Course material

Course:

Ethics in Emergencies

Video:

6a Informed consent

Concepts (extracted from automatically generated subtitles):

Day-to-day conduct of implementation research. Research participants. Ethical issues. Type of study. Best protect participants autonomy. Ethical conduct of research. Consent process. Potential participant. Conduct of implementation research. Potential risks. Participant autonomy. Relevant information. Research teams. Use of videos. Clinical trials.

to video sequence search
(within Ethics in Emergencies.)

to video

CHAPTER 3A

Ethical considerations in the conduct of implementation research in emergencies

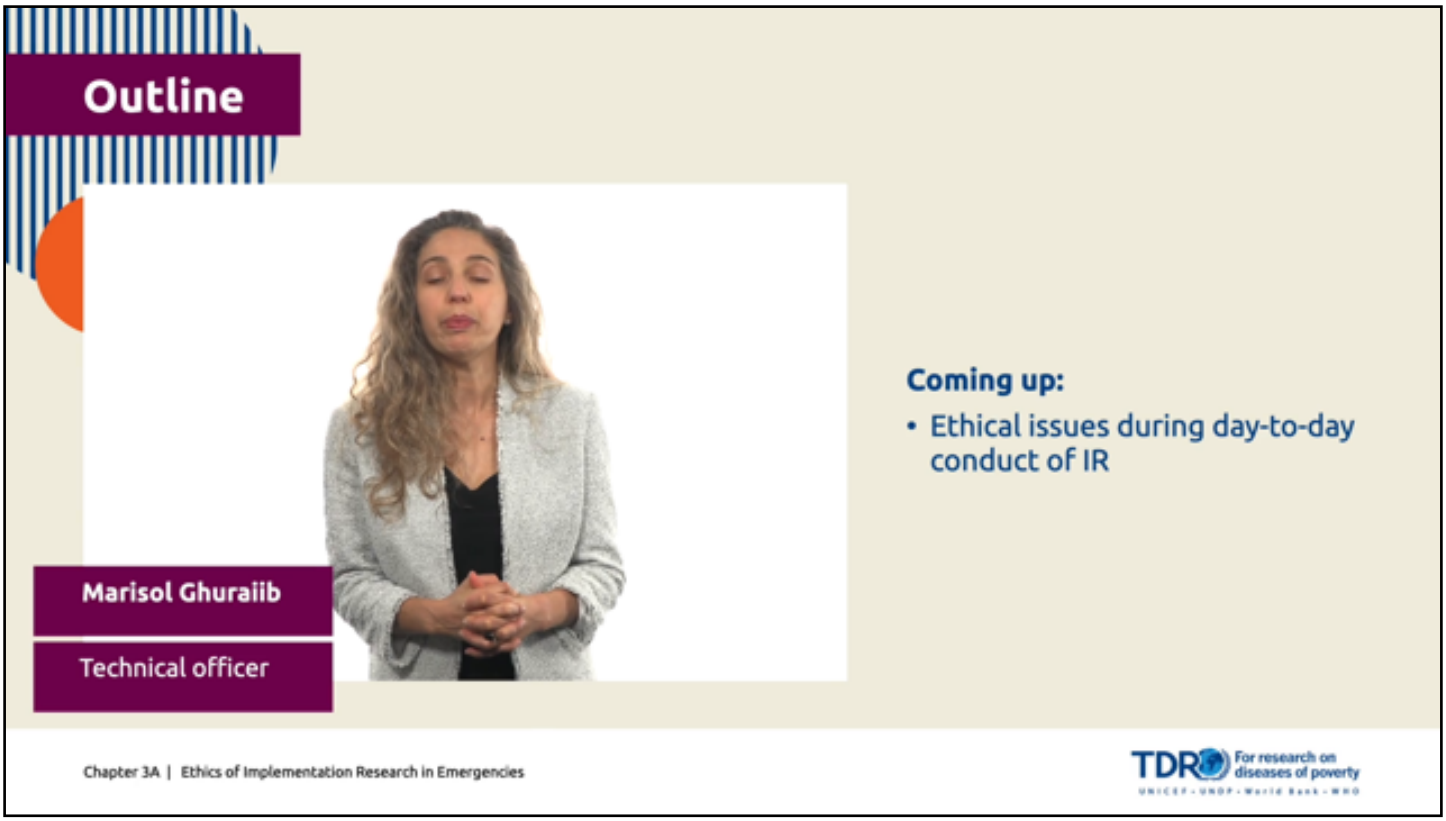
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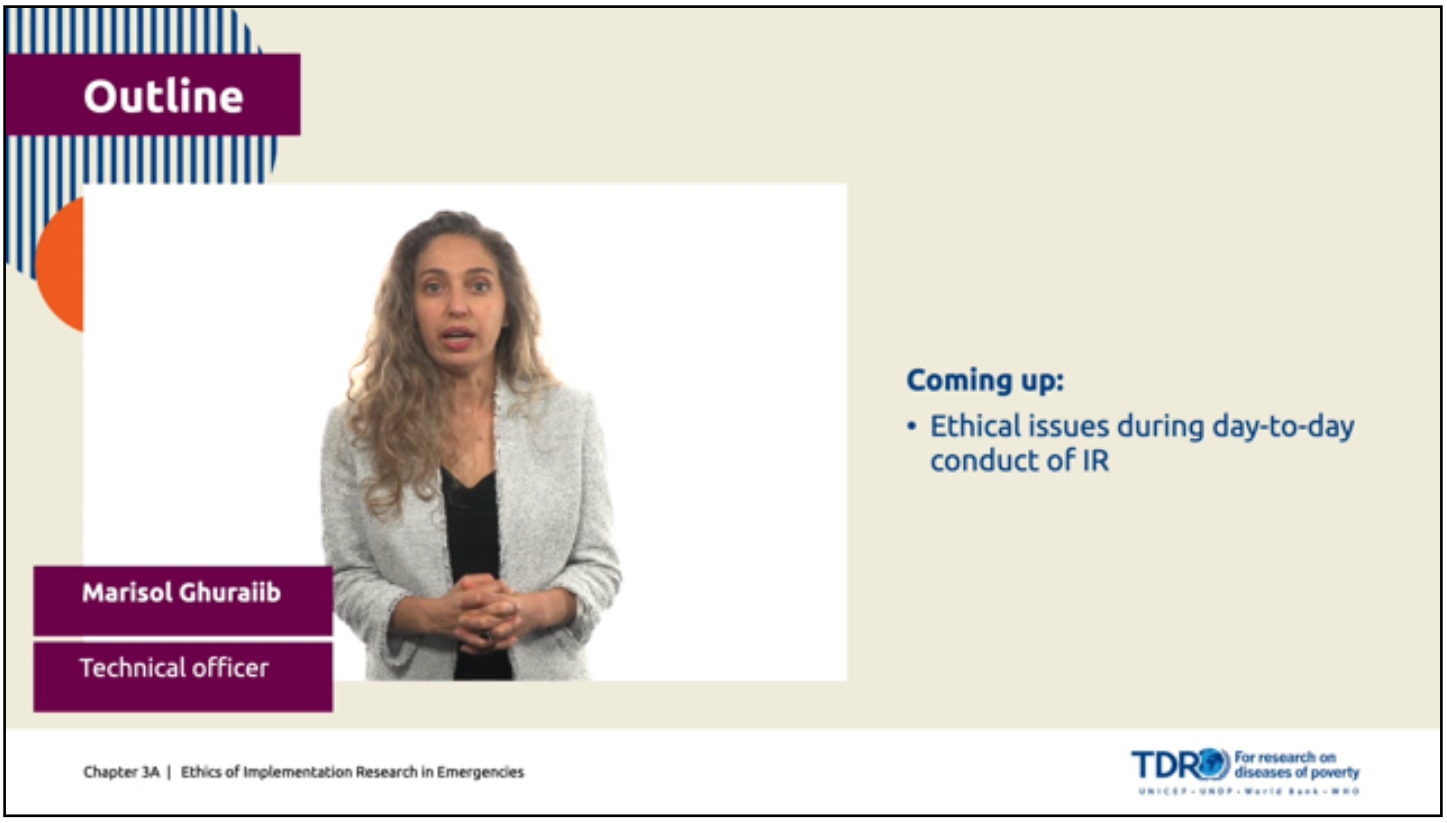


Hello. My name is Marisol Ghuraiib, and I work within the secretariat of the Ethics Review Committee at the World Health Organization. In this chapter, we will discuss the ethical issues that are most relevant

