As such, clinician-researchers are bound not only by the clinical trials-specific provisions of the ICH-GCP but also by the broader ethical principles outlined in the Declaration of Helsinki and other Helsinki-inspired research ethics guidelines.

These guidelines emphasize that the protection of the rights, safety, and well-being of participants lies at the heart of clinician-researcher duties in the conduct of clinical trials. This includes various measures designed to minimize risks and promote participants’ welfare. These measures closely align with the legal duties of clinicians and include informed consent (23), rigorous study design (23), safety reporting², maintaining accurate records (21), overseeing the proper handling and administration of the investigational products (23), and ensuring participants receive appropriate medical care where necessary.³ While certain responsibilities may be delegated to other research personnel, such as study nurses, clinician-researchers still retain ultimate responsibility for the delegated activities and are accountable for maintaining proper oversight of the clinical trial (23,77).

Legal Norms

Under Canadian law, clinicians have several obligations that derive from case law, legislation, and professional codes of ethics. These include the duties to inform, to instruct, to follow up, to diagnose, and to maintain patient confidentiality (professional secrecy) (78,79). We will address these duties in detail in the following section.

There is controversy as to whether the legal duties of clinicians also apply to the research context. There has been much written in the literature concerning the unique position of clinician-researchers as medical professionals who both conduct research and provide direct clinical care to patients. Much of this debate stems from the differing primary goals of clinical care and research. Clinical care focuses on the well-being of the individual patient. Clinical research, on the other hand, focuses on a group of patients with a certain disease or condition, aiming to generate knowledge that can help future patients (80). Consequently, in research, “the therapeutic best interests of a particular individual [...] are] not the main aim of the study” (81). Based on these differences, some authors have argued that research can be viewed as a natural extension of clinical care and, thus, generate similar duties (82,83). Prince et al. (82), for instance, argue that a researcher who is also the participant-patient’s physician might owe that person a fiduciary duty, even with respect to the research aspects of the relationship. Conversely, other authors have argued that research generates its own distinct duties (83,84).

There has been limited case law on this question in Canada. Nonetheless, Canadian case law supports the view that the duties of clinicians in the clinical context also apply to research, albeit at more exacting standards than in the clinic (85). Indeed, courts have imposed stricter standards on clinicians when conducting research (86,87); and the highest standard of care expected of a clinician is when employing an experimental procedure (79). As in the clinical context, the relevance of each duty to research will depend on the specific circumstances of the study.

Relevant Canadian case law on this issue has focused on the duty to inform. In clinical care, prior to treatment, clinicians must provide patients with adequate information to help them make informed decisions (79). This includes disclosure of risks that either a reasonable person in the patient’s position would want to know (the common law standard) (79) or that a reasonable physician would disclose in the circumstances (the civil law standard) (78).

In clinical trials, disclosure for research purposes and for medical care are treated differently to avoid therapeutic misconception. This occurs when participants do not properly understand that the primary goal of research is to produce generalizable knowledge and, thus, may not provide any therapeutic benefit (71). Given their dual role, clinician-researchers should “take all necessary measures to separate their role as researcher from their role as clinician” (71).

Because research is experimental in nature, Canadian courts have affirmed that the standard of disclosure in research is higher than for clinical care (86). In *Halushka v University of Saskatchewan*, for instance, the defendant physicians were conducting a research study that involved the administration of a new anesthetic drug. The plaintiff decided to participate in the study after being told by the defendants that the procedure was a “perfectly safe test” (86). However, the defendants did not inform the plaintiff of the risks of participating in the experiment. The plaintiff suffered cardiac arrest and sued the defendants for damages. The Saskatchewan Court of Appeal ultimately held that, because the plaintiff was a research participant who did not receive any therapeutic benefit from the experiment, he was entitled to a “full and frank disclosure of all the facts, probabilities and opinions” that a reasonable person might be expected to consider before consenting to the procedure (86). As a result, in research, investigators are obliged to provide patients with more detailed and precise information than in clinical settings (79,88,89).

