# VIEWS AND OPINIONS

## ETHICS PERSPECTIVE

Institut des humanités en médecinee

## INFORMED CONSENT IN DECENTRALISED CLINICAL TRIALS THROUGH AN ETHICAL LENS

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Decentralised clinical trials raise ethical questions regarding informed consent because the consent process often takes place remotely. This article explores the challenges (such as fewer in-person interactions) and opportunities (including new possibilities for exercising autonomy and engaging a more diverse research population) that a remote informed consent process raises for research participants. In addition, the article contains several approaches for mitigating the ethical problems that obtaining informed consent remotely raises in decentralised clinical trials, including moving toward a more dynamic informed consent process and using teleconference technologies to give regular feedback to participants, which may help increase transparency and foster trust between research participants and the research team.

The COVID-19 crisis led to a significant expansion of decentralised approaches to clinical trials, a tendency that is expected to increase even more in the coming years.[1,2] While these new decentralised models are considered a more cost-effective way to conduct trials, the ethical issues they raise have not yet been sufficiently explored. Because decentralised clinical trials (**DCTs**) involve the use of remote tools and methods to facilitate research without physical contact, they have had an important impact on participant recruitment, informed consent, and interactions between research participants and research teams. In order to understand the full implications of these new models, the participant's perspective is needed.[3]

## INFORMED CONSENT IN DECENTRALISED CLINICAL TRIALS

This contribution looks at what DCTs change for participants, and in particular their capability for informed consent. In the context of this article, the term informed consent refers to the real opportunities and resources available to research participants that enable them to be adequately informed of their participation in a clinical trial and be empowered to act according to their desires. In medical ethics, informed consent is not just a tick-box exercise. Instead, it is considered necessary for guaranteeing that a research participant is able to act with intention, with comprehension, and without interference from others.[4] Ensuring informed consent is therefore quite demanding for participants and research teams, even in the usual consent process. It means giving participants the right to be informed and engaged in the research process and giving research teams the responsibility to produce an environment in which participants can be empowered.

In the new model of DCTs, the consent process may take place remotely. While methods vary, there is an increasing use of software that allows prospective trial participants to read and sign informed consent documents remotely. It is important to explore the potential harms and benefits of these models and, based on the challenges and opportunities identified, provide some ideas on how to move forward. Research on the patient's perspective is still needed, however, to fully grasp the ethical considerations of these new models.

## REMOTE INFORMED CONSENT: CHALLENGES AND OPPORTUNITIES

To begin with, it is important to consider how a research participant's experience changes when consent is provided at home. Because decentralised trial models involve exchanging information at a distance, they offer fewer opportunities for a participant to interact and have discussions with the research team. While this may mean that participants have more time to read and understand information, fewer in-person interactions make it more difficult for them to ask questions and for the research team to understand their hesitations and concerns. Moreover – going back to the ethical framework – this long-distance interaction makes it challenging for the research team to ensure that a participant is acting with intention, with comprehension, and without interference by another person or group. While there is also no guarantee of this in more centralised trial models, decentralised models make this task harder due to the more limited opportunities for interaction.

On the other hand, from the perspective of participant autonomy, these models may give prospective research participants more time and space to read relevant documents, look for outside resources, and discuss the trial with their family members, friends, and other participants. They may also feel less pressured to give consent when the process is managed remotely compared to in person. All of these possibilities may help participants feel more in control and able to exercise their autonomy.

In terms of greater representation in clinical trials, using a remote consent process is promising. Given the need for a more diverse participant population, these new methods have been advocated as a way to increase access, in particular for those in rural areas who may not otherwise participate in trials due to transport and time costs or insufficient resources where they live. [5]

## APPROACHES TO REMOTE INFORMED CONSENT

This brief discussion has demonstrated that obtaining consent remotely in DCTs offers several promising opportunities – but also entails risks. To prepare for its future implementation, several approaches may be pursued to identify these opportunities and address the challenges.

In the first place, under the DCT model, the relationship between a research participant and the research team needs to remain a priority. This is important not only to ensure that consent is obtained but also to develop the trusting relationship necessary to ensure study quality and mitigate potential harms for the participant. While some tools may be sent electronically, such as the informed consent form (e-consent), it is still necessary to plan in-person sessions to ensure that participants are fully informed and engaged.[6,A] Therefore, while it may be possible to perform some tasks remotely, the need for regular, in-person interactions still exists. Where this is not possible (e.g. when a participant lives in a rural area), regular communication opportunities (e.g. via teleconference technologies) still need to be provided.

Furthermore, in the overall discussion on informed consent, it is increasingly being recognised that consent does not happen in a vacuum, nor is it a one-off event. Indeed, there is increased advocacy for a more *dynamic* consent model.[7] In other words, consent is not "just" a document to be signed but a process that needs to continue throughout a trial to ensure that participants are adequately informed of each step of the process, that they are willing to continue, and that any harms or other unforeseen circumstances are addressed. In practice, this means the research team should regularly check in with participants to inform them of the study process, ensure participants understand the information being given to them, and make themselves available to answer participants' questions. This model also has the advantage of being compatible with both traditional and decentralised clinical trials since more regular communication is now possible with videoconference technologies.

## THE NEED FOR A GREATER UNDERSTANDING OF THE PARTICIPANT'S PERSPECTIVE

This discussion underscores that, from an ethical standpoint, the fundamental principles of informed consent remain largely unchanged, even when consent is obtained remotely in decentralised trial models. Each participant continues to have rights related to informed consent, and the research team continues to have the responsibility to ensure consent is obtained. Furthermore, a relationship based on transparency and trust is the means to ensure research quality and avoid participant harm. In the end, decentralised clinical trials call for researchers to become more creative – but also critical – when deciding how to best use technology to better achieve these goals. Because this is an evolving subject, the participant's perspective (obtained, in particular, through qualitative research) is sorely needed in order to better understand and anticipate these and other emerging ethical challenges posed by these new models.

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[A] The use of e-consent is now permitted in Switzerland following the entry into force of the revised Human Research Act (**HRA**) ordinances on 1 November 2024. swissethics defines electronic informed consent as the "use of electronic systems and processes that may employ multiple electronic media […] to convey information related to the study and to obtain and document informed consent". For more details, see swissethics' guidance on electronic informed consent from 25 August 2024.