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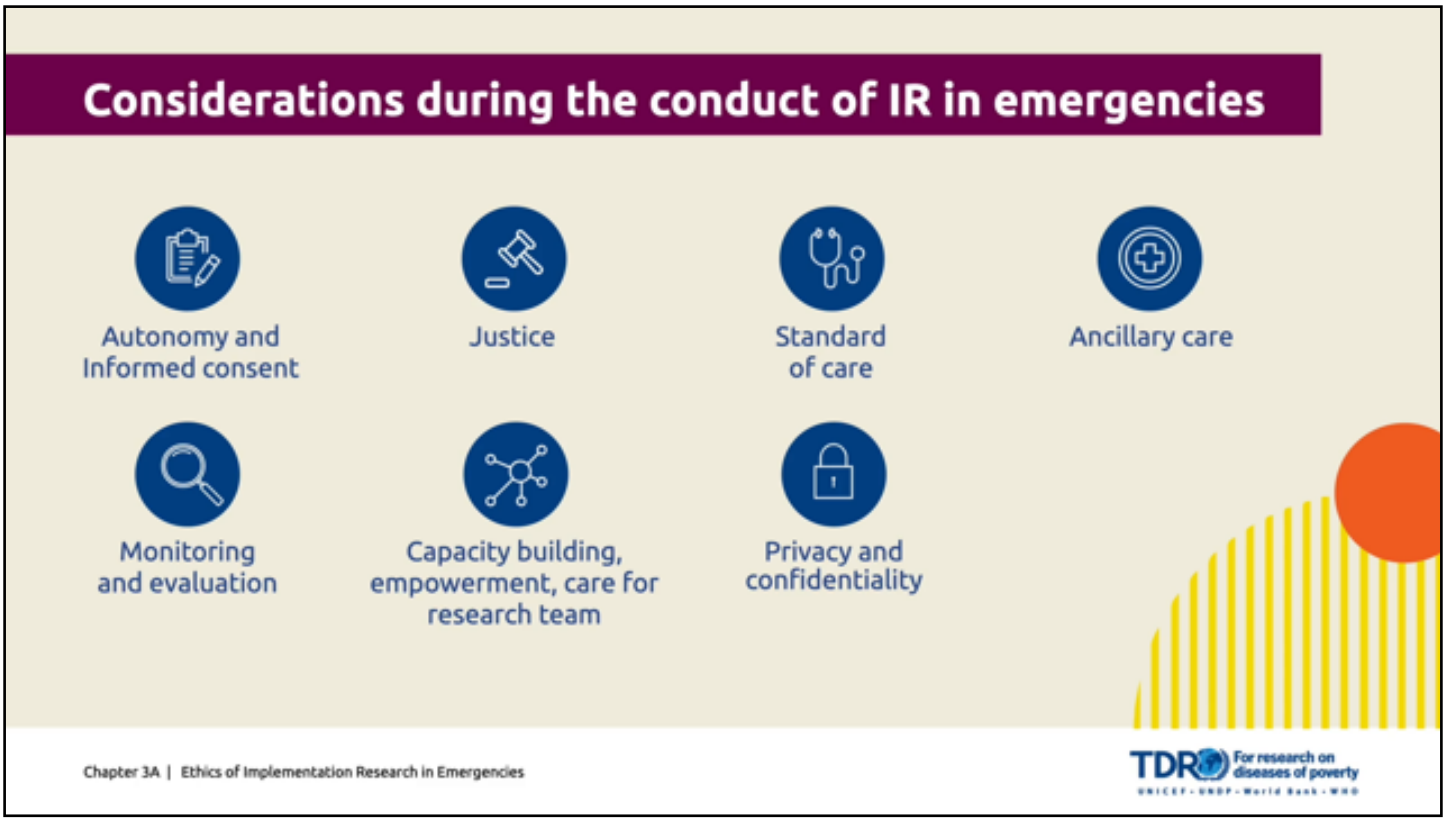


during the day-to-day conduct of implementation research, especially during emergencies, and

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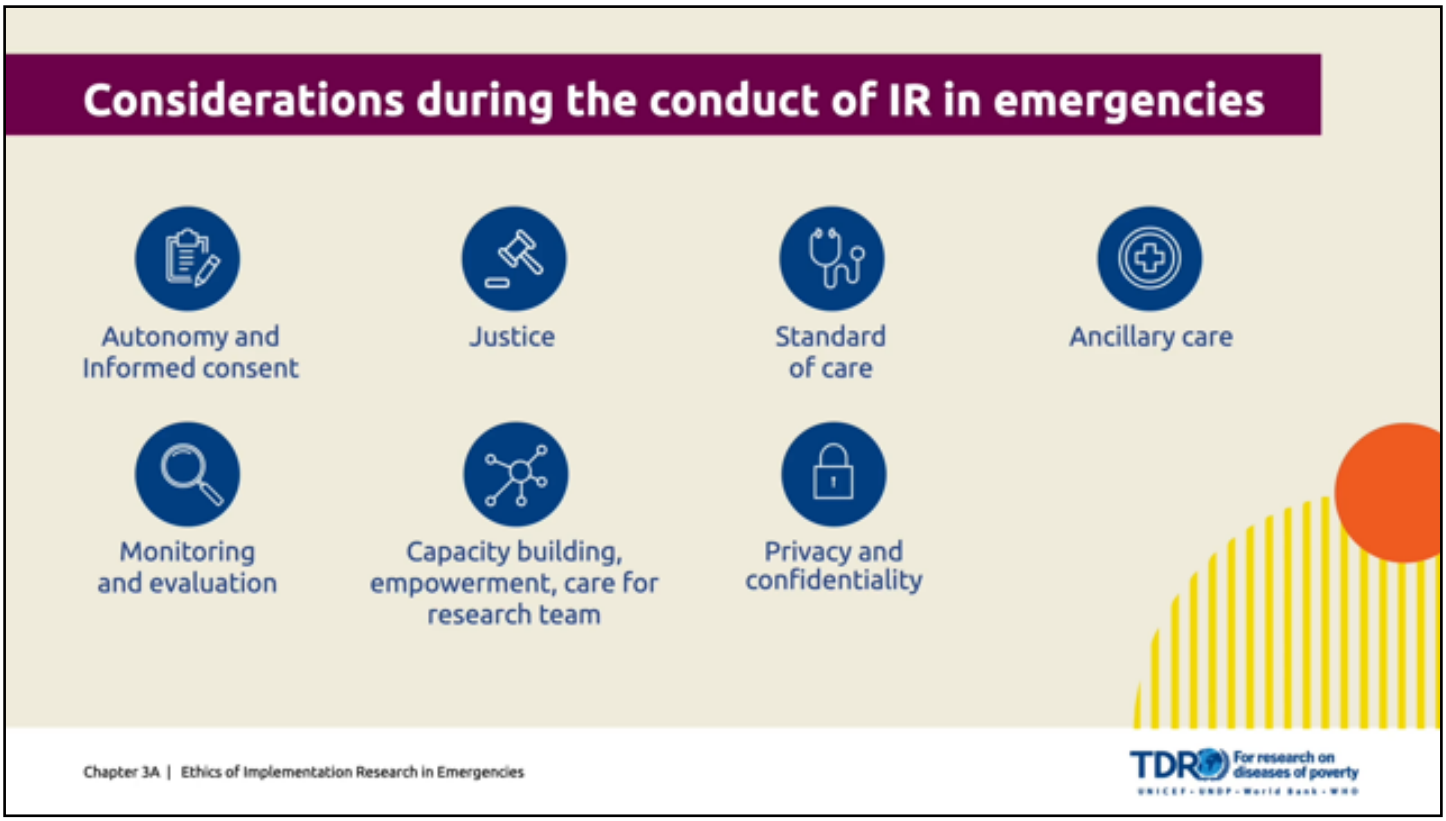


increase awareness of all these issues and how their relevance may change from one day to another, is critical for the ethical conduct of research. In this chapter, we will focus on the

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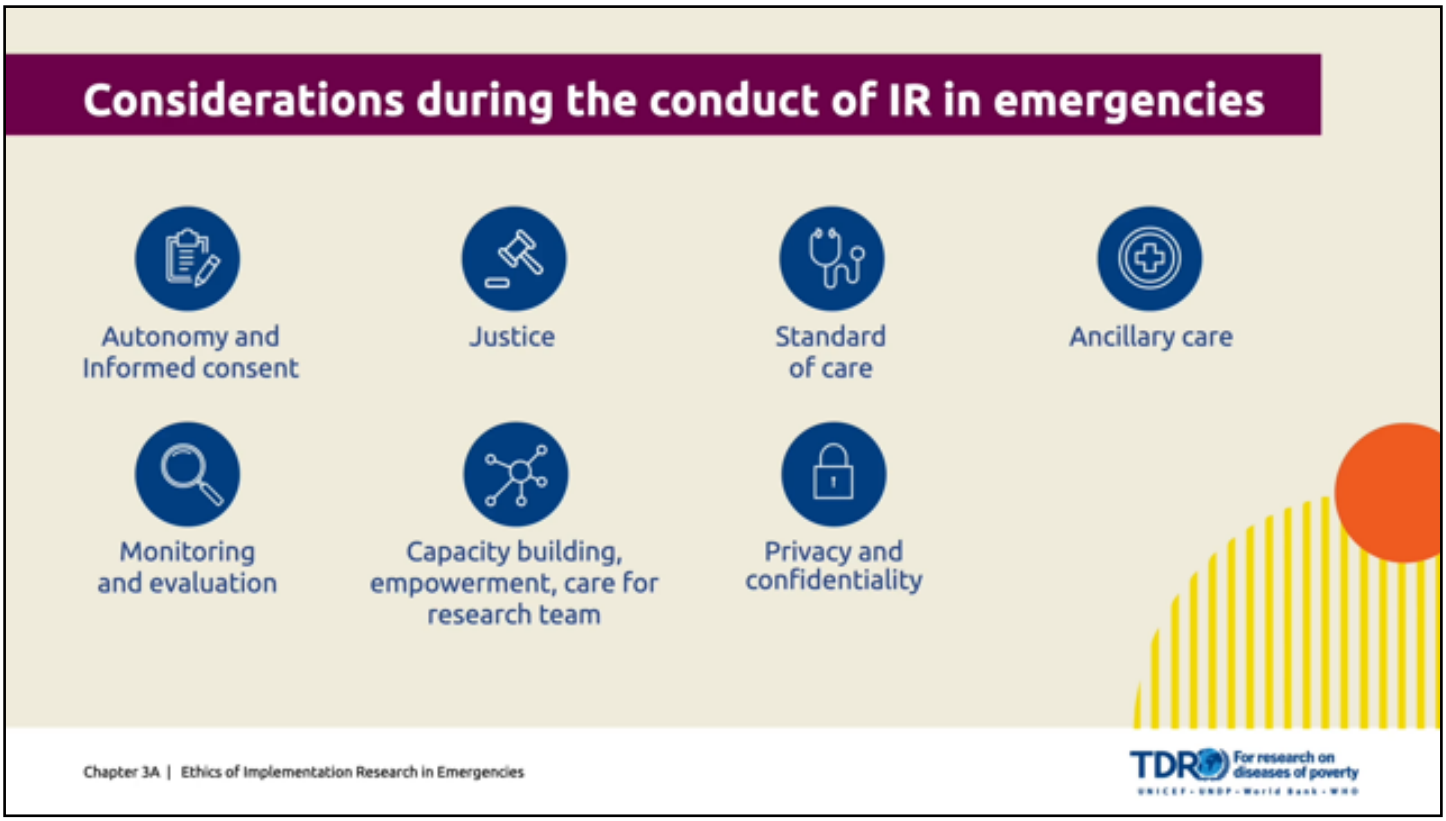


issues which are particularly relevant during the conduct of implementation research in emergencies,