² Safety reporting includes timely reporting of adverse events (unfavourable medical occurrences in a trial participant) and serious adverse events (unfavourable medical occurrences that are considered serious at any dose if they: 1) result in death; 2) are life-threatening; 3) require in-patient hospitalization or prolongation of existing hospitalization; 4) result in persistent or significant disability/incapacity; or 5) are a congenital anomaly/birth defect). Safety reporting also includes reporting deaths of participants (23).

³ Both during and after the course of the clinical trial, the investigator or institution should ensure that “adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial”. In addition, participants should be informed when medical care is required “for intercurrent illness(es) of which the investigator becomes aware” (23).

Having provided a brief overview of the sources of clinician-researchers' duties, in the next section we consider how some of these duties may be engaged in DCTs and what types of issues clinician-researchers should consider when conducting DCTs.

IV. CLINICIAN-RESEARCHERS' DUTIES IN DCTS: POINTS TO CONSIDER

In this section, we focus on four ethico-legal duties of clinician-researchers — to inform, to maintain participant confidentiality (professional secrecy), to follow up, and to instruct — and examine how these duties are likely to be engaged in DCTs. We have chosen to limit our discussion to these duties for several reasons. For one, much of the Canadian case law on research has focused on the duty to inform and the duty to maintain confidentiality, thus making them compelling points of analysis for DCTs. Furthermore, courts have stated that, in the context of clinical care, when clinicians delegate certain tasks to patients, they must instruct their patients on how to properly carry out these tasks (79). In addition, the challenges that DCTs pose for safety monitoring warrant consideration of how the duty to follow up may be engaged in this context. While these duties may not differ in kind in the DCT context, they may differ in degree and therefore require modulation for DCTs.

Informed consent

Consent to both clinical care and to participation in research must be fully informed and voluntary (71,86,90). Clinician-researchers have an ethical and legal duty to provide adequate information to enable informed decision-making. Research ethics guidelines require that prospective participants be fully informed of the objectives of the research, its methods, anticipated benefits, potential risks, and other relevant information (23,75). Furthermore, Canadian case law has established that prospective participants are entitled to “full and frank disclosure” of all relevant information that a reasonable person might be expected to consider before consenting to participate (86). This includes disclosure of all known risks, even if rare or remote, especially if they entail serious consequences for the prospective participant's well-being (87).

In addition to the known risks related to the investigational product and study procedures, the risks associated with decentralization should also be disclosed to prospective participants. As described in Section II, there are several privacy and confidentiality risks in DCTs associated with the use of digital technologies and more complex data flows. These include risks associated with passive data collection, location tracking, and data sharing with third parties. Prospective participants must therefore be thoroughly informed about these risks, the nature and scope of the data being collected, and who will have access to their data.

However, merely providing information to prospective participants is insufficient to obtain informed consent. Prospective participants must also thoroughly understand this information, and ensuring this is an essential part of the informed consent process (75). As discussed in Section II, many people have limited digital literacy or insufficient knowledge of how digital technologies work. Full comprehension and appreciation of the risks may therefore be difficult to achieve. However, difficulties associated with informed consent processes are not unique to DCTs nor to clinical trials more broadly. Traditional informed consent models, based on paper consent forms, are becoming increasingly complex, characterized by lengthy documents that contain technical and formal language (91, 92). Informed consent processes can nonetheless be more challenging in DCTs, especially if current practices involving lengthy and complex forms are translated “as is” to digital form (10,57).

DCTs provide an opportunity to simplify existing complex procedures by mobilizing remote consent models. The use of digital platforms can be customized to meet the specific needs of prospective participants. They can manage the information they get, modulating when, where, and how they receive it, such as by re-reviewing instructional materials, pausing and returning to the materials, or seeking advice from others (10,57). Moreover, research indicates that users feel more informed through the use of audio-visual tools and interactive platforms, rather than traditional written consent forms (10,57).

However, even with technological support, informed consent for DCTs should still involve face-to-face communication — whether in-person or remote — between the prospective participant and the clinician-researcher or a designated member of the study team. Face-to-face communication is essential to assess the prospective participant's capacity to provide informed consent. A voluntary and informed decision to participate may be compromised if the prospective participant is unable to comprehend information, communicate effectively, reason, or deliberate.

