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Practical guide for determining whether healthcare providers are research participants in cluster randomised trials

Hayden P Nix [1], Cory E Goldstein [2,3], Monica Taljaard [2,3], Charles Weijer [4,5,6]

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[1]Department of Medicine, Dalhousie University, Halifax, Canada
[2]Methodological and Implementation Research Program, Ottawa Hospital Research Institute, Ottawa, Canada
[3]School of Epidemiology and Public Health, University of Ottawa, Ottawa, Canada
[4]Department of Medicine, Western University, London, Canada
[5]Department of Philosophy, Western University, London, Canada
[6]Department of Epidemiology & Biostatistics, Western University, London, Canada

Correspondence to
Dr Hayden P Nix; hnix@dal.ca

ABSTRACT

Introduction In cluster randomised trials (CRT), groups (rather than individuals) are randomised to intervention and control conditions. Since the publication of the *Ottawa Statement* on the Ethical Design and Conduct of CRTs, the accurate identification of research participants has continued to challenge researchers and research ethics committees.

Objective In this article, we focus on CRTs involving healthcare providers and provide a practical framework for applying *Ottawa Statement* criteria for identifying research participants. We illustrate key lessons with example CRTs.

Framework Study procedures should be analysed in relation to the study objective. A study intervention confers research participant status on healthcare providers if the study objective is to evaluate its effect and it is delivered to or targeted at healthcare providers. A data collection procedure confers research participant status on healthcare providers if it informs a study outcome used to achieve the study objective and it involves interactions between researchers and healthcare providers to collect their data, or the collection of healthcare providers' identifiable private information.

Key lessons In CRTs, healthcare providers may be research participants because of study interventions, data collection procedures, or both; conversely, they may simply be research collaborators. Some study interventions confer research participant status on both healthcare providers and patients. Collecting data on healthcare provider behaviour may confer research participant status on healthcare providers.

Conclusions Accurately identifying research participants in CRTs is essential to their ethical conduct. When healthcare providers are research participants, their rights and welfare should be protected in accordance with research ethics guidelines.

INTRODUCTION

In cluster randomised trials (CRTs), intact social groups (eg, hospitals, long-term care homes or primary care clinics) are randomised to intervention or control conditions. CRTs are often complicated. In a single CRT, the units of randomisation, intervention and data collection can differ. For example, a CRT can randomise hospitals, intervene on physicians and collect data from patients. Further, CRTs can evaluate interventions at multiple levels. Cluster-level interventions are delivered to the social group as a whole and cannot be avoided by individual cluster members (eg, anti-smoking campaign delivered to communities).[1] Professional-level interventions are delivered to healthcare providers to produce an effect on patients (eg, education sessions on central venous catheter care delivered to intensive care nurses).[2] And individual-level interventions are delivered to each cluster member separately (eg, vaccinations delivered to patients).[3]

The complexity and heterogeneity of CRTs can make it difficult to identify research participants, especially when healthcare providers are involved. In CRTs, healthcare providers can be involved as the unit of randomisation, the target of the study intervention, or the target of data collection procedures. They can also help researchers deliver interventions to or collect data from patients. Determining whether healthcare providers are research participants in a CRT is important because it dictates whether they are entitled to protections provided in research ethics guidelines, including informed consent, confidentiality, balanced risks and benefits, and equitable distribution of research harms and benefits.[4–6]

The *Ottawa Statement* on the Ethical Design and Conduct of CRTs was the first international ethics guideline specific to CRTs.[7] Since its publication in 2012, the *Ottawa Statement* has been cited approximately 300 times, and several national and international research ethics guidelines and regulators have adopted provisions from the *Ottawa Statement*.[4–6]

The *Ottawa Statement* defines a research participant as 'an individual whose

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Box 1 The *Ottawa Statement* criteria for identifying research participants[7]

A research participant is an individual:
1. who is the intended recipient of an experimental (or control) intervention; or
2. who is the direct target of an experimental (or control) manipulation of his/her environment; or
3. with whom an investigator interacts for the purpose of collecting data about that individual; or
4. about whom an investigator obtains identifiable private information for the purpose of collecting data about that individual.

interests may be affected as a result of study interventions or data collection procedures' and specifies four independently sufficient criteria to operationalise the definition (box 1).[7] According to the *Ottawa Statement*, research participant status may be conferred on an individual by a study intervention, if it is delivered to or targeted at the individual; or a data collection procedure, if it involves an interaction with a researcher or the collection of private identifiable information.[7]