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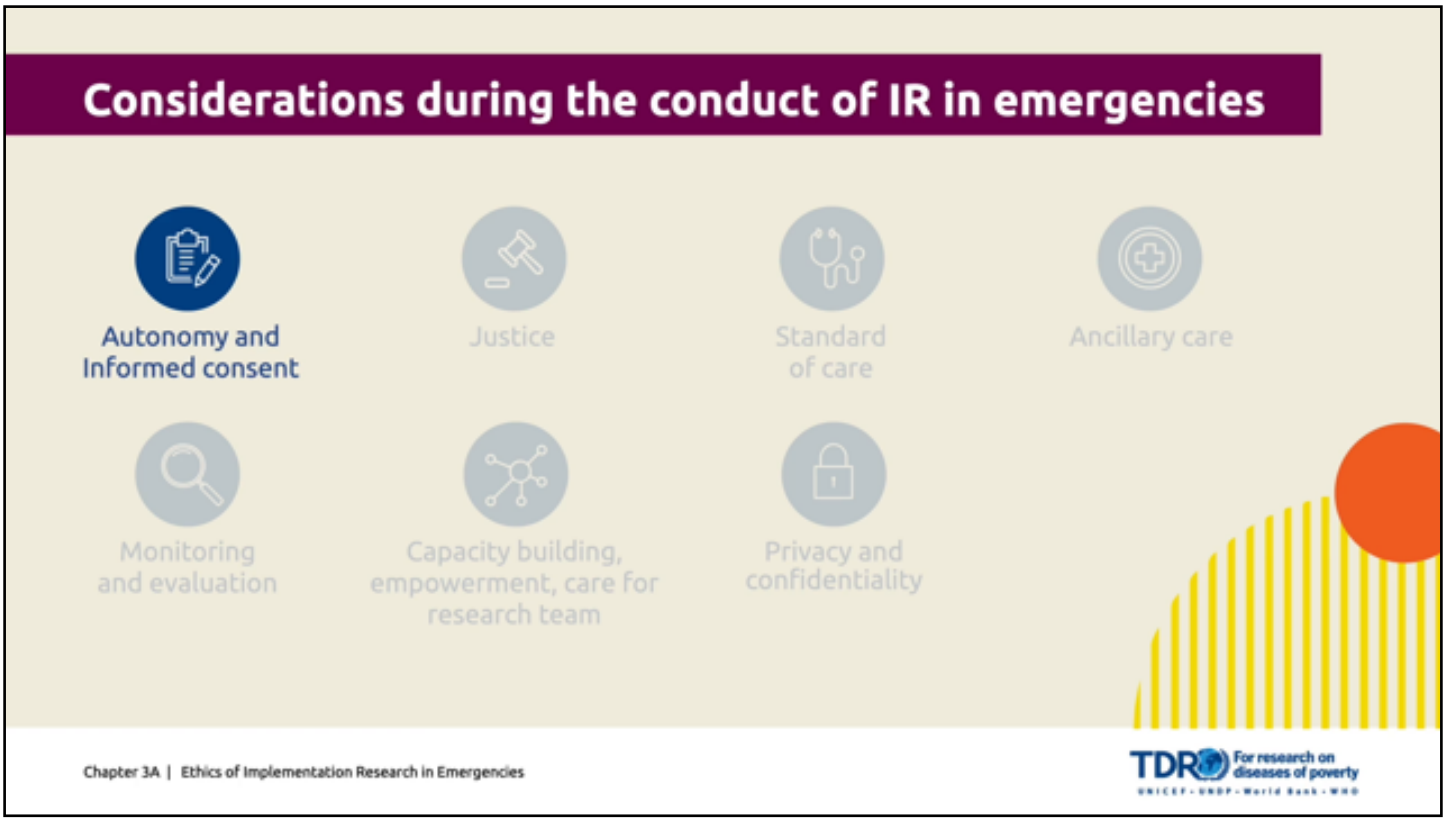


which encompass respect for research participants, broader issues of justice and fairness, and issues related to obligations towards the local health workers and the research teams. We will begin by

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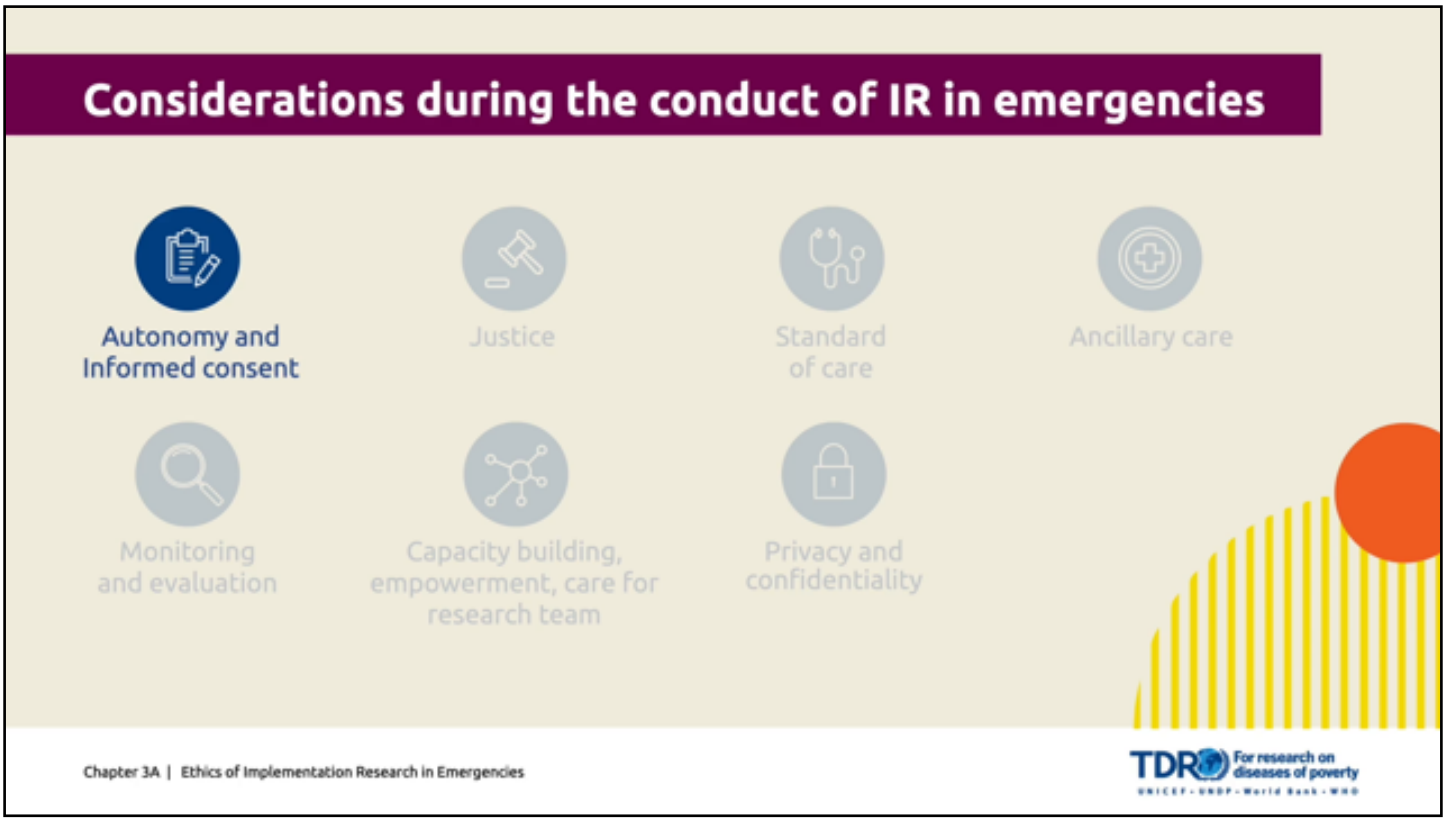


discussing how to best protect participants autonomy, and make sure that the consent process

