Collaborative Institutional Training Initiative (CITI)
Good Clinical Practices & Conflict of Interest Training

Kaiser Permanente (KP) contracted with the Collaborative Institutional Training Initiative (CITI) Program to provide Good Clinical Practices (GCP) and Conflict of Interest (COI) training for investigators and study site staff.

Kaiser Permanente is committed in protecting the rights, safety, and welfare of clinical trial participants and to reinforce that value, investigators and study site staff are required to complete GCP training before getting involved in a clinical trial, and maintain the certification during the course of their involvement.

How to Register with CITI

To access the training go to the CITI web site home page at:
https://www.citiprogram.org/Default.asp

Click: **New Users Register Here**
1. Under "Select Your Organization Affiliation" type Kaiser Permanente in the text box
2. Enter your Personal Information
   - Name and Email address (must be your KP email address)
3. Create your Username and Password
   - Type in a username (must be your NUID) and password (create your own)
   - Select your Security Question and Security Answer
4. Enter Country of Residence
5. Answer the question, "Are you interested in the option of receiving Continuing Education Unit (CEU) credit for completed CITI Program courses?" It is optional to request for CEU credit. Costs of credits range from $70.00 to $90.00 depending on your profession.
   - Answer the question, "Can CITI Program contact you at a later date regarding participation in research surveys?"
6. Provide the following information requested by Kaiser Permanente (Questions with **"*"** next to them are required fields)
   - Institutional email address – Must type in your KP email address
   - KP Regional Code – must select SCAL from the drop-down list
   - Type in your Department
   - Select your Role in Research from the drop-down list
7. Select Curriculum – See How to Select the CITI Training Modules/Learner Groups below
8. Click Complete Registration

How to Select the CITI Training Modules/Learner Groups

Select the appropriate Learner Group (Clinical Trials PIs, sub-investigators, and all Key Personnel are Level I.).

1. Click on the radio button next to your Learner Group. Select only one.
   Note: The most comprehensive training is *Level I Investigator-Initiated Drug and Device Trial* and will satisfy the requirement of any type of clinical trial.
2. Click Complete Registration
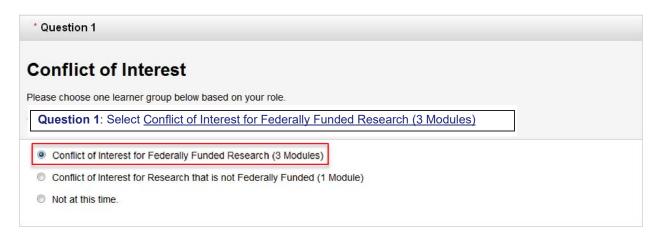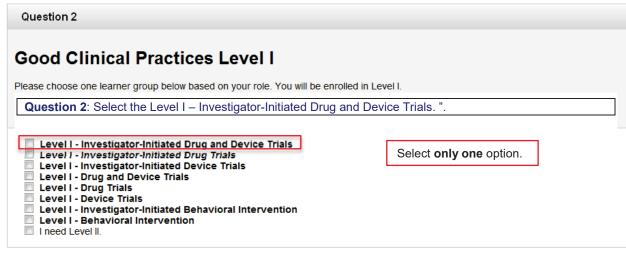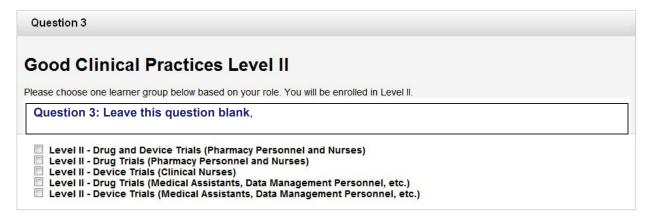3. Complete "The Integrity Assurance Statement" before beginning the course.

4.   Open and complete the required training modules. See screenshots of CITI web page below.
- Conflict of Interest training (Question 1, 3 Module Course only)
- Good Clinical Practice (GCP) course (you may log-in as often as you like)

The training takes approximately 3 hours for Level I.

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* Question 1

Conflict of Interest

Please choose one learner group below based on your role.

Question 1: Select Conflict of Interest for Federally Funded Research (3 Modules)

- ⦿ Conflict of Interest for Federally Funded Research (3 Modules)
- ○ Conflict of Interest for Research that is not Federally Funded (1 Module)
- ○ Not at this time.

Question 2

Good Clinical Practices Level I

Please choose one learner group below based on your role. You will be enrolled in Level I.

Question 2: Select the Level I – Investigator-Initiated Drug and Device Trials. ".

- ☐ **Level I - Investigator-Initiated Drug and Device Trials**
- ☐ *Level I - Investigator-Initiated Drug Trials*
- ☐ **Level I - Investigator-Initiated Device Trials**
- ☐ **Level I - Drug and Device Trials**
- ☐ **Level I - Drug Trials**
- ☐ **Level I - Device Trials**
- ☐ **Level I - Investigator-Initiated Behavioral Intervention**
- ☐ **Level I - Behavioral Intervention**
- ☐ I need Level II.

