Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Simplified consent models within the new clinical trial regulations - The theory behind it and the ethical considerations

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8th July 2025

Learning outcomes

- Understand the principles and reasons behind simplified consent in the new clinical trial regulations
- Discuss the benefits, challenges and ethical considerations of simplified consent
- Explore the opportunities for using simplified consent models in the right settings

Background on the Clinical Trial Regulations and GCP - This is where we are

The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended)

Clinical trial regulations govern the design, conduct, and reporting of trials

ICH GCP E6 R2

GCP ensures ethical standards, participant safety, and data integrity

Background on the Clinical Trial Regulations and GCP - This is where we are going

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Clinical trial regulations govern the design, conduct, and reporting of trials

ICH GCP E6 R3

GCP ensures ethical standards, participant safety, and data integrity

What do you need to know?

- The Medicines for Human Use (Clinical Trials) Regulation 2004 is being revised.

- ICH GCP E6 **R3** will be implemented in the regulations above.

28 April 2026

Your thoughts?

- What does the term, ‘simplified consent,’ mean to you?
- What do you hope to take away from this workshop today?

Simplified consent

Simplified consent may be suitable for studies which carry no greater risk than usual clinical care.

In this workshop, we are only focussing on research consent with adults with capacity.

Topics raised

Benefits

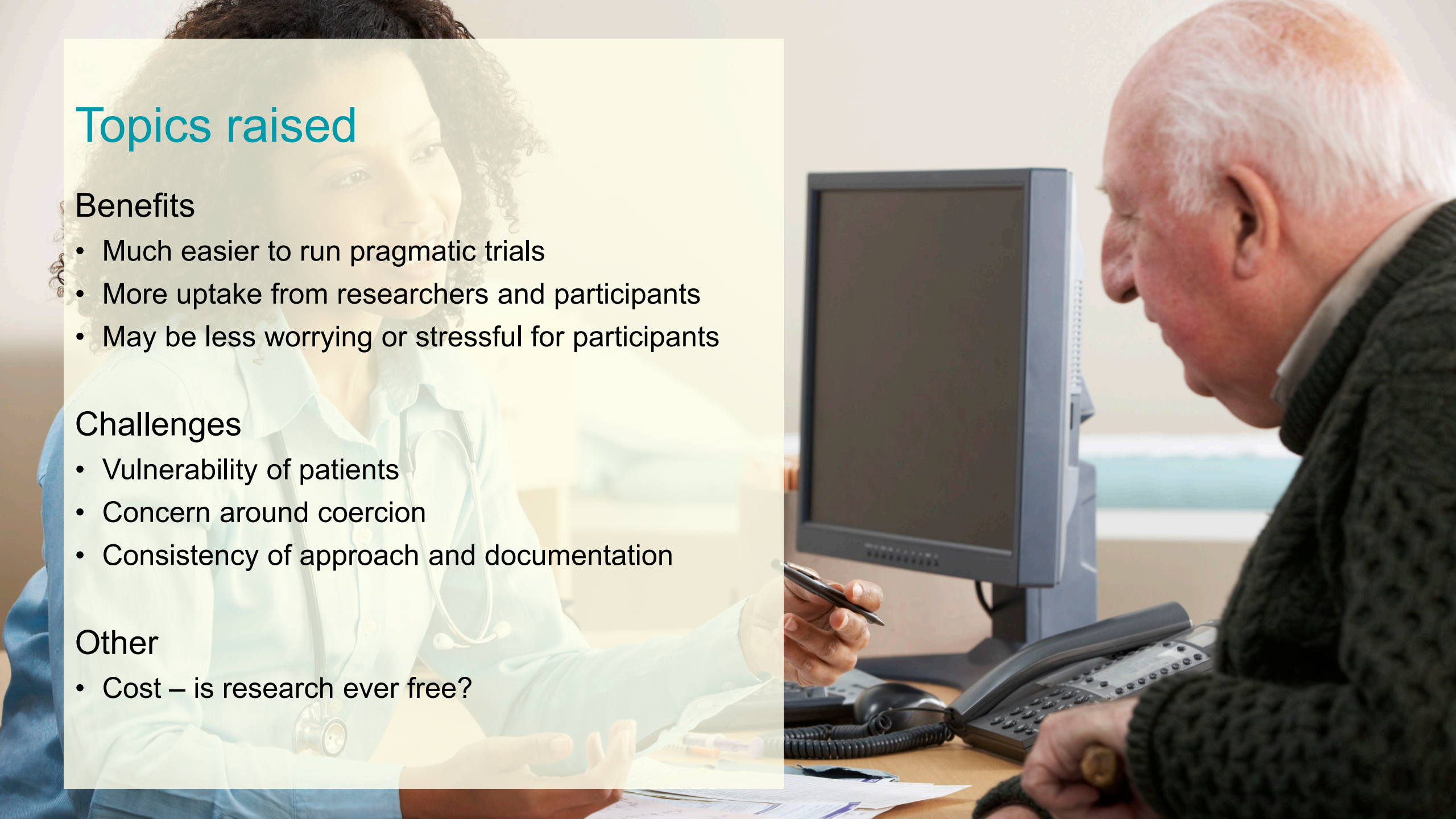
- Much easier to run pragmatic trials
- More uptake from researchers and participants
- May be less worrying or stressful for participants