Since the publication of the *Ottawa Statement*, determining whether healthcare providers are research participants in CRTs has continued to challenge researchers and research ethics committees. A systematic review of 1988 pragmatic trials published from 2014 to 2019, including 127 CRTs of professional-level interventions, found that the evaluation of professional-level interventions in CRTs is associated with increased odds of not obtaining informed consent.[8] Further, a systematic review of 160 stepped-wedge CRTs published from 2016 to 2022 found that, out of 92 CRTs evaluating professional-level interventions, 60 failed to report whether consent was obtained from healthcare providers.[9] This suggests that researchers and research ethics committees require additional guidance to recognise when healthcare providers are research participants in CRTs.

In this article, we aim to help researchers and research ethics committees determine whether healthcare providers are research participants in CRTs. We provide a practical framework for applying the *Ottawa Statement* criteria for identifying research participants to CRTs involving healthcare providers. We begin by introducing the framework. We then outline nine key lessons for applying the framework (table 1). Each lesson is illustrated with an example CRT (online supplemental file 1). We have previously argued that identifying research participants is the first step in navigating issues of informed consent in CRTs.[10] In this article, we focus solely on identifying research participants in CRTs involving healthcare providers. Downstream issues of informed consent and other ethical protections in CRTs are outside the scope of this article.

Table 1 Framework and associated key lessons for determining whether healthcare providers are research participants in CRTs

Framework		Key lessons
Study intervention	1. What study interventions are evaluated to achieve the study objective? 2. Are any study interventions delivered to or targeted at healthcare providers? If "yes", to question two, then the study intervention confers research participant status on healthcare providers.	Healthcare providers may be research participants exclusively because of a study intervention (eg, Pain Trial). A study intervention may simultaneously confer research participant status on healthcare providers and patients (eg, Clot Trial). Study interventions that are merely delivered by healthcare providers do not confer research participant status on healthcare providers (eg, Eat Trial).
Data collection	1. What data collection procedures inform study outcomes to achieve the study objective? 2. Do any data collection procedures involve interactions between researchers and healthcare providers for the purpose of collecting healthcare provider data, or the collection of healthcare providers' identifiable private information? If "yes" to question two, then the data collection procedure confers research participant status on healthcare providers.	Healthcare providers may be research participants exclusively because of a data collection procedure (eg, Memory Trial). Collecting data on healthcare provider behaviour by direct observation may confer research participant status on healthcare providers (eg, Agitation Trial) Collecting data on healthcare provider behaviour from patient medical records may confer research participant status on healthcare providers (eg, Bloodwork Trial) Collecting data on healthcare provider behaviour that is not used to evaluate the effect of the study intervention does not confer research participant status on healthcare providers (eg, Eat Trial)
General	Each study intervention and data collection procedure should be analysed in relation to study objectives and outcomes.	Healthcare providers may be research participants in CRTs for more than one reason (eg, Needle Stick Trial). Healthcare providers can be involved in CRTs as research collaborators—not research participants (eg, Eat Trial)

CRTs, cluster randomised trials.

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FRAMEWORK

To determine whether healthcare providers are research participants in CRTs, key features of the trial should be systematically analysed to determine whether the *Ottawa Statement* criteria for identifying research participants obtain. First, study interventions should be analysed in relation to the study objective:

1. What study interventions are evaluated to achieve the study objectives?
2. Are any of the study interventions directly delivered to or targeted at healthcare providers?

If 'yes' to question two, then the study intervention confers research participant status on healthcare providers. Next, data collection procedures should be analysed in relation to the study outcomes:

1. What data collection procedures inform study outcomes to achieve the study objective?
2. Do any of the data collection procedures involve interactions between researchers and healthcare providers for the purpose of collecting healthcare provider data, or the collection of healthcare providers' identifiable private information?

If 'yes' to question two, then the data collection procedure confers research participant status on healthcare providers.

KEY LESSONS

In this section, we outline key lessons for applying the framework to CRTs involving healthcare providers, organised according to the aspect of the framework to which they pertain: study interventions, data collection procedures and the trial in general.