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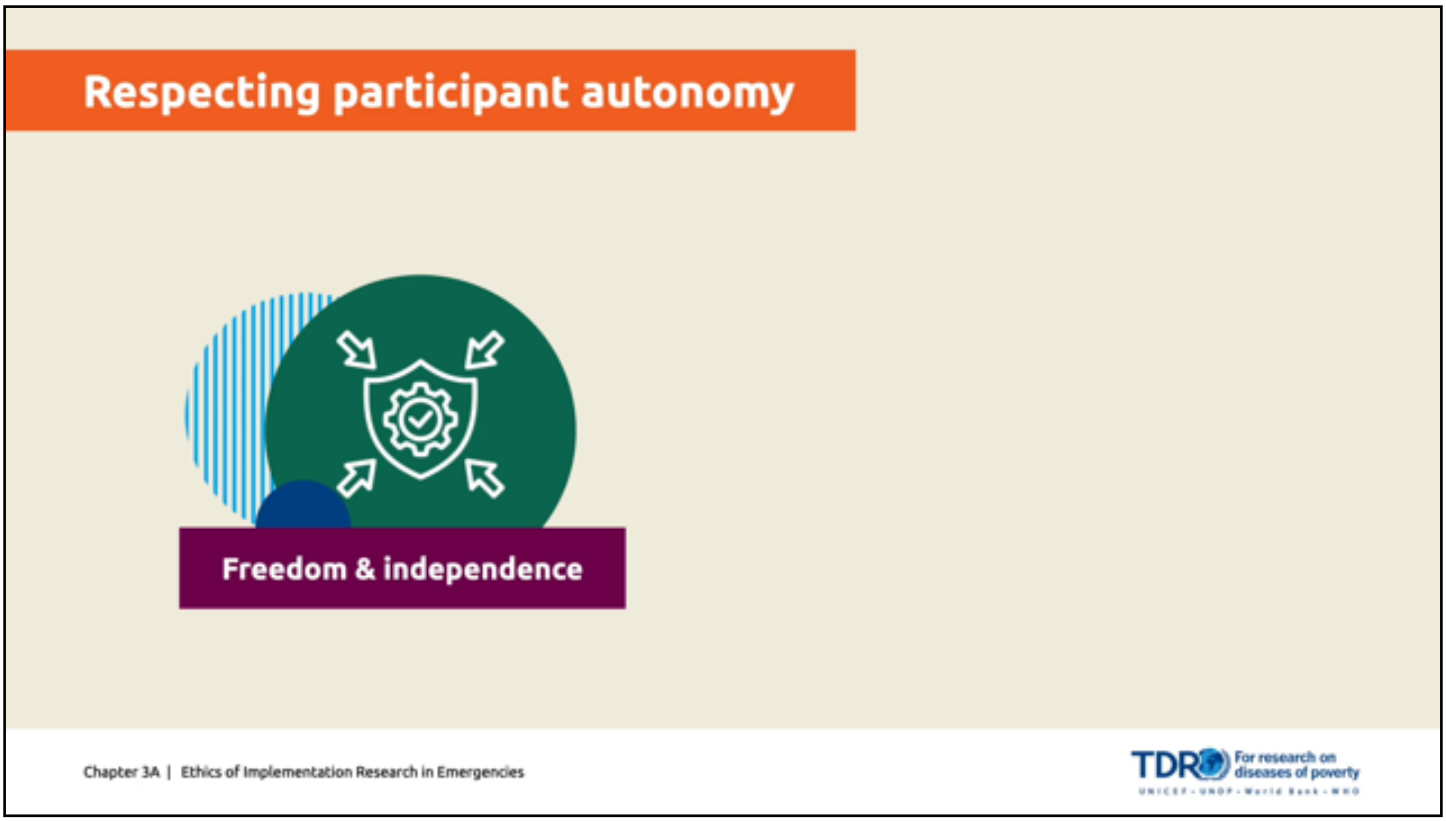


is informed during implementation research conducted in emergencies. It is to note that, even though, during emergencies, particular circumstances will influence the consent process,

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principles of informed consent should be applied as with any other type of study. Respecting participant autonomy in research means that the potential participant should be free from external influence when deciding whether to take part in research. They should be independent in

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the decision-making process, and have the freedom to decide whether they wish to participate in a study. Their decision should be informed and for this to happen, all relevant information should be given to them. Perhaps you're familiar with the consent process that is followed in clinical

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trials. For example, if a new drug to treat leprosy is being studied, individuals who meet the

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eligibility criteria are approached to participate. In the study, the new drug will be compared with the existing therapy. In such a case, potential participants must be fully informed, among other things, of what the study entails, what is expected from them, the potential

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Participant autonomy in clinical trials versus IR

Classical clinical trials:

- Inform participants about the study, potential risks and benefits
- Documented with signed consent form



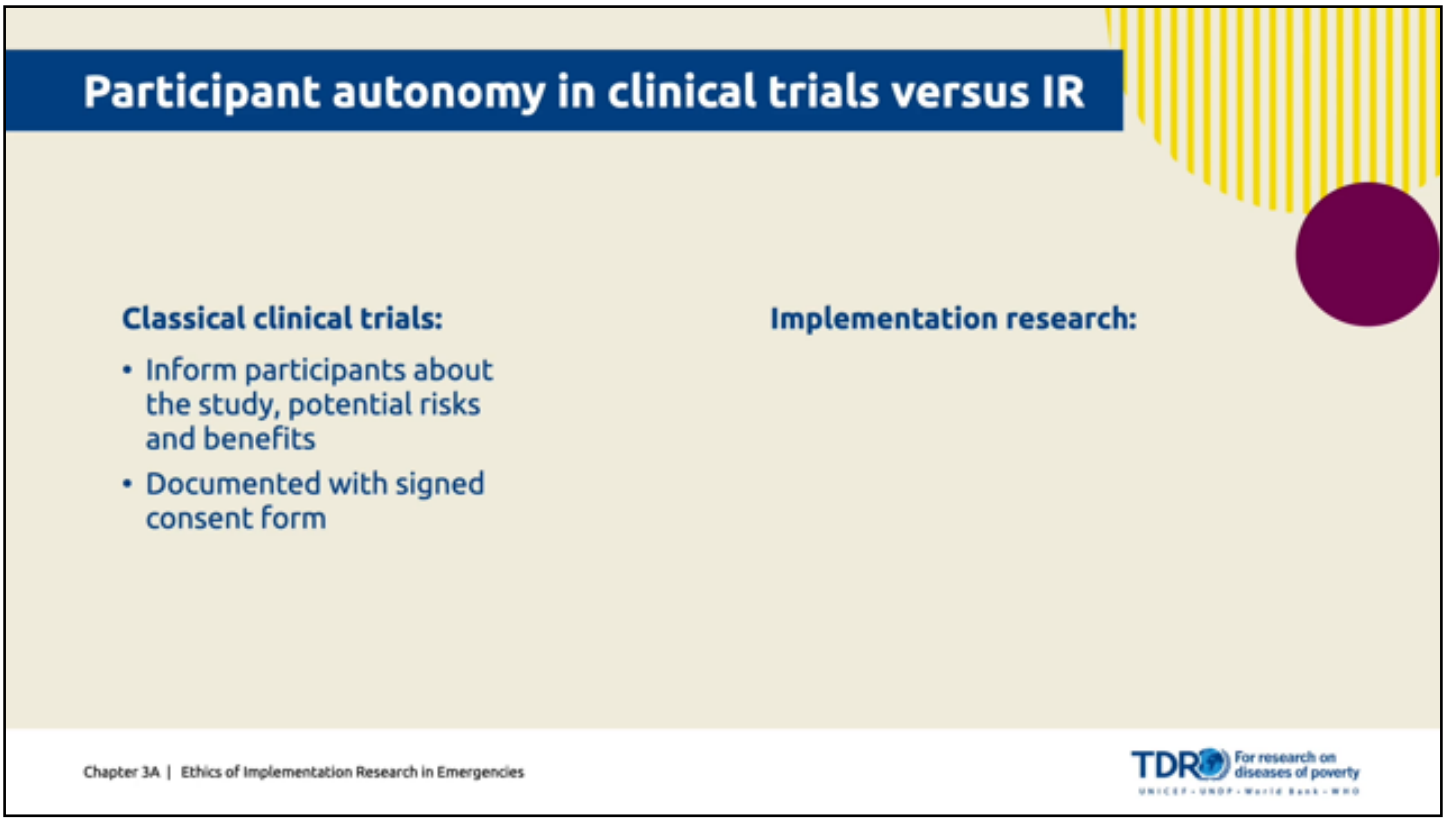
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risks and the potential benefits of the study and can decide by themselves if they wish to

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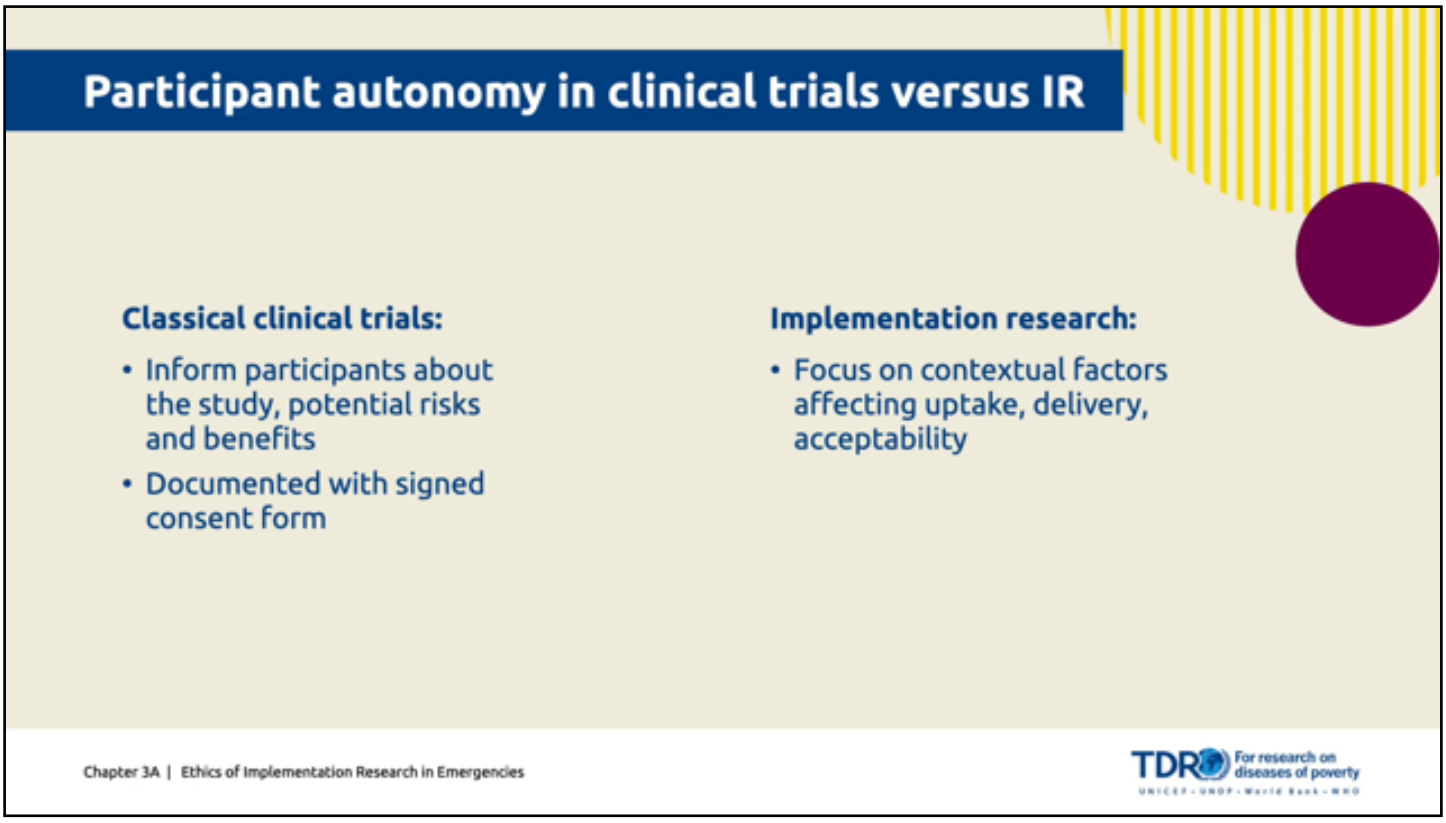