Challenges

- Vulnerability of patients
- Concern around coercion
- Consistency of approach and documentation

Other

- Cost – is research ever free?



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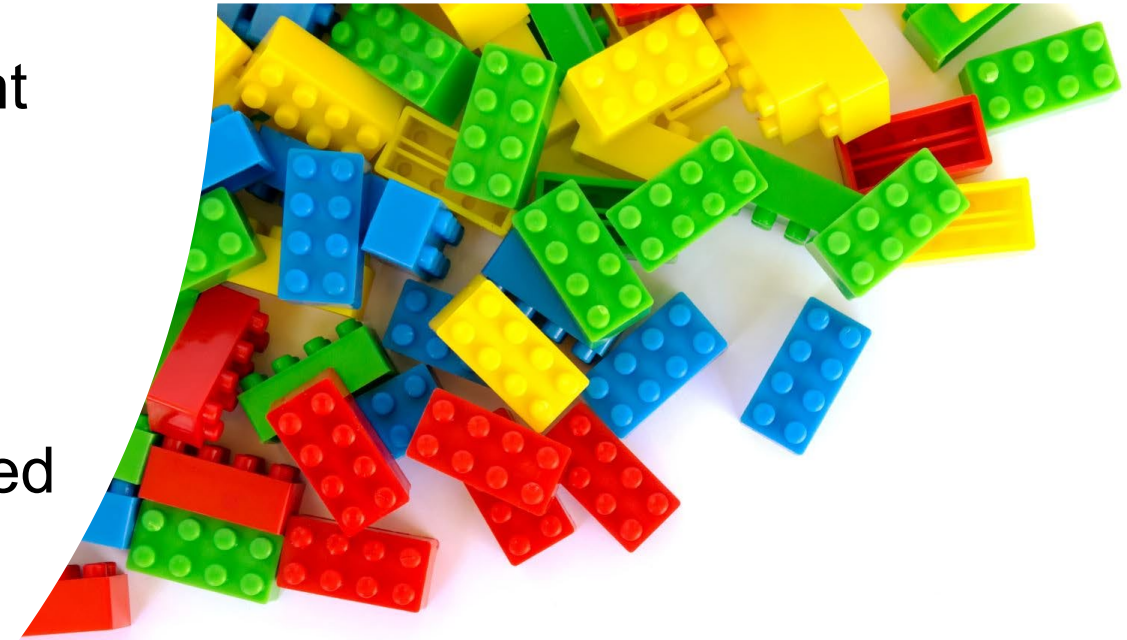
Group activity

