



DAIDS APPLIED RESEARCH TRAINING (DART) INFORMED CONSENT (IC)

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Informed Consent Activity

What is it?

The following activity is meant to facilitate group discussion by having participants review four topic cards on Informed Consent Form, document considerations and challenges they may face with each category, and document challenges and identify best practices on the corresponding poster. In addition, participants will observe a role play where they will raise red flags or their hands to identify any incorrect action, issue or risk and follow this by a large group discussion and review. In the subsequent sections you will find the instructions and materials needed in order to complete these activities.

When can I use this Activity?

This activity is good for a variety of events and purposes. The following list shows alternatives ways to use it:

- Self-Reflection and reviewing concepts learned during an event
- New Employee Training
- Cooperative Learning
- Team Building
- Critical Thinking
- Refresher Training
- Risk Analysis
- Individual self-assessments
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

What Materials / Resources do I need?

- Informed Consent Facilitator Instructions 15Nov2019
- Informed Consent Slide Deck 15Nov2019
- Informed Consent Topic Cards_15Nov2019
- Informed Consent Role Play Activity Instructions 15Nov2019
- Informed Consent Worksheet 15Nov2019
- Informed Consent Activity Posters 15Nov2019
- Informed Consent Quick Reference Card 15Nov2019

How long does it take?

Allow for approximately forty-five minutes to complete the entire activity.

How do I prepare?

First, access the DART website and verify you have access to the course. Then proceed with the following steps:

- Open the file: Informed Consent Slide Deck 15Nov2019. Review the Power Point presentation and determine if you will use this during your activity. Feel free to add information or customize for the needs of your site.
- Open the file: Informed Consent Topic Cards_15Nov2019. Print Topic Cards on cardstock (optional) or on standard paper according to your printer specifications and cut to size (There are four cards included on the file) and distribute one card per table.
- Open the file: Informed Consent Worksheet 15Nov2019 and print on standard paper and distribute individually.
- Open the file: Informed Consent Role Play Activity Instructions 15Nov2019. Print two copies of the Informed Consent Role Play Activity Instructions on standard paper according to your printer specifications.
- Ask two volunteers from the group to perform the ICF role play and provide them with a copy of the script to read prior to the activity.
- Open the file: ICF_ActivityPosters_15Nov2019. Print the Activity Posters on standard paper according to your printer specifications and cut to size. Post/tape ICF Activity posters on the wall.
- Open file: ICF Quick Reference Card 15Nov2019. Print quick reference cards on cardstock (optional) or on standard size paper according to your printer specifications and cut to size for distribution to the participants.

How do I do it?

Now you are ready for the next steps. As a facilitator, do the following:

- Distribute one Informed Consent Topic Card per table.
- Ask participants to read the ICF category card as a group.
- Instruct participants to work as a group to determine considerations and challenges related to their ICF category card and to document the considerations and challenges on the corresponding poster placed on the wall. They can use their worksheets to write notes while they are working through the activity.
- Collect cards at the end of the activity to re-use them at another time.
- Proceed to introduce the Informed Consent Role Play activity to participants.
- Distribute one red flag (optional) to each participant at the event/session.
- Instruct participant to raise their red flags (if available) or their hands during the skit for any incorrect actions, issue or risk they identify during this and to follow it by a large group discussion and review.
- Distribute a copy of the ICF Infographic to each participant to take home.

How can I modify this activity?

Don't want to conduct this activity as suggested? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it. For example, you can have the topics on a Power Point presentation or written in a large Poster Board/Easel Pad and ask several participants to read aloud to the group. Or, you can read it yourself. Make sure you allow time for the table groups to re-read silently from either source and discuss as a group before sharing their responses with the larger audience.

Another alternative, is to print all topics, have them cut out individually and place them in a bowl in the center of the table. You can proceed to direct participants to draw one topic at a time for them to read and discuss as a group as well.

Or, you can conduct an Informed Consent Form (ICF) activity at your site to get ready for a monitoring visit. Verify if the IC on file is the original form or a copy, has it been signed and dated by the participant. Ask how they can verify if participant was given ample time to make an informed decision to participate in the study. Inquire if they know which document a monitor is going to review first during a monitoring visit? Host an activity to verify if your site's ICFs are adhering to Accurate, Legible, Contemporaneous, Original, Attributable, and Complete, Consistent, Enduring and Available (ALCOA-C) principles and if staff/participants understand the importance of these.

Another alternative is to have your staff look at your site's ICFs and conduct an on-site Quality Control initiative to identify and correct any errors within the forms and adhere these to Good Documentation Practices (GDP).