Select **only one** option.

Question 3

Good Clinical Practices Level II

Please choose one learner group below based on your role. You will be enrolled in Level II.

Question 3: Leave this question blank,

- ☐ **Level II - Drug and Device Trials (Pharmacy Personnel and Nurses)**
- ☐ **Level II - Drug Trials (Pharmacy Personnel and Nurses)**
- ☐ **Level II - Device Trials (Clinical Nurses)**
- ☐ **Level II - Drug Trials (Medical Assistants, Data Management Personnel, etc.)**
- ☐ **Level II - Device Trials (Medical Assistants, Data Management Personnel, etc.)**

Question 4

Responsible Conduct of Research

Please make your selection below to receive the courses in the Responsible Conduct of Research.

Question 4: Select **Not at this time.** This is not applicable for KPSC.

- ☐ Biomedical Responsible Conduct of Research Course
- ☐ Social and Behavioral Responsible Conduct of Research Course
- ☑ Not at this time.

Question 5

Human Subjects Protection Basic

If your region requires you to take the Human Subjects Protection – Basic Course, select either the Biomedical or the Social-Behavioral-Educational Basic Course according to the type of research you will conduct. You will be enrolled in that Basic Course.

Question 5: **For NIH funded projects only** otherwise, leave this question blank. If you are participating in NIH funded project or otherwise instructed by your PI or R&E Clinical Trials Division select the Biomedical option.

- ☐ Biomedical Human Subjects Protection – Basic
- ☐ Social-Behavioral-Educational Human Subjects Protection – Basic

Question 6

Human Subjects Protection Refresher

If your region requires you to take the Human Subjects Protection – Refresher Course, select either the Biomedical or the Social-Behavioral-Educational Refresher Course according to the type of research you conduct. You will be enrolled in that Refresher Course.

Question 6: **Leave this question blank**. This is not applicable for KPSC.

- ☐ Biomedical Human Subjects Protection – Refresher
- ☐ Social-Behavioral-Educational Human Subjects Protection – Refresher

Frequently Asked Questions (FAQs)

Questions	Answers
1. How long will it take for me to complete the CITI GCP training?	Level 1 training takes approximately 3 hours to complete.
2. If I want to complete the GCP training that will cover me for any type of clinical trial that I may do in the future, which learner group should I choose?	You only need to select Level 1 – Investigator-Initiated Drug and Device Trial, which is the most comprehensive. This learner group includes all the training modules within Level 1 – Drug Trial, Level 1 –

Questions	Answers
	Device Trial, Level 1 – Behavioral Trial and those that apply to Investigator-Initiated clinical trials.
3. Do I need to be connected to a Kaiser Permanente network to complete the training?	No. This is a web-based training hosted by CITI Program and can be accessed at https://www.citiprogram.org/Default.asp as long as you are connect to the internet.
4. Can I use the CITI GCP training I completed from another institution to satisfy this requirement?	CITI now allows an individual to affiliate themselves to multiple institutions. You may do so by going into your profile and selecting "*Click here to affiliate with another institution*" and completing the form indicating Kaiser Permanente as the new institution. If the other institution has the same required modules as Kaiser Permanente then you will be required to get approval from the Division of Clinical Trials Research. To request a review/approval, please send an email to clinical-trials-training@kp.org. Caution: Individuals using another institution's GCP training to satisfy the requirement will not receive any reminder notifications for upcoming expiration dates.
5. What do I do with my CITI GCP Training completion report?	After completing the course, a link becomes available to view and print/save a .pdf of your Training Completion Report. Submit a copy to your PI and/or Project Manager, and retain a copy for your records.
6. When do I need to renew my training?	CITI GCP training is required every 3 years and Conflict of Interest (COI) training is required every 4 years for as long as you're involved in the conduct of an active clinical trial.
7. How would I know if my training is about to expire?	CITI Program will automatically send you an email notification starting 60 days prior, then 30 days prior and a final notification 7 days prior to the expiration date.
8. What should I do if I am not involved in a clinical trial and have no plans to do so in the future?	Send an email to clinical-trials-training@kp.org informing Division of Clinical Trials Research that you no longer wish to renew your CITI GCP and/or COI training along with the reason.

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Questions	Answers
9. How long is the renewal training?	Level 1 refresher course takes approximately 1 ½ hours to complete. The refresher course is automatically applied to your profile when renewing the training.
10. If I have question regarding CITI GCP training for clinical trials, who should I contact?	Send an email to clinical-trials-training@kp.org John Huang, Research Associate III R&E Division of Clinical Trials (626) 564-3620 John.Huang@kp.org
11. If I have questions regarding CITI COI training, who should I contact?	Kelvin L. Kelley, Manager Research Finance -Sponsored Projects Administration Kelvin.L.Kelley@kp.org