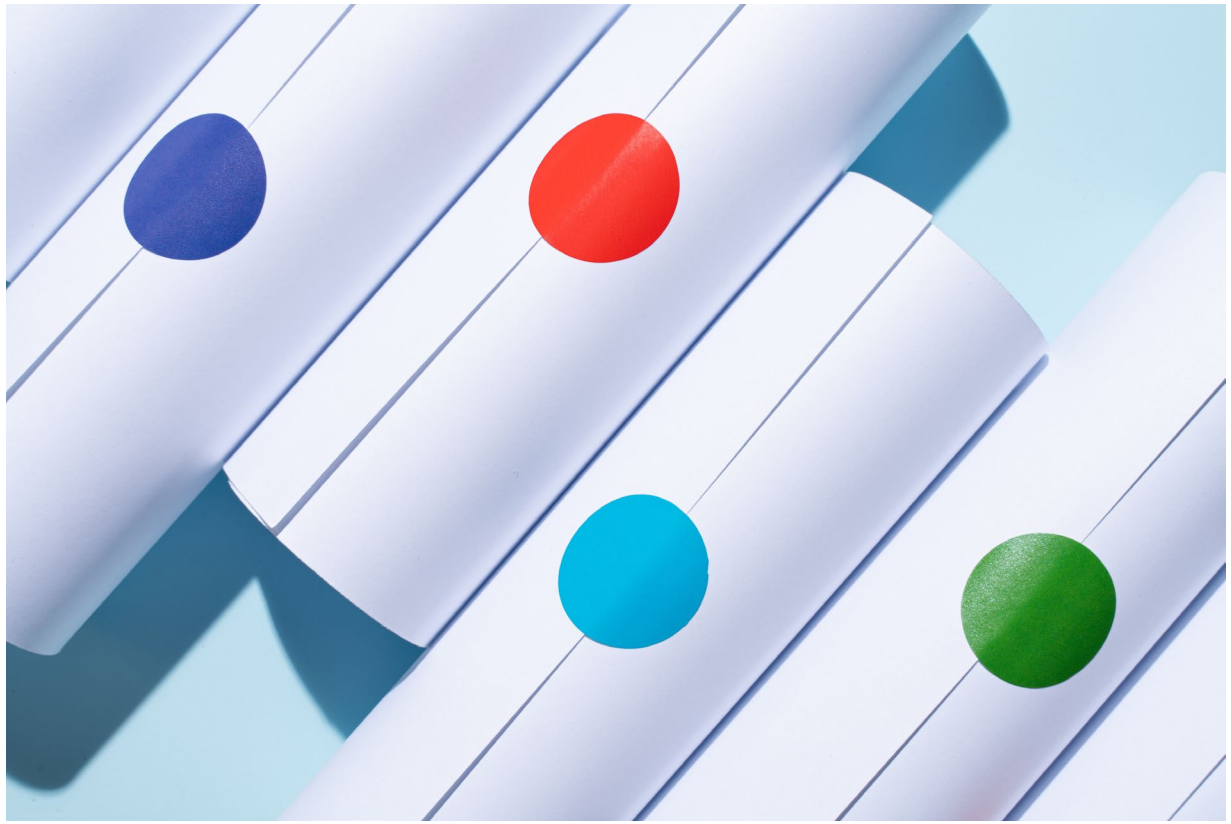
In your groups, use the materials on your table to create something that reflects one (or more!) of the below:

- The benefits of simplified consent
- The challenges of simplified consent
- Ethical considerations of simplified consent