Study interventions

Healthcare providers may be research participants exclusively because of a study intervention

Some CRTs evaluate interventions that are delivered to healthcare providers to produce an effect on patients (ie, professional-level interventions). This kind of intervention seems to make identifying research participants particularly difficult.[8 9] One possible reason for this confusion is that researchers and research ethics committees may not be familiar with trials that have separate units of intervention and data collection. Our framework clarifies this point of confusion. If the study objective is to evaluate the effect of an intervention that is delivered to or targeted at healthcare providers, then healthcare providers are research participants. This means that the study intervention may confer research participant status on healthcare providers, even if no healthcare provider data are collected and the only effect under evaluation is at the patient level.

For example, consider the Pain Trial (online supplemental file 1). The study objective was to evaluate the effect of a multifaceted education intervention on pain control in patients admitted to intensive care units.[11] The study intervention consisted of an online audit and feedback application displaying information related to patient pain control and guideline-based recommendations on pain management, and education sessions to teach healthcare providers how to use the application. Both components of the intervention were delivered directly to healthcare providers. Therefore, healthcare providers were research participants because of the study intervention. The study outcome used to achieve the study objective was patient pain control. Data collection procedures used to inform the study outcome consisted of four pain assessment tools. None of these tools involved interactions between researchers and healthcare providers. Further, they did not collect healthcare providers' private identifiable information. If the study outcome was physician analgesia prescribing behaviour (eg, concordance with clinical practice guidelines on pain management), and data on analgesic prescribing were collected and identifiable, then the data collection procedures would have also conferred research participant status on physicians. However, patient pain control is merely an indirect measure of physician analgesic prescribing behaviour and may be influenced by other factors. Therefore, data collection procedures did not confer research participant status on healthcare providers in the Pain Trial; they were research participants exclusively because of the study intervention.

A study intervention may simultaneously confer research participant status on healthcare providers and patients

Another reason professional-level interventions make identifying research participants challenging is that some professional-level interventions confer research participant status on patients, while others do not. Some CRTs evaluate professional-level interventions that aim to improve healthcare provider concordance with clinical practice guidelines (ie, knowledge translation interventions). These interventions are not experimental at the level of the patient because they aim to promote uptake by healthcare providers of recommended clinical practice. Therefore, they confer research participant status on healthcare providers, but not patients.[12] By contrast, other CRTs evaluate professional-level interventions that aim to produce an effect on patients by altering healthcare provider behaviour in a way that does not promote the uptake of established clinical practice guidelines. These interventions are simultaneously experimental at the level of the patient and the healthcare provider, and therefore confer research participant status on healthcare providers and patients.

Professional-level interventions that are experimental at the level of the patient may make it difficult to recognise that healthcare providers are research participants. However, when determining whether healthcare providers are research participants, it does not matter whether the intervention is experimental at the level of the patient. If the intervention is delivered to healthcare providers, and the study objective is to evaluate the effect of the intervention, then healthcare providers are research participants.

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For example, consider the Bloodwork Trial (online supplemental file 1). The study objective was to evaluate the effect of electronic reminders on primary care physicians' rates of appropriate monitoring with routine bloodwork.[13] The study intervention was a decision support algorithm embedded in clinic electronic medical records. The algorithm prompted physicians to order routine bloodwork to monitor for side effects of commonly prescribed medications, in accordance with five published clinical practice guidelines. This intervention is targeted at primary care physicians. Therefore, the study intervention conferred research participant status on physicians. The study intervention was not experimental at the level of the patient because it aimed to promote the uptake of existing clinical practice guidelines. Therefore, the study intervention did not confer research participant status on patients.

By contrast, consider the Clot Trial (online supplemental file 1). It was a hybrid implementation effectiveness CRT. The study objective was to evaluate the effect of prompting physicians to use 'electronic Venous Thromboembolism' (eVTE) to decide whether to prescribe extended thromboprophylaxis to patients at discharge from hospital on physician prescribing behaviour and patient outcomes.[14] eVTE is a clinical prediction model that predicts the risks of venous thromboembolism and major bleeding. The intervention involved embedding eVTE into electronic medical records. When discharging patients from hospital, physicians were electronically prompted to prescribe extended duration thromboprophylaxis to patients with eVTE scores indicating high risk of venous thromboembolism and low risk of major bleeding. The intervention was delivered directly to physicians. Therefore, it conferred research participant status on physicians. The intervention did not promote the uptake of existing clinical practice guidelines. While some clinical practice guidelines recommend considering extended duration thromboprophylaxis for specific patient groups, they do not recommend using the eVTE clinical prediction tool to identify appropriate patients.[15 16] Therefore, the intervention is experimental at the level of the patient and thereby also confers research participant status on patients.