participate. This process of informed consent is usually documented by a participant signing a consent form. In implementation of research, as we know, even if an intervention was proven effective, in a clinical research context, its effectiveness will be different in a real life situation. For

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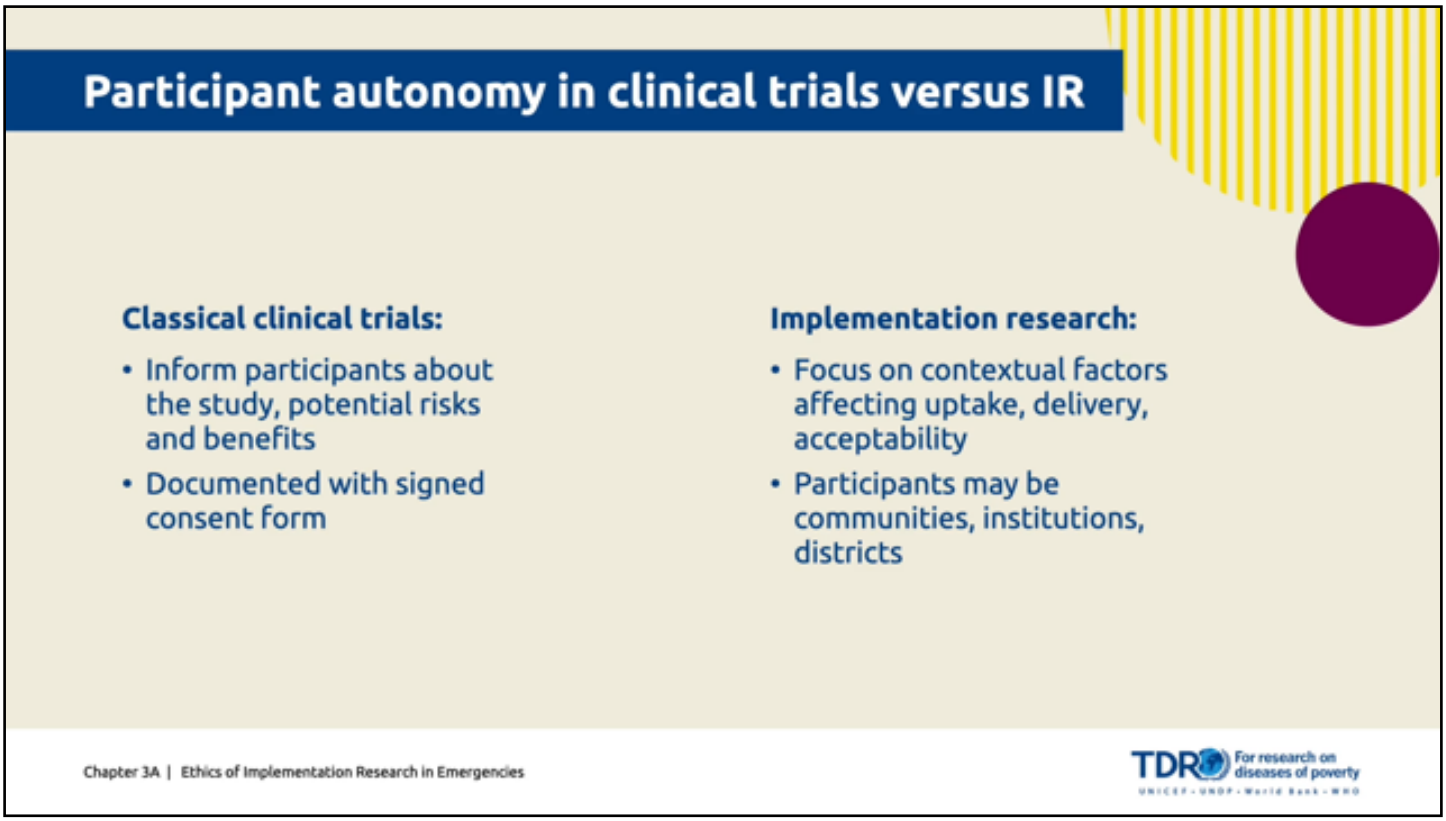


this reason, the focus of implementation research studies will be more likely related to contextual

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factors which may impact the delivery, acceptability, or uptake of a health intervention.

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Identification of participants

- Intervention performed in one group, outcome measured in another



Because of this, the research participants in implementation research may not only be individuals, but also communities, institutions or districts. As we discussed earlier, at

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times in implementation research, an intervention may be done in one group but measured in another.

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Identification of participants

- Intervention performed in one group, outcome measured in another

  Intervention in health workers, changes expected in patients



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For example, we could investigate the uptake of an application, prompting clinicians to adhere to

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Identification of participants

- Intervention performed in one group, outcome measured in another

  Intervention in health workers, changes expected in patients



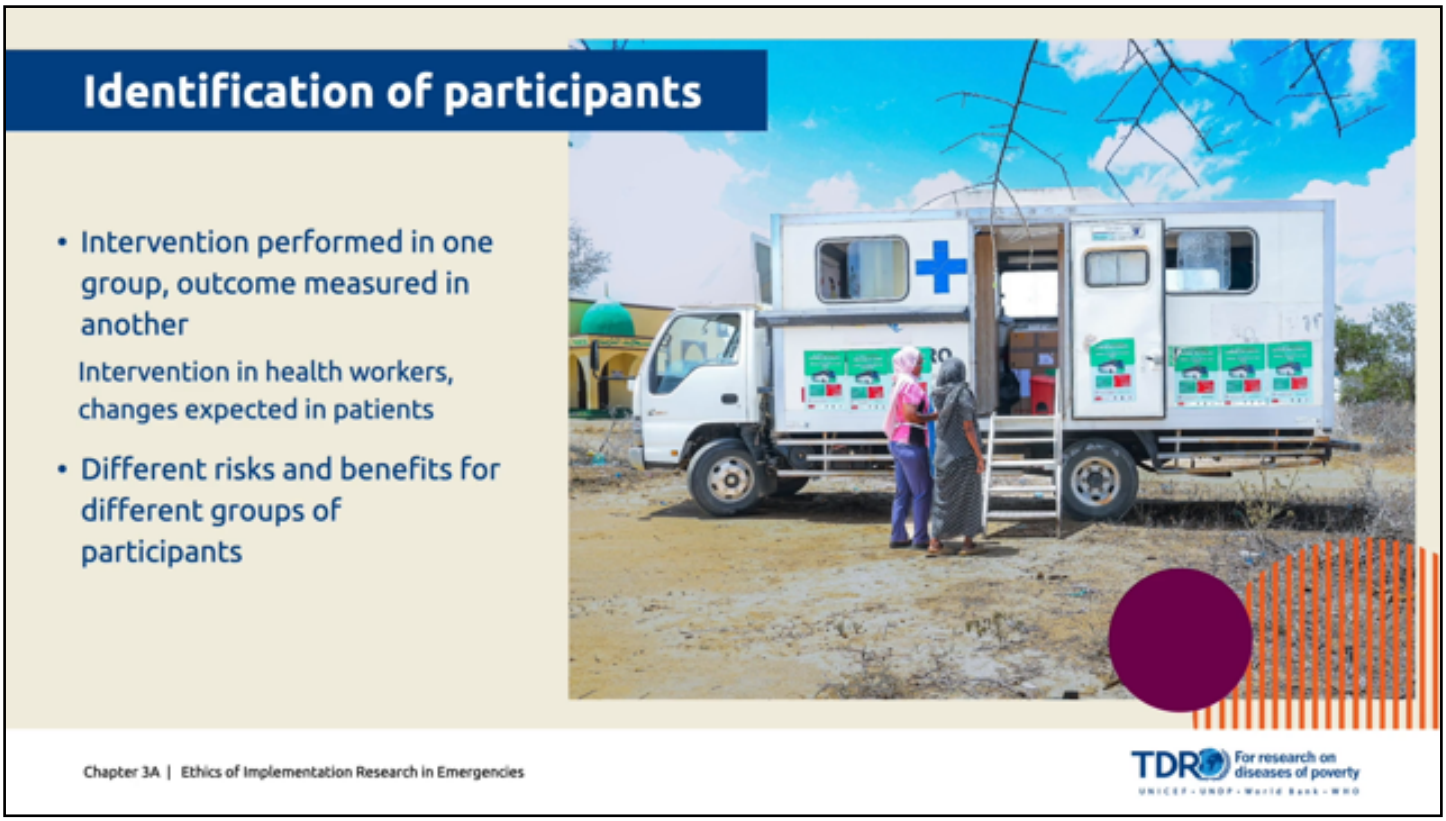
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infection control measures. The intent is to reduce hospital-acquired infections in mobile clinics in a conflict zone. The outcome of the intervention will be measured in terms of