While legal capacity is presumed for individuals of full age, face-to-face communication allows the clinician-researcher to conduct an assessment if they suspect that the prospective participant may lack the capacity to provide informed consent (93). This can be done, for instance, by looking at visual cues or assessing the prospective participant's responsiveness. When informed consent procedures are done solely on digital platforms, the ability to assess capacity is more limited. Even in cases where capacity is established, face-to-face communication can enhance the prospective participant's comprehension, allowing a study team member to support the informed consent process in real time and supplement the use of digital tools and platforms.

Clinician-researchers are ultimately responsible for obtaining informed consent from participants. In the research context, this requires a high standard of information disclosure, particularly regarding risks. The risks associated with DCTs must be clearly explained, and prospective participants must fully understand the risks. While many of these risks stem from the use of digital technologies, these tools can also be leveraged to improve informed consent processes and enhance comprehension.

Privacy and confidentiality

Professional secrecy is the obligation of professionals to keep information shared by their patients or clients confidential. This duty is both ethical and legal in nature and applies to both research and clinical care. It is also enshrined in the medical codes of ethics across Canadian provinces and in Quebec's Charter of Human Rights and Freedoms (78,79,94-96). Provincial privacy legislation also reinforces this duty by requiring an individual's consent before their personal information can be disclosed to third parties, subject to certain exceptions (97,98). In both clinical care and research, the duty to keep information confidential arises from the trust relationship that exists between the patient or participant and the clinician-researcher, and which underpins the fiduciary nature of the clinician-patient relationship (99).

In the research context, clinician-researchers must take all necessary precautions to protect the privacy and confidentiality of participants' personal information (75). This duty applies across the full life cycle of the information: collection, use, dissemination, retention, and disposal (71). Any record of information that could identify a participant must be protected, in accordance with applicable regulatory requirements (23).

The duty to maintain confidentiality can be threatened or undermined when digital technologies are used to collect, store, and analyze personal information, notably due to increasingly common data breach events. In the US, for example, health care entities covered by the federal Health Insurance Portability and Accountability Act (HIPAA) reported more than 330 breaches affecting 41.4 million people in the first half of 2023 alone, according to the US Department of Health and Human Services' (HHS) Office for Civil Rights (100). Indeed, the potential for unauthorized data access, ransomware attacks, and potential misuses of sensitive personal information can significantly compromise participants' privacy if robust security measures are not implemented. Unauthorized disclosure or interception of participants' personal information poses risks to the patient's privacy and confidentiality (101). As outlined in Section II, disclosure of such information can be prejudicial to individuals, resulting in discrimination, stigmatization, and other types of harm (50).

With their heavy reliance on digital technologies for remote participation and data collection, DCTs may be particularly vulnerable to data security risks (10). While traditional clinical trials also entail privacy risks, the use of digital technologies may heighten these, thus requiring the implementation of stricter security safeguards (10). With the privacy and confidentiality challenges raised by DCTs, fulfilling the duty to maintain confidentiality will require additional efforts on the part of clinician-researchers and the study team.

Indeed, the ICH-CGP requires that records identifying the participant be kept confidential and not be made publicly available, to the extent permitted by applicable regulatory requirements (23). Given the unique privacy and confidentiality considerations raised by DCTs, additional safeguards will need to be implemented to safeguard participants' rights and interests (10). Depending on the trial and the types of digital tools or technologies used, measures such as data encryption, deidentification, and data minimization may be employed to mitigate privacy risks. Privacy impact assessments (PIAs) should also be conducted, where necessary, to identify potential impacts on participants (10). In certain cases, conducting a PIA may be a legal requirement in order to collect personal information (102).

In addition to risk disclosure, clinician-researchers should also be primarily responsible for ensuring that privacy risks are mitigated by implementing basic measures and safeguards such as those mentioned above. However, responsibility for mitigating privacy risks should also be shared with other stakeholders involved in the clinical trial. Institutions should be responsible for providing the infrastructure and resources to ensure that these measures are consistently applied throughout the trial. As in all clinical trials, sponsors are responsible for ensuring that the trial is conducted in accordance with both the protocol and applicable ethical and regulatory requirements.