Study interventions that are merely delivered by healthcare providers do not confer research participant status on healthcare providers

In some CRTs, study interventions are delivered by healthcare providers to patients. It may be difficult to distinguish between study interventions that are delivered by or delivered to healthcare providers. A careful examination of the study objective is key to drawing this distinction. If healthcare providers receive training to deliver an intervention to patients, but the study objective is not to evaluate the effect of the training, then the training intervention does not confer research participant status on healthcare providers. This is akin to educating healthcare providers about a novel medication to facilitate the evaluation of the medication in a clinical trial.

For example, consider the Eat Trial (online supplemental file 1). The study objective was to evaluate the effect of a psychological intervention on the nutritional status of patients receiving radiation treatment for head and neck cancer.[17] The study intervention was a protocolised series of motivational interviews. In the trial, dietitians received training on how to conduct the motivational interviews. The training was delivered to dieticians. If the study objective had been to evaluate the effect of the training on dieticians' ability to conduct the motivational interviews, then the training would have conferred research participant status on the dieticians. However, the study objective was not to evaluate the effect of the training on healthcare provider behaviour; it was to evaluate the effect of the motivational interviews on patients. Therefore, the training delivered to dieticians did not confer research participant status on them. The study objective was to evaluate a study intervention that was delivered by—not delivered to—dieticians.

Data collection

Healthcare providers may be research participants exclusively because of a data collection procedure

In some CRTs, data collection procedures confer research participant status on healthcare providers. In this kind of CRT, healthcare providers are research participants, even if the study intervention does not confer research participant status on them.

For example, consider the Memory Trial (online supplemental file 1). The study objective was to evaluate the effect of a patient education intervention on the timeliness of dementia diagnosis.[18] The study intervention consisted of a patient education leaflet and a signed letter from general practitioners (GPs), mailed to patients' homes. This intervention was not delivered to or targeted at healthcare providers; it was delivered exclusively to patients. Therefore, the study intervention did not confer research participant status on GPs in the Memory Trial. One of the study outcomes used to achieve the study objective was the effect of the study intervention on 'GP practice report of negative comments from patients or relatives sent the interventions'.[18] Data collection procedures included interviews between researchers and all GPs. During the interviews, GPs were asked to report 'inappropriate presentations, patient distress and whether the intervention led to an unacceptable number of presentations'.[18] The interviews involved interactions between researchers and GPs for the purpose of collecting data related to their practices, and the collection of identifiable private information. Therefore, data collection procedures conferred research participant status on GPs in the Memory Trial; they were research participants exclusively because of data collection procedures.

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Collecting data on healthcare provider behaviour by direct observation may confer research participant status on healthcare providers

In some CRTs, data on healthcare provider behaviour in clinical settings are collected by direct observation. If data on healthcare provider behaviour are identifiable and inform a study outcome used to achieve the study objective, then they are research participants because of the data collection procedure. This is because observation of healthcare provider behaviour in clinical settings for the purpose of a clinical trial constitutes the collection of private information. Privacy can be defined as 'the freedom of the individual to pick and choose… the time and circumstances under which, and most importantly, the extent to which, [one's] attitudes, beliefs, behaviour and opinions are to be shared with or withheld from others'.[19] Whether information is private depends on the context in which it is collected. Like all employees, healthcare providers' behaviour and performance at work may be observed 'for the purpose of creating, managing or terminating an employment relationship'.[20] Therefore, when employers collect data to monitor healthcare provider performance and patient safety, it is not an invasion of privacy. However, data collection in research serves a different purpose: the generation of generalisable knowledge. Collecting data for this purpose removes it from the norms that govern employee–employer relationships. Outside of this relationship, healthcare providers have a right to determine how their information—including their performance at work—is collected, disclosed and disseminated. Therefore, the collection of data about performance at work for research constitutes the collection of private information. If the data inform a study outcome, healthcare providers are research participants because of the data collection procedure.

For example, consider the Agitation Trial (online supplemental file 1). The study objective was to evaluate the effect of educating nursing home care staff and physicians about patient-centred care and antipsychotic use on agitation in people living with dementia in nursing homes.[21] In this trial, one of the secondary outcomes used to achieve the study objective evaluated the effect of the study intervention on the quality of interactions between care staff and patients. To inform this study outcome, researchers observed interactions between nursing home care staff and patients and evaluated them using the Quality of Interactions Scale. Researchers observing interactions between care staff and patients constitute the collection of healthcare providers' private identifiable information. Therefore, data collection via direct observation conferred research participant status on nursing home care staff.

