DAIDS Applied Research Training (DART) Good Clinical Practice Icebreaker

National Institute of Allergy and Infectious Diseases

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Good Clinical Practice Icebreaker Activity

What is it?

The following icebreaker activity is meant to facilitate group discussion by using twenty question cards on Good Clinical Practices key concepts. The objective of this activity is to generate active discussion and participation not necessarily to reach or find the correct answer. In the subsequent sections you will find the instructions and materials needed in order to complete this activity.

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:

- Breaking the Ice
- Relationship Building
- Refresher Training
- Group Annual Retreat
- New Employee Orientation
- Office / Departmental Meetings

What Materials / Resources do I need?

- ICEBREAKER Facilitator Instructions _ 19Sep2019
- ICEBREAKER Cards.pptx_19Sep2019
- Cardstock
- Your Team

How long does this take?

Allow five minutes for participants to read and discuss as a group and complete this activity. Once participants have finished, call time.

How do I prepare?

First, open file and become familiar with the content, then proceed with the following steps to print the cards:

- Open the file ICEBREAKER Cards.pptx_19Sep2019.
- Print on color cardstock according to your printer specifications.
- Cut to size.

How do I do it?

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

- Distribute one icebreaker card per table.
- Ask participants to read the questions on the card and discuss the answer as a group.
- Give participants an opportunity to talk to each other and focus on questions related to Good Clinical Practices.
- Collect cards at the end of the activity to re-use them at another time.

How to change the Questions?

That is a fantastic idea! For this, we suggest keeping a file with a series of topics with its associated questions. By doing this, you create a bank of topics where you can draw at any given time for a variety of activities.

How can I modify this Activity?

Don't want to make postcards? 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 questions on a Power Point presentation or written in a large Poster Board 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 questions, 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 question at a time for them to read and discuss as a group as well.

Also, you can print these questions on a regular piece of paper, insert them in folders and distribute them by table groups.

Icebreaker Card Questions

1. Describe the three key ethical principles of the Belmont Report: Respect for Persons, Beneficence, and Justice.
2. In what phase of a clinical trial does the submission of work go to a Regulatory Authority?
3. Name the International Guidance used to conduct clinical research.
4. At the site level, who is ultimately responsible for the conduct of the study?
5. Name the most current version of ICH GCP E6.
6. What is the US Code of Federal Regulations that describes the Protection of Human Subjects?
7. What US Department of Health and Human Services regulations describes the protections for vulnerable participants?
8. This entity's main function is to protect the human subjects. One function this group performs is the initial approval of the protocol and its consent. Name this entity.
9. When conducting an observational study (non-IND), does the site have to adhere to ICH GCP, regulations and Sponsor directives?
10. Name two entities who can stop a clinical trial.
11. Could a Principal Investigator refuse to allow monitoring from an outside entity?
12. Your site has an internal policy which is stricter than ICH GCP. Which should your site follow?
13. After 6 weeks in the study, a participant wishes to end their participation in the study. Can they? Why can they? What action(s) should your site take?
14. This phase of a clinical trial could include several hundred to several thousand participants who have the disease, are multi-centered clinical trials, are the definitive assessment of the safety and efficacy of the Investigational Product and is the phase prior to regulatory submission.
15. The study protocol requires the child to be brought to the research site by their mother. At this visit, the sister brings the child to the research site because the mother is at home ill. Study visit was completed. Is this a protocol departure?
16. In preparation for today's anticipated number of participants to be consented, the Study Coordinator pre-dates the consents. Is this Good Clinical Practice?
17. A shipment of Investigational Product has been delivered to the research site. Unfortunately, the receptionist did not realize the Investigational Product should have been placed in a refrigerator to ensure the cold chain remained intact.
18. Due to a variety of factors, the required protocol continuing review submission took place two days after the initial approval period ended. Is this a problem? What should the site do?
19. This Essential Document is required allowing the Principal Investigator to delegate specific research-related activities to his/her staff. Name this document. What other documentation is required to confirm a staff member's competence to perform the assigned study-related activities?
20. Does the revised ICH E6 (R2) Good Clinical Practice Guideline provide new expectations that may affect IRBs/IECs? What other expectations have changed?