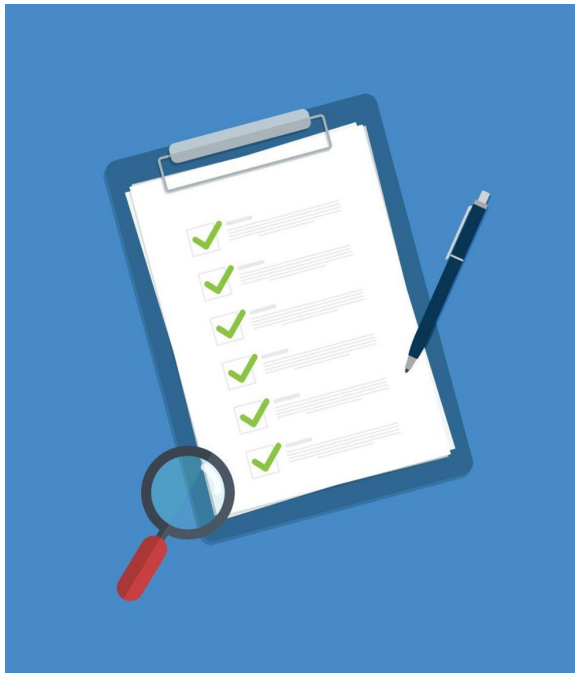



Feedback

UK Clinical Trial Regulations 2025 and simplified consent



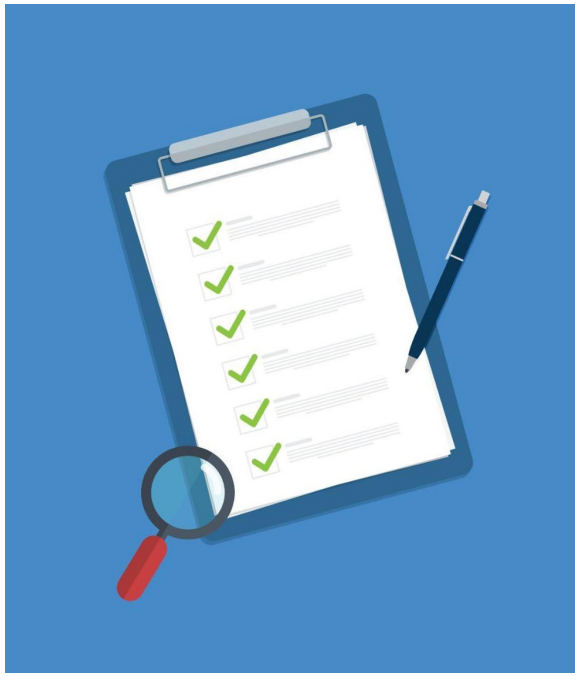
Revision changes at a glance



- Approvals
- Transparency
- Safety Reporting and Pharmacovigilance
- Consent

This revision supports a more streamlined and flexible approach to the regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants.”