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infection rates among patients. The intervention occurs in health workers, but the changes are expected in patients. The risks and benefits in such a study may therefore accrue differently to

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the different groups. The identification of research participants may therefore be less

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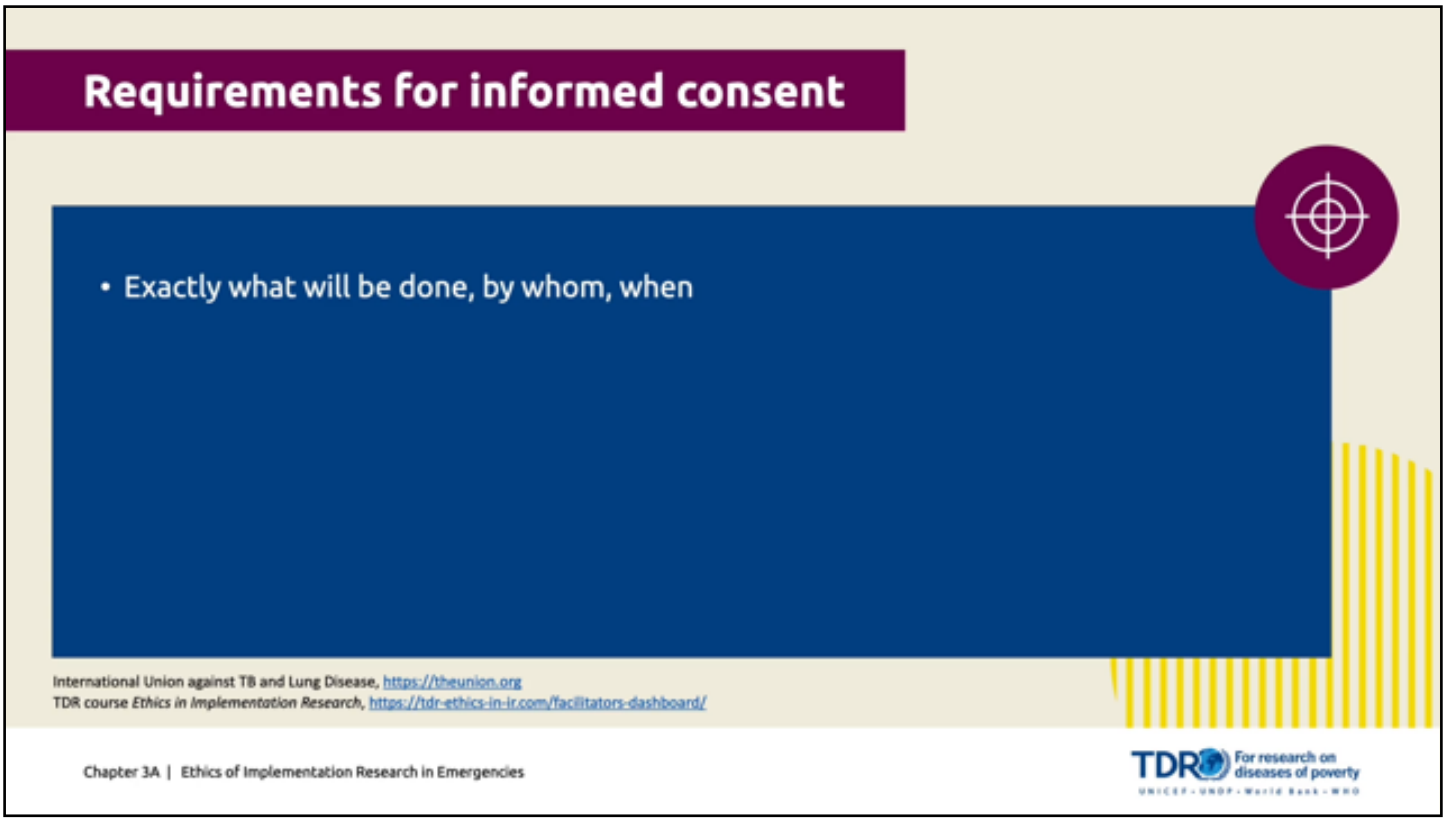


obvious in implementation research than in clinical trials, where the person receiving the intervention is the same person in whom outcomes are measured, and to whom benefits and harms apply.

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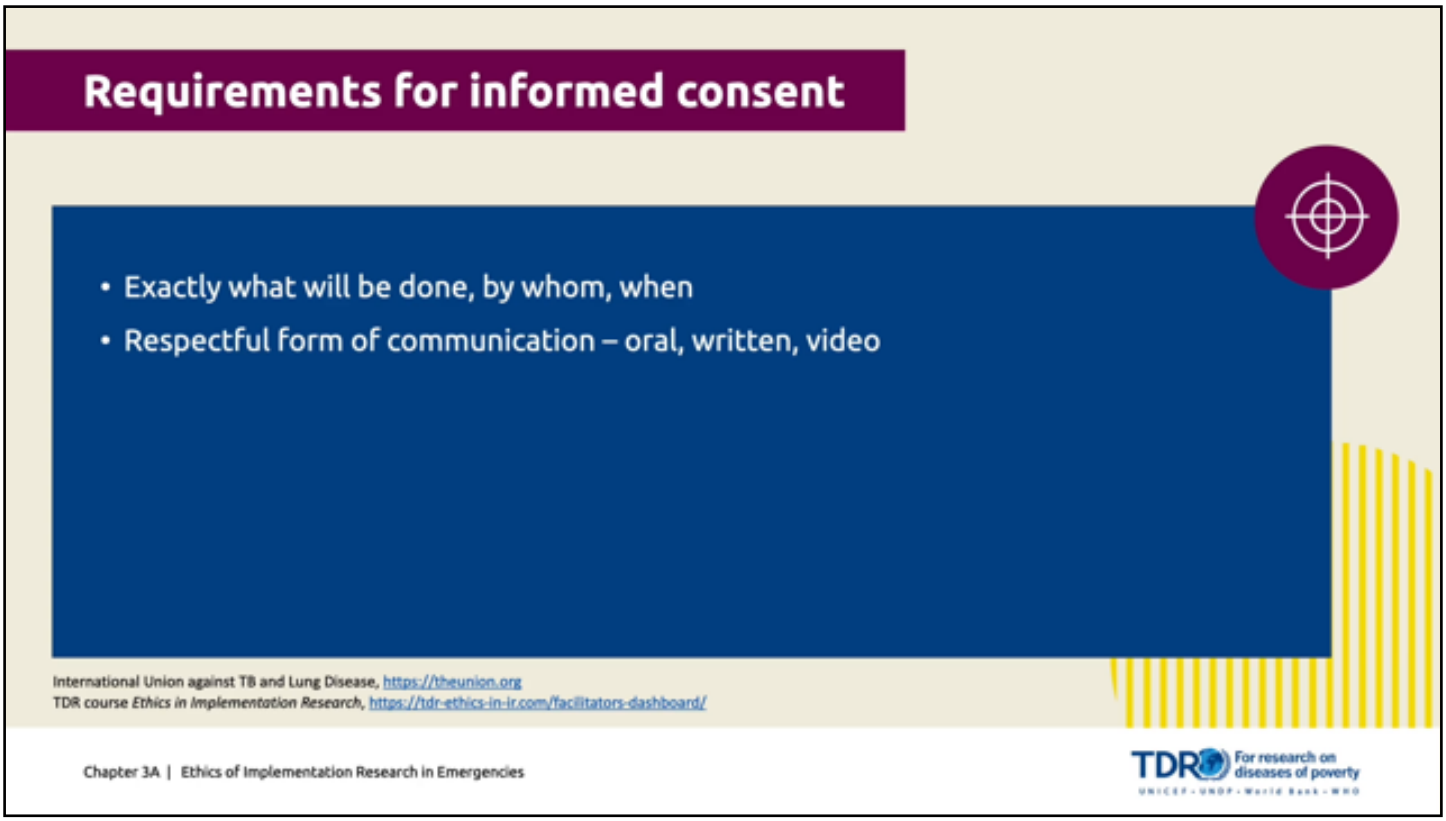


To enable participants to exercise their autonomy, researchers should be transparent and clear when communicating the different aspects of a study. Explanations should be given in an understandable form, making potential participants aware of what will be done during the study, by whom, and when.

