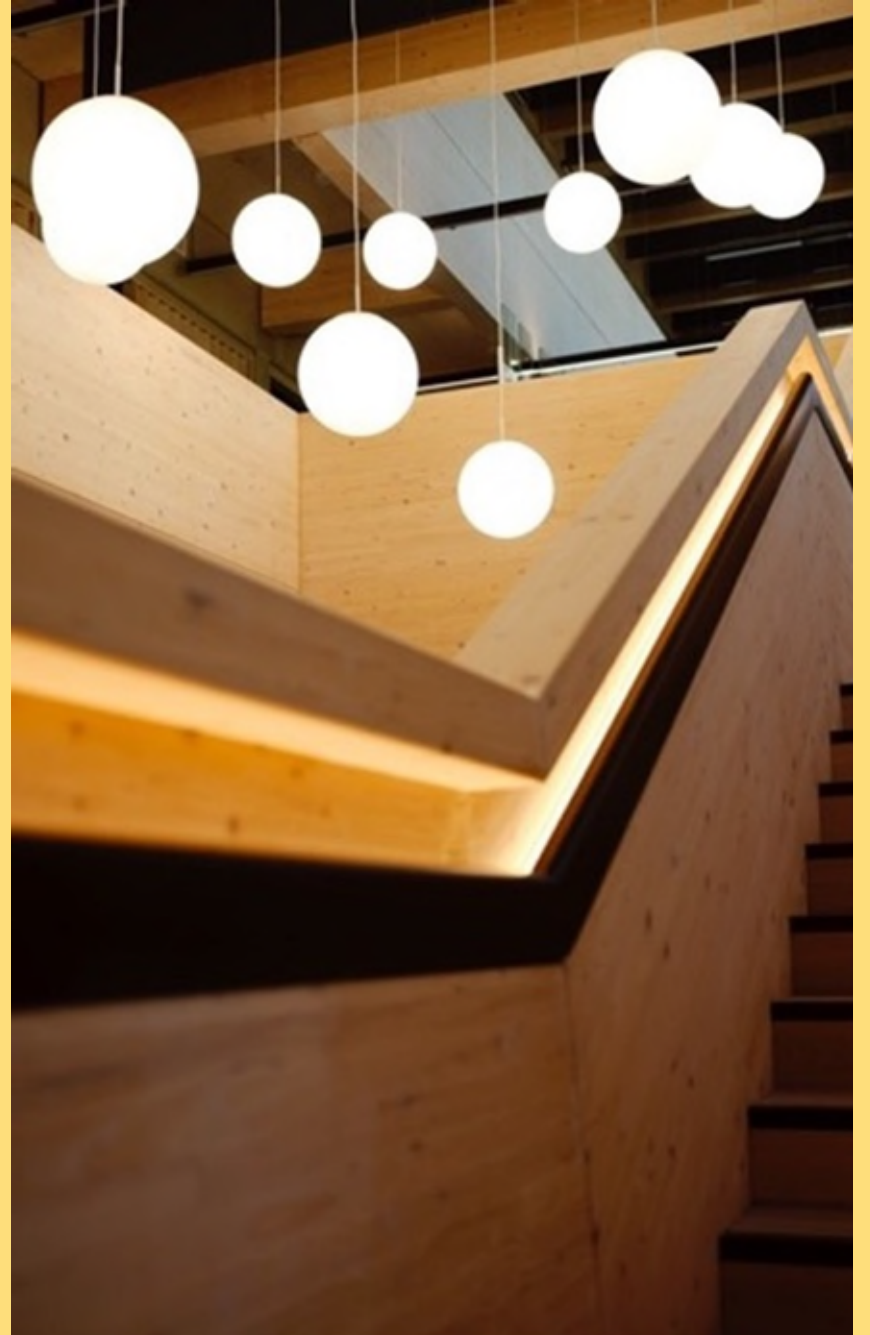




# Informed Consent Training

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R&IS

**UNIVERSITY  
OF WARWICK**



# Today's Session

Informed Consent Best Practice (short presentation)

Practice Informed Consent (hands on practice)



01

# Informed Consent Best Practice



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# What do we mean by 'Informed Consent' and why is it important?

**Key Takeaway: Informed Consent is a process not a tick box**

## What is it?

Ensuring a full and clear understanding of participation, including what it involves, any associated risks, benefits, and payments.

Voluntary

Built into all stages: design, recruitment, execution, follow up.

A record of that agreement to take part has taken place

## Why do we need it?

Protects autonomy, dignity, and participant rights

Strengthens trust between participants and researchers

Required by regulations and institutional policies (UK GDPR, HTA, MHRA, RECs)

Scientific benefit: Protocol that can deliver on aims; adherence to the protocol; honest responses; honest reporting.