Revision changes at a glance



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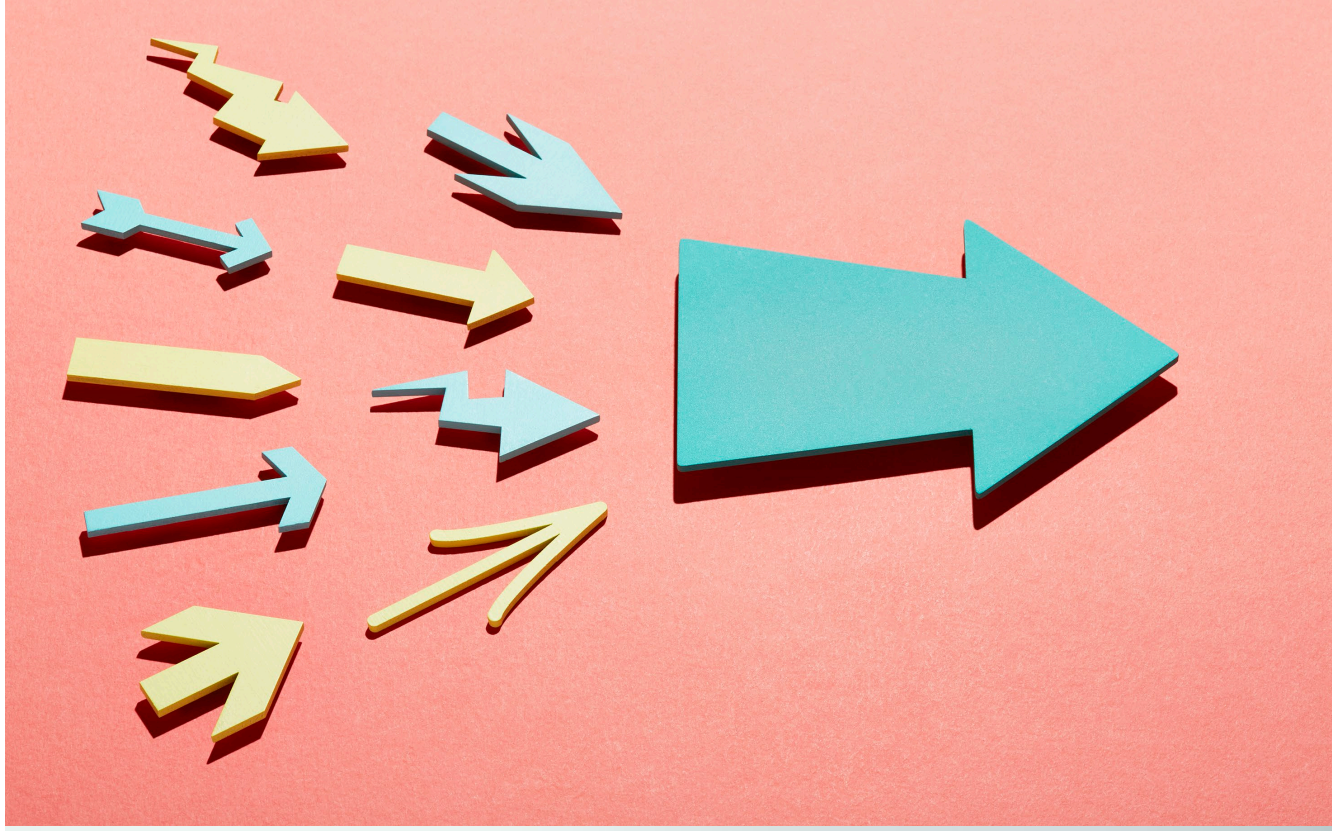
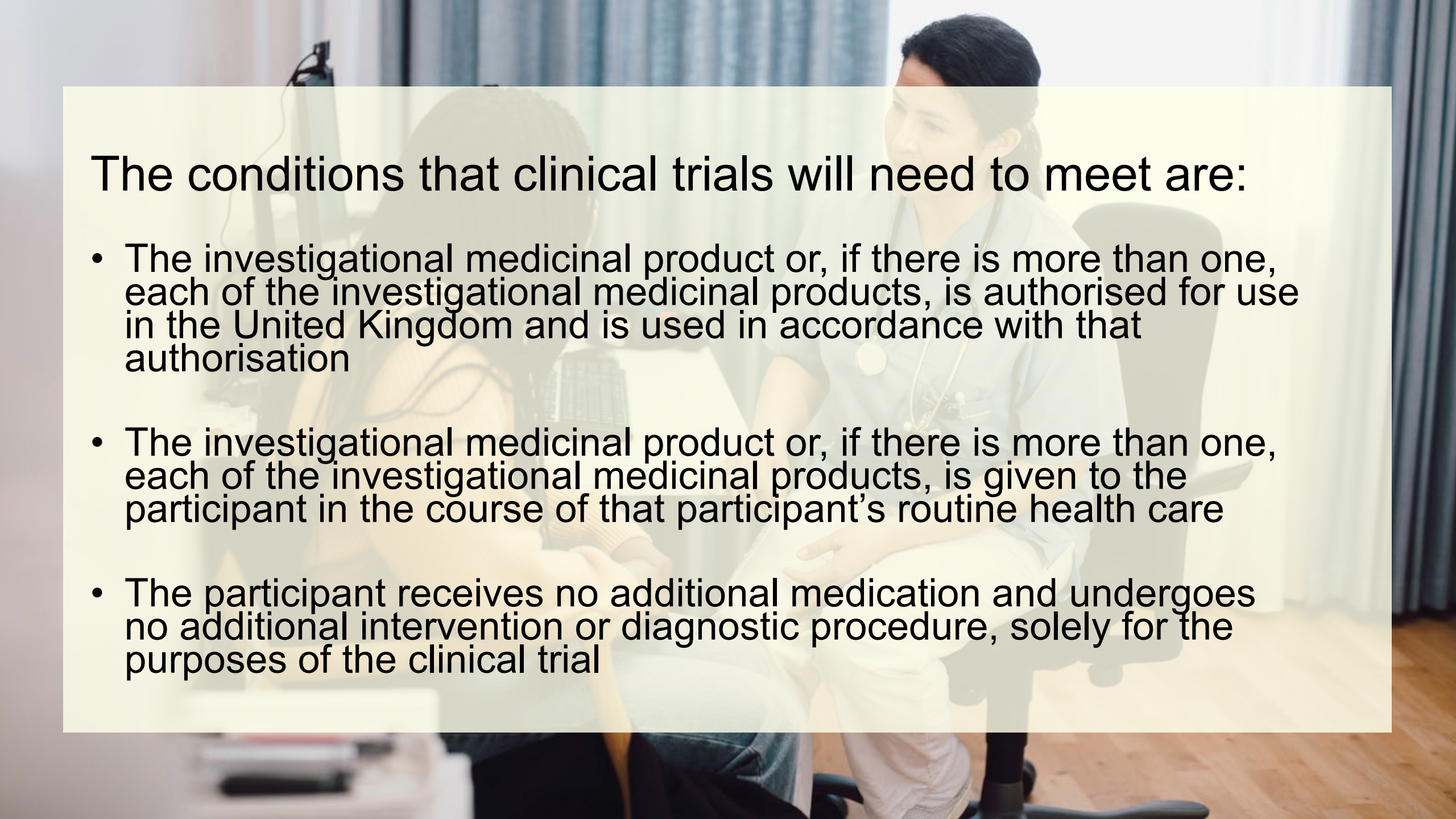
HRA Guidance