The types of mitigation measures will vary by study and depend on applicable regulatory requirements. Nonetheless, clinician-researchers should remain aware of the privacy and confidentiality risks associated with DCTs, including data breaches, unauthorized access, and potential re-identification of participants, and should implement appropriate measures, such as robust encryption, secure data storage, and strict access controls to mitigate these risks.

Participant instruction

In DCTs, there is a shift of responsibility from the study team to participants. With this shift, there may be risks to participants if they do not perform certain study procedures or if they do not promptly report safety issues. Furthermore, participants will have different digital literacy levels, and many will likely require additional support during the trial. It is thus crucial that clinician-researchers (or other designated personnel) provide clear and detailed instructions to participants throughout the trial.

Under Canadian law, clinicians are responsible for giving clear guidance and proper instructions to make sure that patients understand and effectively perform any tasks that are delegated to them (103). Case law on the duty to instruct has focused primarily on postoperative clinical care, where physicians often delegate certain tasks to patients after discharge. The duty to instruct has yet to be judicially analyzed in the research context. However, given the shift of responsibility to patients in DCTs and the potential for risk of harm if certain study procedures, such as the administration of the study drug, are improperly executed, the duty to instruct is particularly relevant to clinician-researchers conducting DCTs.

In Section II, we highlighted safety monitoring as one of the key challenges facing DCTs. To mitigate associated risks, clinician-researchers (or other designated personnel) should provide detailed instructions on how participants should perform delegated study procedures (60), as well as how to report and respond to adverse events (60).

Alongside providing detailed instructions, the duty to instruct also includes verifying that participants have properly understood instructions and ensuring that they have the necessary tools to carry out their required tasks (104). For example, in the context of administering investigational products, Vayena et al. recommend offering participants “comprehensive instructions” via “dedicated apps or websites, with user-friendly communication tools, such as visual aids, infographics, and videos” (10). Considering that some participants may have limited digital literacy or have difficulty using digital technologies, the need for user-friendly, comprehensive instructions is imperative.

Furthermore, the duty to instruct requires physicians “to consider the patient’s ability to understand and follow instructions” (104). Consequently, even if user-friendly communication tools are developed to aid participant comprehension, this does not automatically fulfill the duty to instruct. For certain individuals, participation in a DCT, whether fully decentralized or in hybrid format, may not be appropriate (60). Even with additional support, some participants may not be able to participate in a DCT. Clinician-researchers should therefore conduct thorough assessments to ensure that prospective participants have the capacity to understand and follow all necessary instructions. Clinician-researchers should also consider alternative measures to include patients who may not be able to participate in DCTs, such as by allowing more in-person check-ins with certain participants.

Overall, in clinical care, the duty to instruct requires that clinicians provide detailed instructions when delegating certain tasks to patients. In DCTs, where many trial-related tasks are delegated to participants, this duty becomes a critical component of clinician-researchers’ responsibilities. Although Canadian courts have yet to analyze the duty to instruct in the research context, DCTs highlight its relevance in that particular setting.

Participant monitoring

In clinical trials, clinician-researchers are responsible for monitoring participant safety throughout the trial (71). They must take appropriate measures to minimize risks and burdens to participants and continuously assess these throughout the study (75). Both during and following the end of the clinical trial, adequate medical care must be provided to participants for any trial-related adverse events (23). Clinician-researchers must also develop plans for monitoring participant safety, evaluate the efficacy of the intervention, and establish criteria for withdrawing participants from the trial for safety reasons (71).

In traditional clinical trials, a participant’s progress is typically monitored during in-person study visits. These may include physical examinations, reviews of study medications and symptoms, and any necessary laboratory tests. In DCTs, by contrast, participants can be monitored remotely by different means, such as telecommunications visits, data monitoring, or other remote modalities. As in traditional clinical trials, in DCTs clinician-researchers have the same fundamental monitoring responsibilities. However, the way in which these are carried out must be adapted to the remote context of DCTs. Clinician-researchers must therefore have systems in place to monitor the safety of participants, detect and report adverse events in a timely manner, and monitor participants’ data for integrity and validity.