# Elements of Informed Consent

1. Capacity
2. Information
3. Voluntariness
4. Decision (and communication/record of decision)

These are inter-related.



# Informed Consent Best Practice Recruitment Materials

Informed Consent can start with recruitment.

Well-considered recruitment materials and a clear recruitment strategy will help with screening, leading potential participants to learn more about the study while screening out those not eligible to take part (inclusion/exclusion criteria can be restated on the PIL).

Consider recruitment materials as working in tandem with your PIL/CF to provide the right information at the right time.



# Informed Consent Best Practice Participant Information Leaflet (PIL)

- A good PIL should provide everything the potential participant needs to know about the study. Templates are available to help you make sure you don't miss anything important.
- But remember – the templates are just templates! You know who your potential participants will be and it's your job to tailor the information to them.
- Write your PIL for your potential participants, not for the ethics reviewer(s).
- Be proportionate. A 5-minute non-sensitive online survey will likely not need a 3-page PIL but if you are asking a lot from your participants, they may need more detailed information, clearly presented.
- Simple and concise language often works best. Too much information can put people off – focus on providing the right information in the right order.
- Consider pictures or diagrams where appropriate.



# Informed Consent Best Practice Consent Form (CF)

- No new information should be on the CF, everything should have been covered in the PIL and recapped on the CF.
- Initials are preferable to ticks.
- Keep language clear, concise and accurate.
- If there are choices, (e.g. consenting to be video recorded or not) make it as easy as possible for the potential participant to understand which boxes are mandatory and which are optional.
- One copy for you and one copy for the participant
- Digital signatures (typed names) are generally accepted, especially for low-risk studies.





## Follow-Up

- Consent should be checked at the end of the activity and/or throughout where appropriate.
- Store consent forms securely (on approved software in password-protected files, separately from the research data). Paper copies should be digitised as soon as possible and then the paper copy securely destroyed.
- Participants should have the right to withdraw their data after participation wherever possible and practical. (Withdrawal details should be outlined in the PIL/CF).
- Consider whether participants might want/need to check transcripts/write ups where they are being quoted directly.
- Dissemination – best practice in study design is to consider participants in dissemination plans – can copies of the results be made available to them if they wish?





# 02 Practice Informed Consent

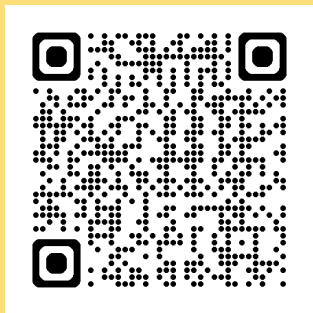


# Research Culture Week

23 - 26 March 2026

Celebrating research culture through a programme of engaging events hosted by colleagues from across the university.

Everyone is welcome.....come along and be part of the conversation!



**Find out more and sign up to events.**

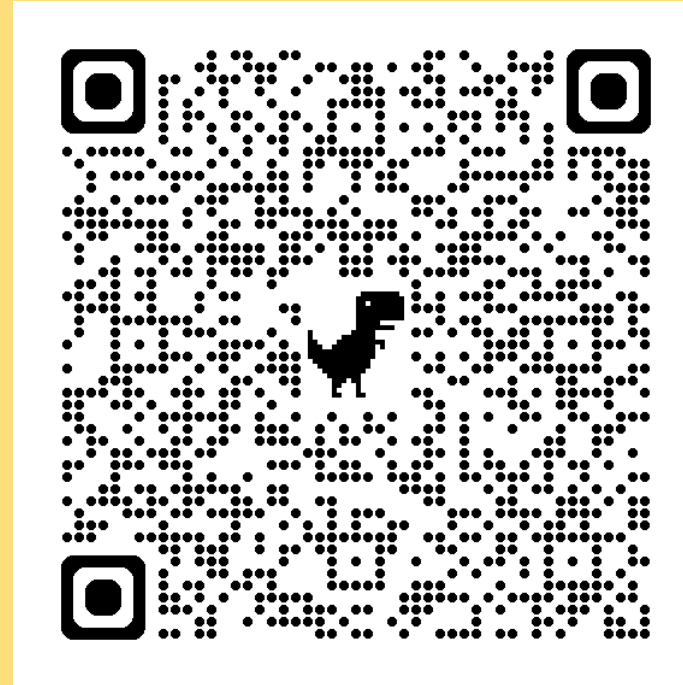


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*Thank you for taking part!*



**We value your feedback:**



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