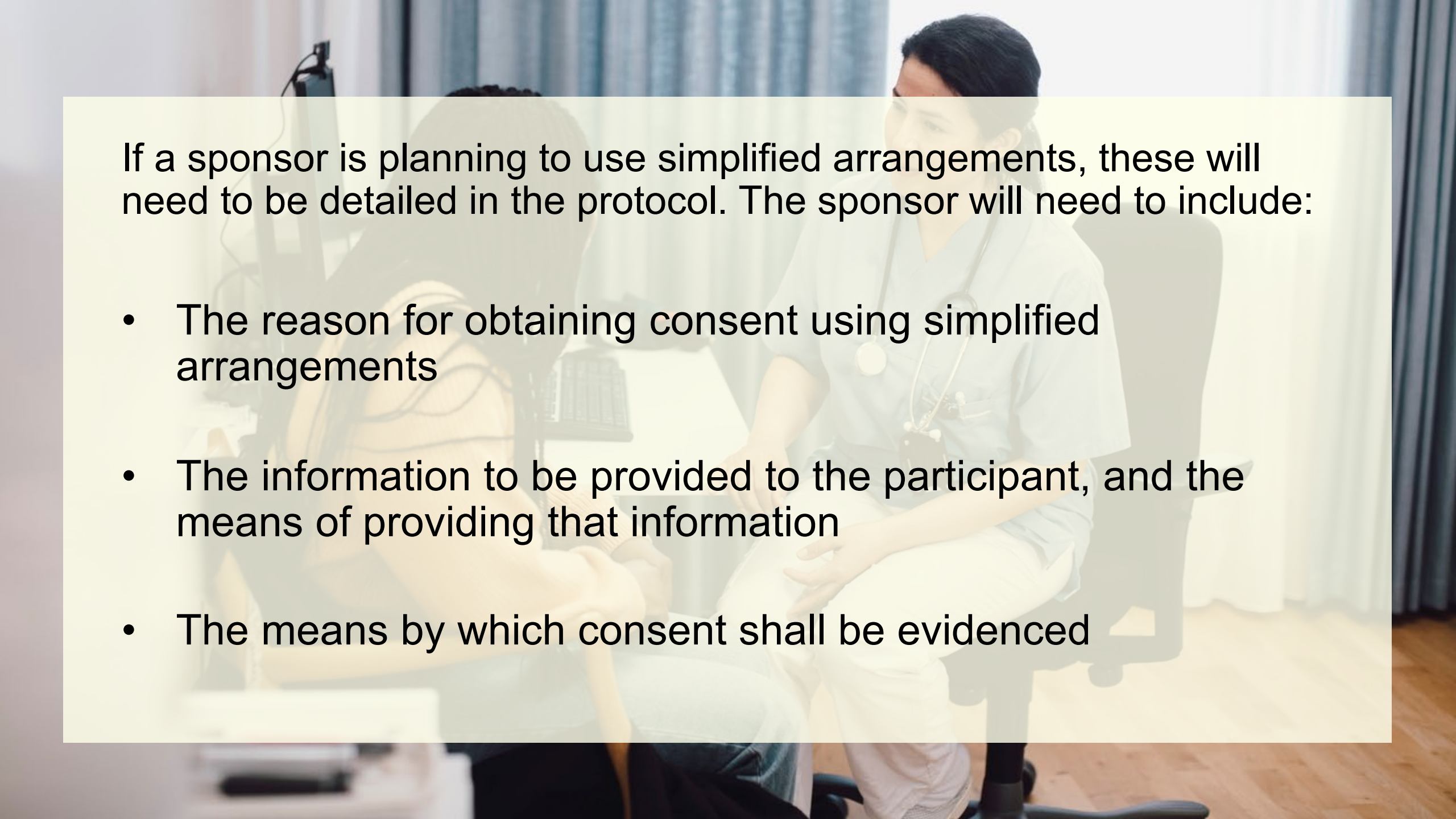
"The new clinical trials regulations will offer sponsors of clinical trials that meet certain conditions the option to use simplified arrangements for seeking and evidencing informed consent." (HRA guidance on changes to clinical trial regulation, Jun 2025)





The conditions that clinical trials will need to meet are:

- The investigational medicinal product or, if there is more than one, each of the investigational medicinal products, is authorised for use in the United Kingdom and is used in accordance with that authorisation
- The investigational medicinal product or, if there is more than one, each of the investigational medicinal products, is given to the participant in the course of that participant's routine health care
- The participant receives no additional medication and undergoes no additional intervention or diagnostic procedure, solely for the purposes of the clinical trial