Collecting data on healthcare provider behaviour from patient medical records may confer research participant status on healthcare providers

In some CRTs, data collected from patient medical records is used to evaluate healthcare provider behaviour. Like observing behaviour in clinical settings, collecting data on healthcare provider medical decisions for the purpose of research constitutes the collection of private information. Healthcare provider behaviours that are commonly evaluated in CRTs include diagnostic decisions (eg, whether to order an investigation) and treatment decisions (eg, which medication to prescribe). If data on clinical decisions collected from patient medical records are identifiable and inform a study outcome used to achieve the study objective, then healthcare providers are research participants because of the data collection procedure.

For example, consider the Bloodwork Trial (online supplemental file 1). As mentioned above, it evaluated the impact of electronic reminders on primary care physicians' rates of appropriate monitoring for medication side effects with routine bloodwork.[13] The primary study outcome was the rate of recommended laboratory monitoring within 14 days after a clinic visit. To inform this outcome, data on the incidence of reminders and whether the physician subsequently ordered routine bloodwork were collected from patient medical records. The data were linked to the patient's treating physician, constituting the collection of private identifiable information. Therefore, data collection via extraction from patient medical records conferred research participant status on primary care physicians.

Collecting data on healthcare provider behaviour that is not used to evaluate the effect of the study intervention does not confer research participant status on healthcare providers

Collecting healthcare provider data does not necessarily confer research participant status on healthcare providers. Data collection procedures only confer research participant status if the data inform a study outcome that is used to achieve the study objective (ie, evaluate the study intervention). In CRTs, healthcare provider behaviour data are commonly collected to monitor treatment fidelity. If treatment fidelity is monitored to determine whether the study was conducted as planned (ie, a process measure)—rather than to evaluate the effect of the study intervention—then the collection of treatment fidelity data does not confer research participant status on healthcare providers, even if it is listed as a secondary outcome. This is akin to monitoring the doses prescribed by physicians in trials of medications.

For example, consider the Eat Trial (online supplemental file 1). As mentioned above, it is a stepped-wedge CRT that evaluated the effect of a psychological intervention on the nutritional status of patients receiving radiation for cancer.[17] The primary outcome was patient nutritional status, and the secondary outcomes consisted of several additional patient outcomes (eg, quality of life). Data collection procedures consisted of audio-recording intervention sessions, clinical assessment tools and patient questionnaires. The audio recordings involved the collection of dieticians' identifiable private information. However, the data from these sessions did

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not inform a study outcome that evaluated the effect of the study intervention. Instead, the audio-recording data were collected merely to ensure that the intervention was being delivered to patients according to the trial protocol. Therefore, data collection procedures did not confer research participant status on dieticians.

General

Healthcare providers may be research participants for multiple reasons

In some CRTs, healthcare providers are research participants for multiple reasons. A single study intervention or data collection procedure is sufficient to confer research participant status on healthcare providers. But in some CRTs, study interventions and data collection procedures confer research participant status on healthcare providers.

For example, consider the Needle Stick Trial (online supplemental file 1). The study objective was to evaluate the effect of a needle safety device and healthcare provider education on the incidence of needle stick injuries among hospital workers.[22] There were two study interventions: safety needles and interactive workshops. All existing injection needles on the ward were replaced with needles equipped with the safety device in the corresponding intervention arm. In the interactive workshops, researchers taught healthcare providers about needle stick injuries. Replacing all needles with safety needles constitutes an environmental manipulation targeted at healthcare providers, and the interactive workshops were delivered directly to healthcare providers. Therefore, healthcare providers were research participants in the Needle Stick Trial because of the study interventions. Further, the study outcome was the incidence of needle stick injuries among hospital workers. Two data collection procedures were used to inform this outcome: data extraction from a pre-existing hospital database of needle stick injuries and questionnaires completed by healthcare providers. The questionnaires involved interactions between researchers and healthcare providers and the collection of identifiable private information. The data collected in the questionnaires informed the study outcome that achieved the study objective. Therefore, data collection and study interventions conferred research participant status on healthcare providers.