However, there may be challenges to monitoring how DCTs affect participants’ safety and well-being. In their survey of European regulators, De Jong et al. (57) found that many respondents considered missing data to be a challenge associated with DCTs, one that could then raise issues with data interpretation. Furthermore, Daly et al. (105) note that DCTs can impose a higher burden on participants in relation to data monitoring, as they require participants to perform multiple data-related tasks themselves. This may not only burden participants and intrude within their daily setting but may also result in inconsistencies in the data collection process and, consequently, incomplete data. These gaps or inconsistencies not only compromise the scientific validity and operational conduct of the DCT but also negatively affect the safety and welfare of participants. Incomplete or missing data may delay the detection of adverse events or other clinically relevant changes and, thus, lead to delays in intervention or responses.

The duty to follow up is particularly relevant to participant monitoring in clinical trials. Under Canadian law, clinicians are responsible for following up with their patients concerning their treatment and care. Clinicians must use reasonable care in ensuring that important information, such as testing results or referrals, is communicated to patients and acted upon. This includes reviewing and responding to diagnostic tests in a timely manner, advising patients of significant findings, arranging appropriate follow-up appointments, and ensuring continuity of care when delegating or transferring responsibilities to other health-care providers (78,79). In clinical care, this duty ensures continuity of care and allows for the monitoring of patients’ progress (78,79,94,106).

Some authors have suggested that follow-up might be easier in DCTs than in traditional clinical trials, as DCTs allow researchers to “analyze safety issues more continuously than in conventional trials, and possibly protect participants more effectively” (10). Because the need for study visits is reduced or eliminated, clinician-researchers (or other designated personnel) can follow up more frequently with participants, without the additional costs or burdens associated with in-person visits (43). Nevertheless, given the challenges that could be raised in monitoring participants in DCTs, it is crucial that clinician-researchers ensure adequate follow-up with participants throughout the trial’s duration.

In clinical care, patient follow-up can involve the use of patient management software (107) for diagnostic testing result follow-up (108). These systems can play an important role in identifying patients who require follow-up based on abnormal test results or trends and help ensure that appropriate action is taken in a timely manner. For example, if a patient's test results fall outside of a normal range, the system can automatically generate an alert that triggers follow-up by the healthcare provider (109). These systems are increasingly being used to manage post-surgical follow-up through remote monitoring and identification of post-operative complications (110).

These types of follow-up systems can be informative for safety monitoring in DCTs. Ultimately, the level of monitoring required during a DCT will depend on the trial's levels of risk, size, and complexity, among other factors. The use of follow-up systems, as described above, may not be relevant or feasible for all DCTs. Nonetheless, the safety monitoring challenges raised by DCTs may, depending on the circumstances, require implementing novel solutions to monitor the safety and welfare of participants.

In addition to safety monitoring, clinician-investigators should also play a role in monitoring data for integrity and validity in DCTs, though other actors, such as the study sponsor and data safety monitoring boards (DSMBs), where relevant, should also play a role therein. This concurs with ethical and normative guidelines in clinical trials. According to the ICH-GCP, clinician-investigators play a role in ensuring the "accuracy, completeness, legibility, and timeliness of the data" that they report to the trial sponsor in the CRFs and other required reports (23). Furthermore, according to the TCPS2, in their proposals researchers must include a comprehensive data and safety monitoring plan, specifying how safety, efficacy, and validity will be overseen, regardless of whether an independent DSMB is appointed (71). While the establishment of an independent DSMB is strongly recommended, especially for high-risk, multi-site, or blinded clinical trials and those involving vulnerable populations to ensure unbiased scrutiny of accumulating data, it does not absolve clinician-investigators of their obligations. DSMBs augment but do not replace clinician-researchers' monitoring responsibilities (71).

Clinician-researchers are thus responsible for ensuring the implementation of procedures that guarantee data integrity and validity. In DCTs, particular care is needed when participants' data is stored on personal devices, since it can often be connected with other sensitive details, such as contact information, location history, and audiovisual information (34). This not only raises privacy issues but can also affect the integrity and validity of participants' data. Robust data governance mechanisms and auditing and quality control processes should therefore be implemented. Other types of solutions can also be explored. For instance, recent research has recommended integrating personal health records (PHRs) into DCTs to enhance data integrity (111). The use of blockchain technology has also been proposed for data monitoring. Blockchain's use of algorithms can help enhance data security, protecting sensitive information from alteration, manipulation, and cybersecurity threats (112). This is especially important in clinical trials involving study drugs, where "the integrity of data directly impacts patient safety and trial outcomes" (112).