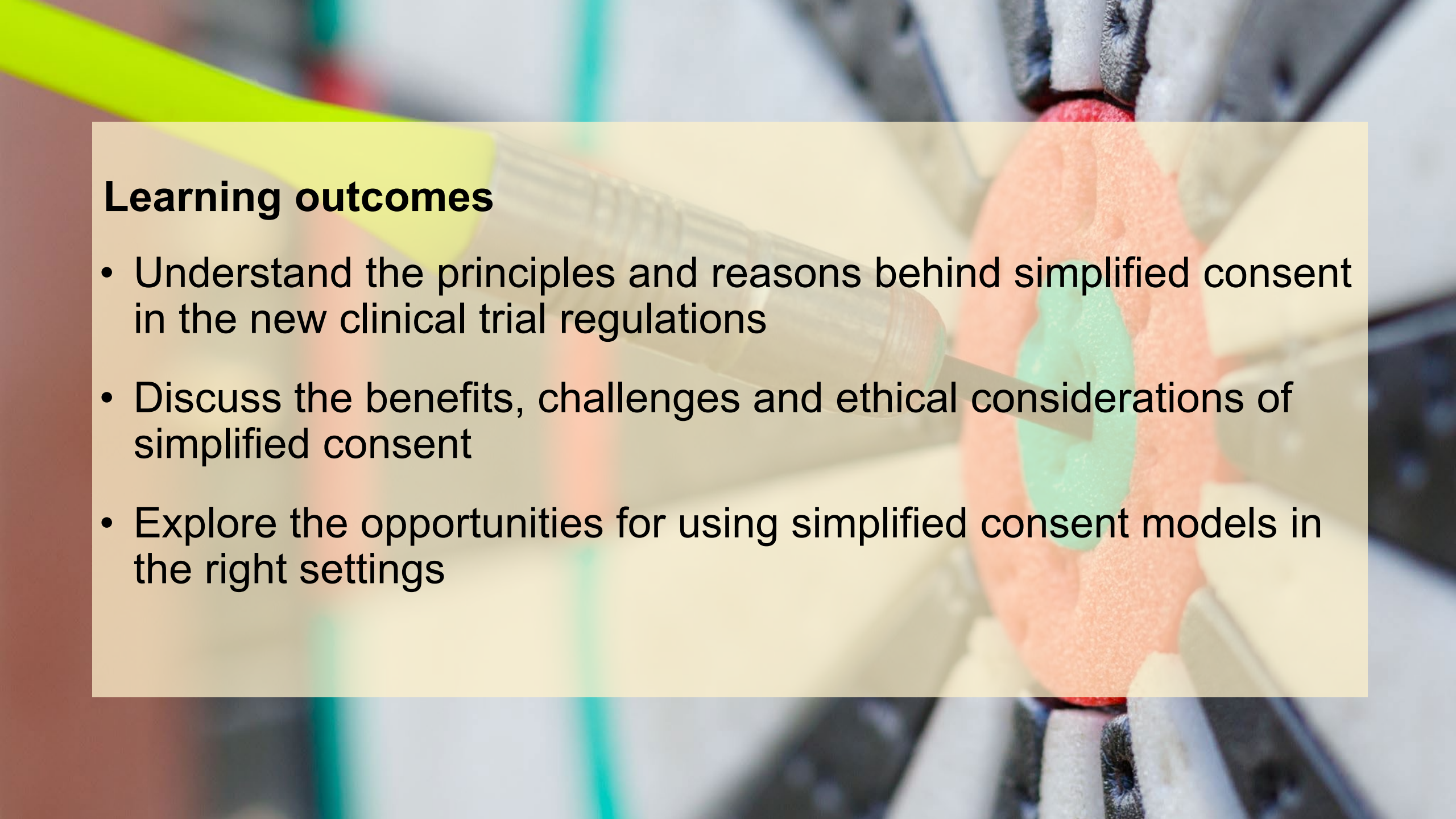


If a sponsor is planning to use simplified arrangements, these will need to be detailed in the protocol. The sponsor will need to include:

- The reason for obtaining consent using simplified arrangements
- The information to be provided to the participant, and the means of providing that information
- The means by which consent shall be evidenced

Your thoughts?

- How would you now define the term, ‘simplified consent?’
- What is your main take away from the workshop today?



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Thank you!