Healthcare providers may be involved in CRTs as research collaborators—not research participants

In some CRTs, healthcare providers are involved as research collaborators. Research collaborators are 'individuals who contribute to the design of or participate in the conduct of a research study'.[12] In this role, healthcare providers often deliver study interventions to, or collect data from, patients in CRTs. Researchers may involve healthcare providers as research collaborators for logistical or financial reasons, or to promote trial pragmatism by facilitating evaluation of the study intervention under the conditions of intended use. It may be helpful to think of research collaborator status as a diagnosis of exclusion; if healthcare providers are involved in a CRT, but none of the criteria for research participant status obtain, then they are research collaborators. When healthcare providers are involved in CRTs as research collaborators, they are not entitled to protections provided in research ethics guidelines. Rather, as research collaborators, they may be acknowledged or, if authorship criteria are met, they may be granted co-authorship.

For example, consider the Eat Trial (online supplemental file 1). The study intervention was delivered by—not delivered to—healthcare providers. And healthcare provider data were collected for treatment fidelity monitoring—not to inform a study outcome used to achieve the study objective. Since none of the criteria for research participant status obtain for dieticians, they were research collaborators, not research participants.

DISCUSSION

Determining whether healthcare providers are research participants in CRTs is challenging. In this article, we have provided a systematic approach to this problem and demonstrated that healthcare providers may be involved in CRTs in manifold ways (table 2). Research participant status may be conferred on them by study interventions,

Table 2 Roles of healthcare providers in the example CRTs

	Healthcare provider research participant status		Patient research participant status	
Example trial	**Intervention**	**Data collection**	**Intervention**	**Data collection**
Agitation Trial[19]	Yes	Yes	No	Yes
Bloodwork Trial[13]	Yes	Yes	No	Yes
Clot Trial[14]	Yes	Yes	Yes	Yes
Eat Trial[17]	No	No	Yes	Yes
Memory Trial[21]	No	Yes	Yes	No
Needle Stick Trial[22]	Yes	Yes	No	No
Pain Trial[11]	Yes	No	No	Yes

CRTs, cluster randomised trials.

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data collection procedures or both; or healthcare providers can be involved as research collaborators.

In this educational article, example trials with relatively simple study interventions and data collection procedures were selected deliberately to illustrate key lessons. By contrast, CRTs commonly evaluate multifaceted and multilevel interventions and have several data collection procedures, making application of our framework more challenging. When analysing multifaceted CRTs, our framework should be applied to all study intervention components and data collection procedures separately, to determine whether each individual study procedure confers research participant status on healthcare providers involved in the trial.

Identifying research participants is foundational to the ethical conduct of CRTs. On one hand, incorrectly identifying a group as research participants and providing associated ethical protections may unnecessarily burden researchers and research ethics committees. On the other hand, failing to recognise a group deserving of research participant status may adversely affect their rights and welfare and erode trust in the research institution.

The framework presented in this article cogently maps onto our previously published three-step framework for navigating issues of informed consent in CRTs: First, identify the research participants; second, determine the study procedure(s) to which they are exposed; and third, determine whether the conditions for a waiver of informed consent obtain for each study procedure.[10] Our framework for identifying research participants in CRTs emphasises the importance of analysing study procedures to determine whether they confer research participant status on individuals involved in CRTs. Research participant status and associated ethical protections (including informed consent) are a function of the study procedures in CRTs.

Our analysis raises questions about what, if any, ethical protections are owed to people who are impacted by CRTs but are not research participants. The Eat Trial demonstrates that healthcare providers may be involved as research collaborators. Further, there is growing interest in the concept of research bystanders: individuals who are impacted by research activities, but do not meet criteria for research participant status.[23] Existing research ethics guidelines focus solely on ethical protections for participants. There is a paucity of guidance pertaining to whether and how individuals who are involved in CRTs in other roles should be protected. We plan to explore these questions in future work.

CONCLUSIONS

This article aims to help researchers and research ethics committees determine whether healthcare providers are research participants in CRTs. To discern whether healthcare providers involved in CRTs are research participants, study interventions and data collection procedures should be identified and analysed in relation to the study objective and outcomes. When healthcare providers are research participants, their rights and welfare should be protected by researchers and research ethics committees in accordance with research ethics guidelines and regulations.

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ORCID iDs

Hayden P Nix https://orcid.org/0000-0002-4205-5857
Cory E Goldstein https://orcid.org/0000-0002-0229-5039
Monica Taljaard https://orcid.org/0000-0002-3978-8961
Charles Weijer https://orcid.org/0000-0002-5510-1074

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