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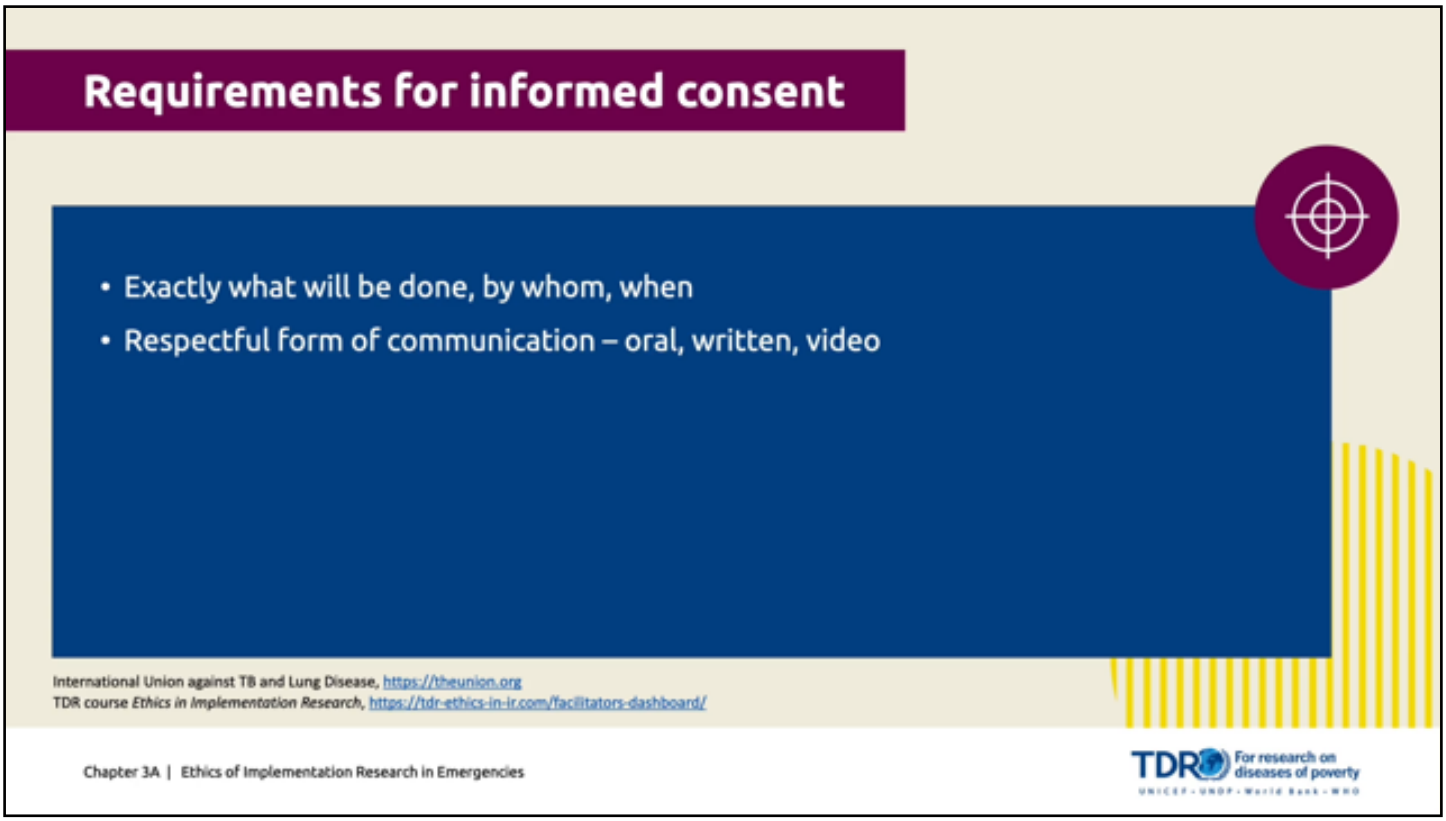


Providing participants with poor literacy skills long sheets of written information is not

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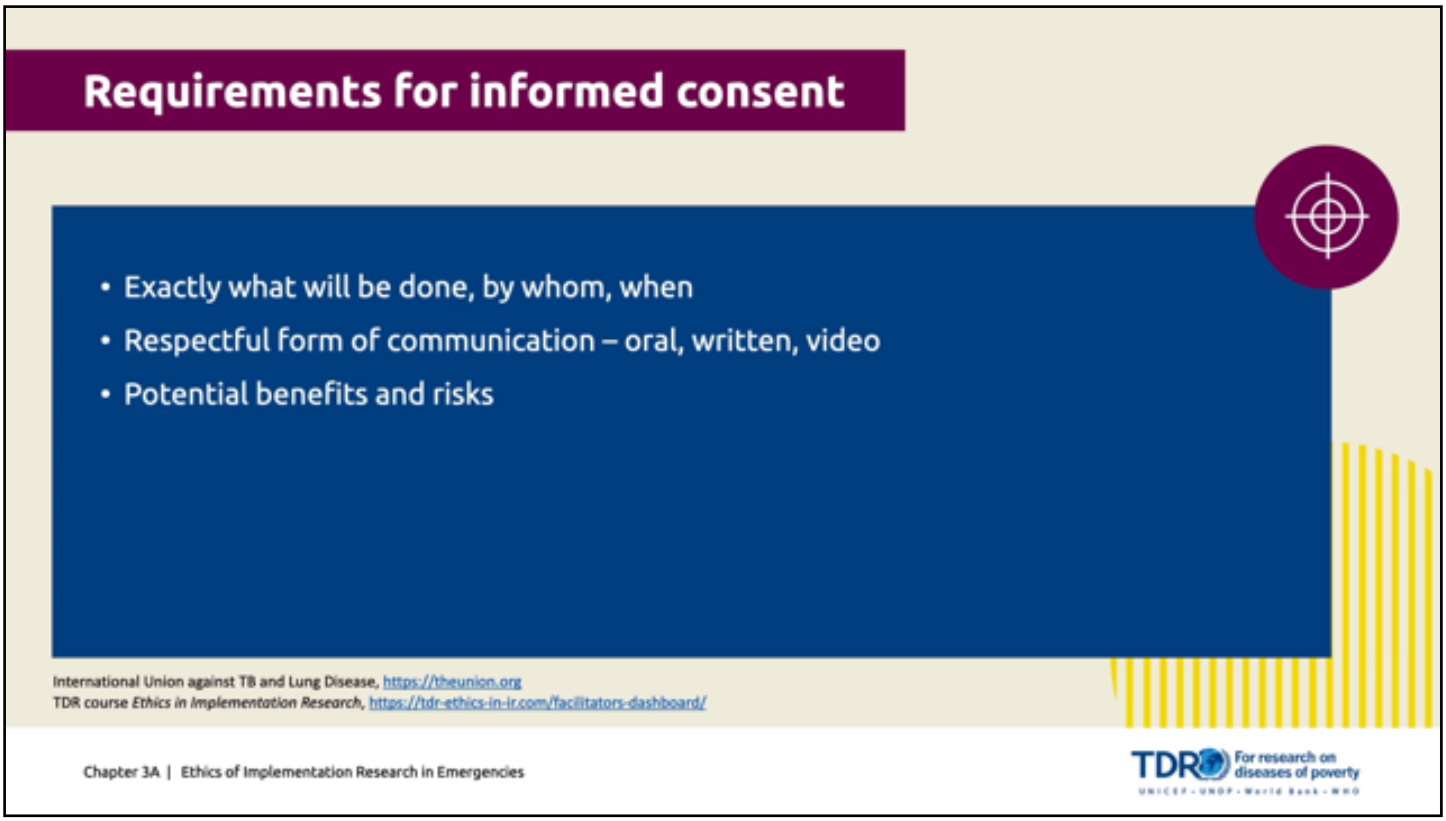


respectful. Use of videos or face-to-face explanations in their own language may be more

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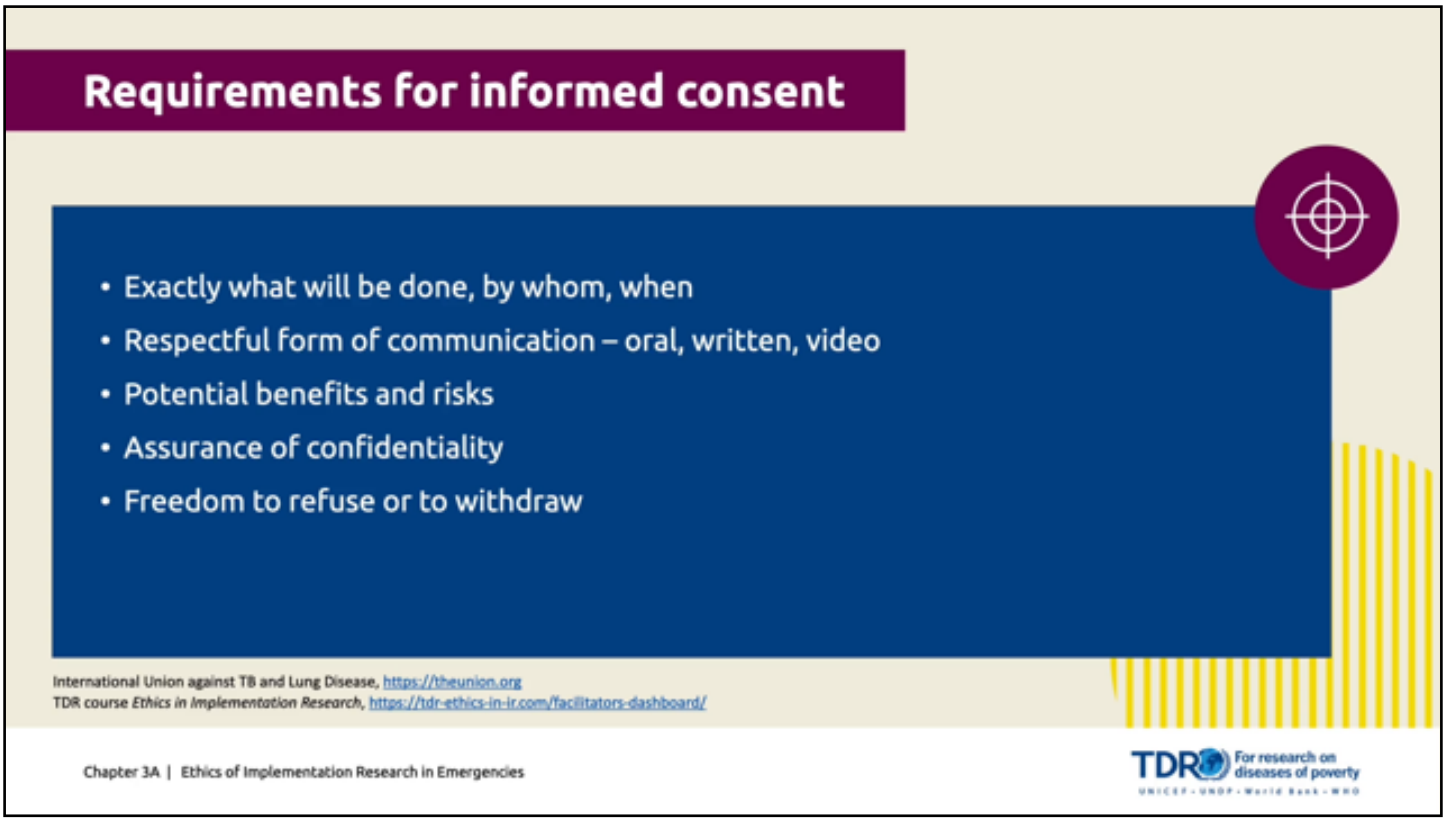


