FOR INSTRUCTORS AND TRAINERS

Teaching Informed Consent: A 45-Minute Educator Kit

A ready-to-teach unit for clinical research, nursing, pharmacy and public health courses, and for site training.

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> **How to use this kit.** Adapt it freely for your class. It teaches what informed consent is and how it is done well. It is not legal advice. Your students should follow their own country's law, their ethics committee and their site's procedures.

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1. At a glance

Topic	Informed consent: what it is, what it must contain, and how to run it as a conversation
Time	45 minutes, plus 20 minutes of reading before class
Level	Introductory. No prior clinical research experience needed
Group size	6 to 40. Works in person or online
You need	This kit, the one-page study summary in section 5 (printed or on screen), and the rights card from the same open resources page

2. Learning objectives

By the end of the session, students will be able to:

1. Explain why informed consent is an ongoing process and not only a signed form.
2. List the main things a person must be told before deciding to take part.

3. Describe the conditions that make consent valid: enough time, no pressure, and language the person understands.
4. Explain a study to a peer in plain words and check understanding with teach-back.
5. Recognize when consent must be revisited during a study.

3. Before class (20 minutes)

Ask students to read two free lessons. No account is needed to read them.

- 'Principles of Informed Consent and Participant Autonomy', Good Clinical Practice course: crln-practice-lab.crln-learn.com/learn/gcp-ich-e6-r3/04-informed-consent-process/principles-of-informed-consent-and-participant-autonomy
- 'The Elements of Informed Consent and Key Information', Human Subjects Protection course: crln-practice-lab.crln-learn.com/learn/human-subjects-protection/04-informed-consent/the-elements-of-informed-consent-and-key-information

4. The 45-minute lesson plan

Time	What happens	Instructor notes
0 to 5 min	Opening question. Ask: "Think of a time you signed something you did not fully read. Why did you sign?" Take three answers.	Link the answers to pressure, time and trust. These are the same forces that can weaken consent.
5 to 15 min	Mini-lecture: consent is a process. Cover the conditions (time to decide, no coercion or undue influence, understandable language) and the main elements a person must be told.	Use the element list in section 6. Note that the US lists (45 CFR 46.116 and 21 CFR 50.25) and ICH E6(R3) overlap, and local law may add more.
15 to 30 min	Activity: teach-back pairs (section 5). Round 1, eight minutes. Swap roles for round 2.	Walk the room. Listen for jargon, rushing, and missing alternatives.
30 to 40 min	Whole-group debrief using the discussion questions in section 7.	Pick three questions. Draw out what made an explanation clear or unclear.
40 to 45 min	Exit ticket: each student writes one thing a participant must always be told, and one way to check understanding.	Grade with the rubric in section 8 if you are assessing.

5. Classroom activity: teach-back pairs

Work in pairs. One student is the research staff member. The other plays a person thinking about taking part. The staff member explains the fictional study below in plain words, without reading it aloud. The other student then explains it back in their own words. The staff member checks the explanation against the element list in section 6 and corrects any gaps.

> Fictional study for practice only. A study is comparing two home exercise programs for people with knee pain. People are put into one of the two programs by chance. Each program takes 20 minutes a day for 12 weeks. There are three clinic visits, each about one hour, where knee movement is measured and a short survey is completed. Possible discomforts include sore muscles and, rarely, a fall during exercise. People may or may not have less knee pain. Instead of joining, people can continue their usual care or ask their own doctor about other options. Study records use a code number instead of a name. There is no cost to take part. Taking part is voluntary, and people can stop at any time without it affecting their usual care.

Round 2 twist: halfway through the study, the team learns that one program causes more falls than expected. The staff member explains this new information and asks whether the person wants to continue.

6. Element checklist for the activity

Did the explanation cover each of these, in plain words?

- That this is research, what it is for, how long it lasts, and what will happen
- Possible risks and discomforts
- Possible benefits, or that there may be none
- Other choices instead of taking part
- How privacy is protected
- Who to contact with questions, and about rights
- That taking part is voluntary, saying no has no penalty, and the person can stop at any time

7. Discussion questions

1. Why might a person sign a consent form without understanding it? What can staff do about each reason?
2. What is the difference between explaining a study and reading the form aloud?
3. What makes an offer of payment or care feel like pressure? Where is the line?
4. When should consent be revisited during a study? Who decides?
5. How would you explain the study to someone who speaks a different language from you? What help would you ask for?
6. A person says, "Just tell me what you would do." How do you respond respectfully without making the decision for them?

8. Grading rubric (teach-back and exit ticket)

Criterion	4: Strong	3: Good	2: Developing	1: Beginning
Completeness	Covers every element in section 6	Misses one element	Misses two or three	Misses most elements
Plain language	No unexplained jargon; short sentences	One or two unexplained terms	Several unexplained terms	Mostly jargon or read aloud
Voluntariness	States clearly that saying no or stopping has no penalty	Mentions it, but not clearly	Mentions it only when asked	Not mentioned
Checks understanding	Uses teach-back and corrects gaps	Asks if there are questions and responds well	Asks only "Any questions?"	Does not check
Re-consent (round 2)	Explains the new information and asks again, with no pressure	Explains but does not clearly ask again	Explains only partly	Does not explain the change

9. Going further: free practice

CRLN offers free practice scenarios. Each one shows a realistic decision a site team member might face, such as a consent question during a visit, and asks the learner to choose what to do. The learner's choice is scored and explained after they answer. The

scenarios, their answers and their scoring are not part of this open kit, so that the practice stays fair for everyone who uses it. Students can try one with no account at crln-practice-lab.crln-learn.com/try.

About this kit

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Not covered by the license: the CRLN name and logo, and CRLN's scored practice scenarios, answer keys and data.

Sources: Built on CRLN's free lessons 'Principles of Informed Consent and Participant Autonomy' (Good Clinical Practice course) and 'The Elements of Informed Consent and Key Information' (Human Subjects Protection course), which cite ICH E6(R3) Annex 1 section 2.8, 45 CFR 46.116, 21 CFR 50.20 and 50.25, and the Declaration of Helsinki (October 2024).