Overall, DCTs, as with all clinical trials, raise challenges regarding safety and data monitoring. The types of measures needed for safety, data integrity, and validity monitoring in DCTs will depend on the trial design and its specific features. For example, a fully decentralized trial relying on wearable devices and patient-reported outcomes may require stronger safeguards compared to a hybrid trial where some data are still collected in person at study sites. Similarly, trials involving vulnerable populations or higher-risk interventions may require additional safeguards, such as enhanced monitoring, independent data verification, or more frequent follow-up with participants. Monitoring measures should therefore be adapted to the nature of the study intervention, data sources, patient population, and degree of decentralization.

CONCLUSION

DCTs show great promise in the evolving clinical trials landscape. Growing evidence suggests that DCTs can help reduce costs, increase patient adherence, and improve data integrity, among many other benefits. However, DCTs also present several challenges. While not all of these are unique to DCTs, they may be amplified with decentralization. In this article, we examined three key challenges: privacy and confidentiality; oversight and monitoring; and digital literacy and participant compliance. If not properly addressed, these challenges may compromise the rights, safety, and welfare of DCT participants.

While there is growing scholarship on the ethical and regulatory challenges raised by DCTs, further attention is warranted to appraise the ethical and legal duties of clinician-researchers and how they are engaged in DCTs. As we demonstrated in this article, clinician-researchers are bound by several ethical, legal, and professional requirements that encompass their dual clinical and research roles. We focused on four duties encompassing clinician-researchers' roles in obtaining informed consent, ensuring privacy and confidentiality, providing instructions to participants, and conducting safety and data monitoring.

Understanding how these duties are carried out is crucial for addressing the challenges raised by DCTs, especially given the central role that clinician-researchers play in overseeing the conduct of clinical trials. Though many responsibilities may be delegated to other personnel, clinician-researchers are ultimately responsible for the performance of delegated tasks and their outcomes. Safeguarding the rights, safety, and well-being of participants in DCTs depends largely on the ethically and legally robust performance of these responsibilities. This article complements existing literature on the roles of clinician-researchers in DCTs. For instance, Besel et al. (113) enumerate the core competencies of clinical research professionals. The competencies, based on the Joint Task Force (JFT) Core Competency Framework, represent eight domains and are assessed

on proficiency levels ranging from fundamental to skilled to advanced: scientific concepts and research design; ethical participant safety considerations; investigational product development and regulation; clinical study operations (good clinical products); study and site management; data management and informatics; leaderships and professionalism; communications; and teamwork (113).

One limitation in our analysis that warrants mention is that our discussion of the legal duties of clinician-researchers is based on Canadian law. Our analysis of the clinician-researchers' legal scope of practice as they apply to DCTs may not be generalizable to other jurisdictions where legal and regulatory frameworks governing research could differ. As such, variations in local laws may limit the generalizability of our findings outside of Canada. Nonetheless, the use of international guidelines in our analysis, such as the Declaration of Helsinki and the ICH-CGP, which provide a unified and harmonized standard for clinical trial conduct, affords generalizability of findings to other settings that recognize these guidelines.

Furthermore, given the heterogeneity of the DCT landscape, we could not account for every possible variance in DCT design. The ways in which a clinical trial is decentralized can raise different challenges, which in turn may engage different duties or render some duties irrelevant. As such, not all Points to Consider in this article may be relevant to all DCTs. Nonetheless, there has been relatively limited scholarly discourse on the duties of clinician-researchers in DCTs. This article therefore fills an important gap in the literature and provides an important point of reference for future research and policymaking in the DCT field.

Finally, while the duties of clinician-researchers in DCTs are an important part of trial conduct, further attention must be given to the roles and responsibilities of other key stakeholders, such as sponsors, research institutions, CROs, regulatory agencies, and institutional review boards (IRBs), who may be less familiar with the ethical challenges of DCTs. Clarifying these roles and responsibilities will help ensure that DCTs can serve as an effective and sustainable model for future clinical trial design and conduct.

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None to declare

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