appropriate, although privacy concerns may increase. The ethical norms of transparency, respect and accountability dictate that participants must be informed of all possible

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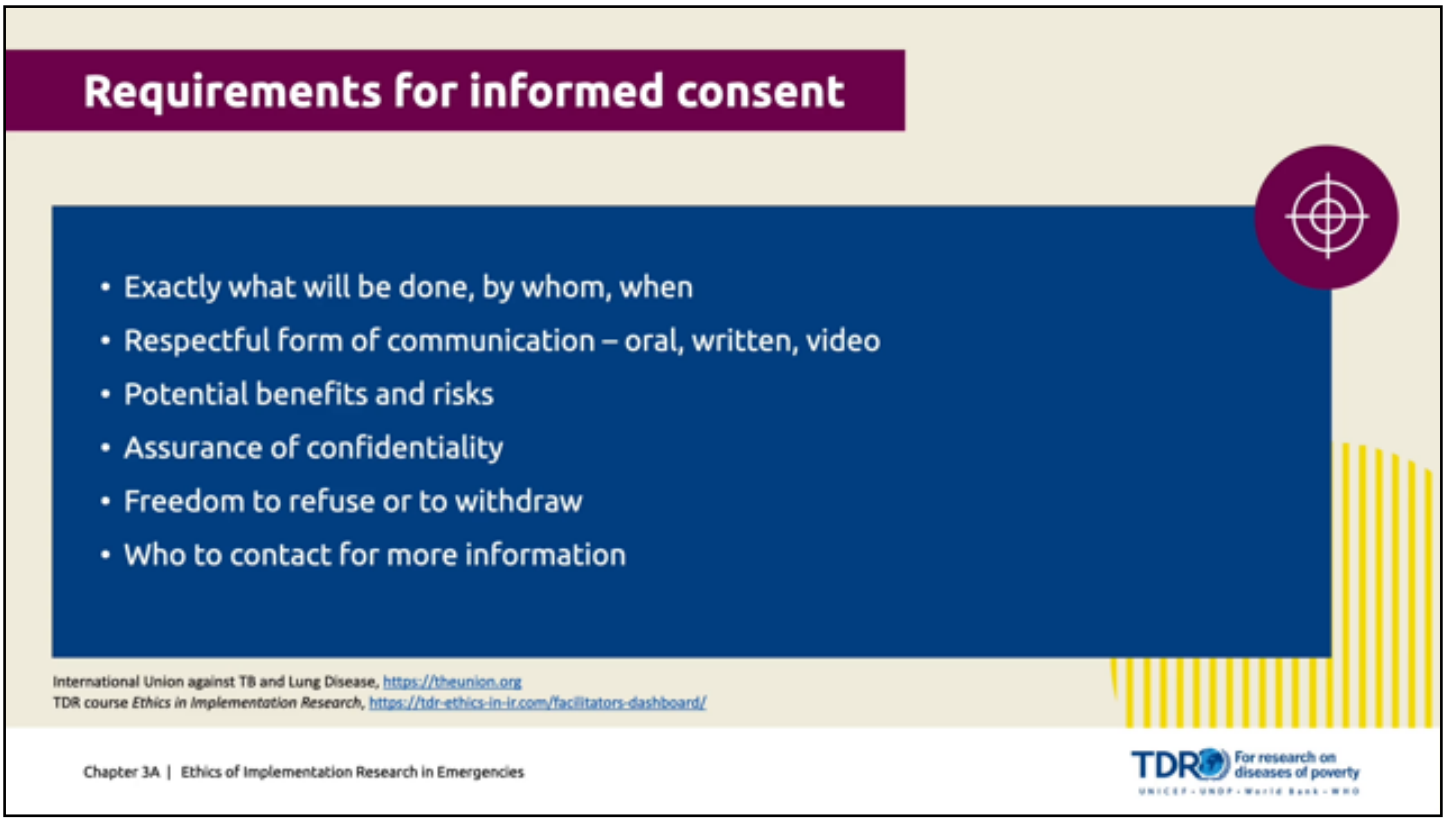


risks and benefits, be explained how confidentiality will be protected, and understand that they can withdraw from the study at any point in time, or up to the point where it is

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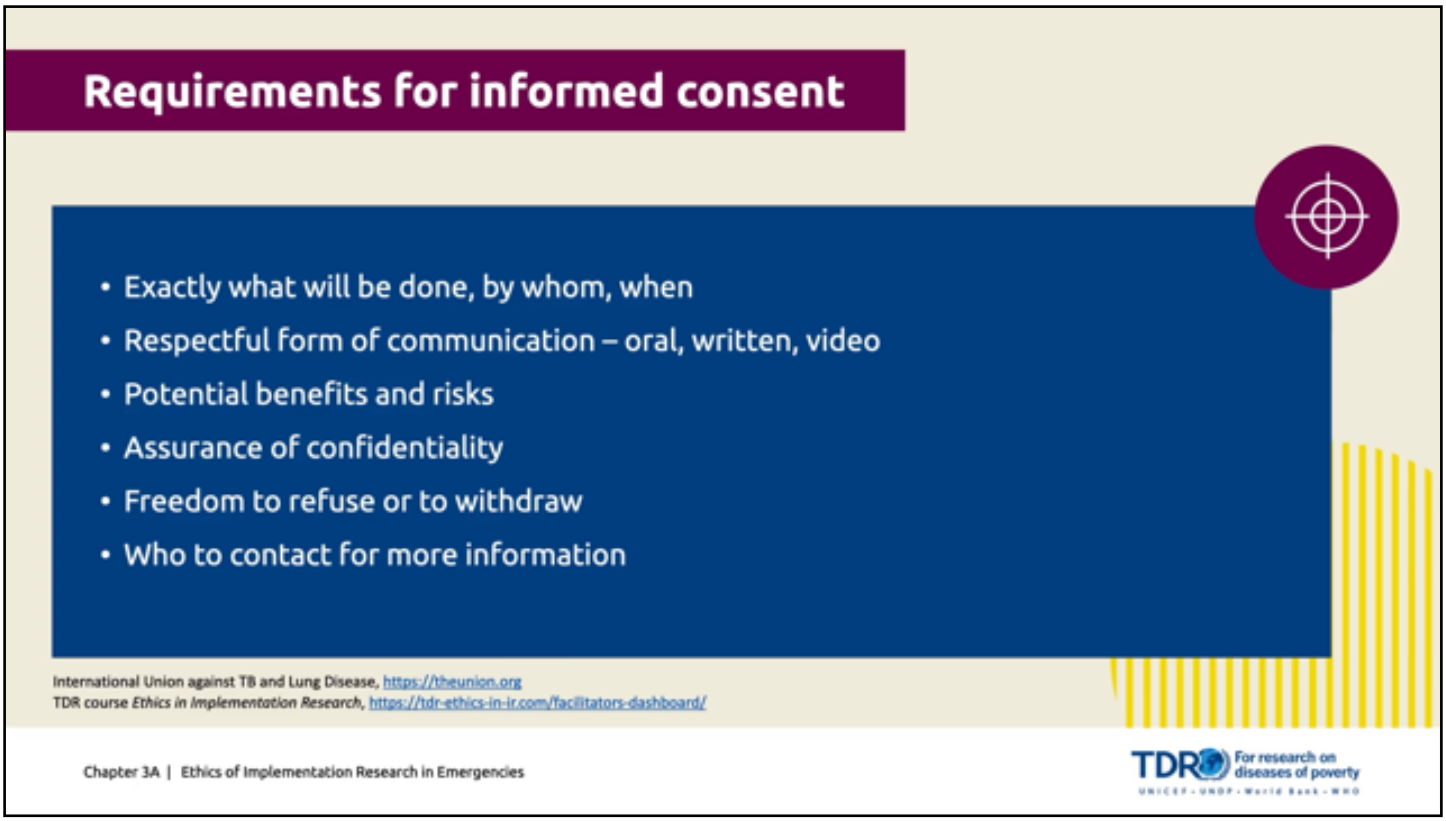


feasible, without any negative repercussions. Researchers must also remain available for

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questions or concerns that may arise during their study, and inform participants regularly about the study progress and findings, as consent is a process to be followed throughout the study, given

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the time constraints and potential communication barriers in implementation research conducted during emergencies, researchers must therefore be prepared to nimble and find effective ways to ensure that potential participants are fully informed.

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