



DAIDS APPLIED RESEARCH TRAINING (DART) INVESTIGATOR RESPONSIBILITIES

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Investigator Responsibilities Activity

What is it?

The following activity has a series of video scenarios meant to facilitate group work and discussion by watching four video scenarios related to Investigator Responsibilities (IR) from the 9 Commitments (Box 9 of United States Food and Drug Administration (FDA) 1572) and the Human Subjects 45 Code of Federal Regulations (CFR) part 46 (Common Rule). The objective of this activity is to generate active discussion, collaboration among participants, completion of a Corrective Action Preventive Action (CAPA) exercise and a Responsible, Accountable, Consulted, Informed (RACI) matrix. 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:

- Decision Making, Re-organization
- Assigning work assignment, Workload Analysis
- Conducting Corrective and Preventive Actions (CAPAs)
- Managing a Project and Conflict Resolution
- Documenting the status Quo,
- Managing employee turnover
- Continuous Quality Improvement
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

What Materials / Resources do I need?

- Investigator Responsibilities Facilitator Instructions 15Oct2019
- Investigator Responsibilities Activity Slide Deck 15Oct2019
- Investigator Responsibilities Activity Worksheet 15Oct2019
- Investigator Responsibilities Activity Worksheet Answer Key 15Oct2019
- Investigator Responsibilities Quick Reference Card 15Oct2019
- IR Video 1 IRB Scenario 15Oct2019
- IR Video 2 Adherence to Protocol 15Oct2019
- IR Video 3 Drug Inventory 15Oct2019
- IR Video 4 Safety Oversight 15Oct2019

How long does it take?

Allow approximately thirty minutes for 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: Investigator Responsibilities Worksheet 15Oct2019.
- Become familiar with the content. Determine how many participants will be attending and assigned to table teams. This will help you decide on how many of the videos you will need to share.
- Launch the videos and determine if you will show all videos or select 1 or more of the 4 videos for your activity. Familiarize yourself with the following videos:
 - 1 IRB Scenario
 - 2 Adherence to Protocol
 - 3 Drug Inventory
 - 4 Safety Oversight
- Review the Power Point presentation and determine if will use this during your activity. Feel free to add information or customize for the needs of your site.
- Print the blank worksheets, Answer Keys and Quick Reference Guides on standard size paper.

How do I do it?

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

- Sort teams into five or six people to a maximum of twenty-four into four table groups and have each table team watch one video (This activity can be completed with a smaller group as well).
- Launch the IR Slide Deck Power Point presentation to help guide you through the activity. This is optional and for your support if you need it.
- Click the video to play it.
- Allow the teams time to view the video more than once if needed.
- Distribute “Investigator’s Responsibility Worksheet” and follow the instructions to complete both activities; Quality Improvement and RACI Matrix (see the below picture).
- Have each table select a speaker to report out solutions for discussion.

Investigator Responsibilities Activity

Room Name: _____ Table Number: _____

Quality Improvement Instructions:

Watch the video scenario, complete the following chart to determine what happened and how to improve site operations and documentation considerations.

Root Cause	Documentation	Corrective Actions	Preventive Actions

RACI Matrix Instructions:

Change is only implemented effectively when responsibility and communication pathways are defined. Determine what role at the site should be included in the responsibility and communication to improve site operations.

Responsible	Accountable	Consulted	Informed

How can I modify this activity?

Don't want to use the provided video scenarios? That will be perfectly fine! The beauty of this activity is that you have multiple ways to go about it.

For example, you can substitute the video scenarios with a monitoring finding or a situation that happens at your site. Also, you can transcribe each video content and use it as a written, case-based scenarios to reinforce the content / knowledge you want participants to gain.

In addition, after having participants read the video written transcription, you can feature a series of Frequently Asked Questions (FAQs) or Questions and Answers (Q&As) session during a face-to-face event.

Also, you can re-purpose the video scenario content by making an Audio Podcast, turn the video into a Blog Post, or edit the Short Form videos together into one longer video.

Another alternative is to print the video scenario transcripts and give it to participants as a way for them to reflect individually on the content and be able to complete the activities associated it with it.