

No-Cost Continuing Education Information for Recertification

SOCRA's Recertification Page of website: <http://www.SOCRA.org/html/recertif.htm>

See the Continuing Education (CE) Requirements section for details regarding the type and quantity of CE accepted for re-certification

Your continuing education units must have occurred during your 3-year Certification period. **22 of the credits must be in the Clinical Operations/Regulatory area and the remainder can be in your Therapeutic area or all 45 CEU's may be from the Clinical Operations/Regulatory area. One CE is given for successfully completing the recertification quiz.**

SOCRA's **Recertification Tracking Tool** is available on the SOCRA website at:

http://www.SOCRA.org/html/recertif.htm#CCRP_Maint

Re-Certification Quiz (1 CE):

Completing the Recertification Quiz = **1 CE** credit, but you will need to include this in writing on the application claiming it for CE.

Self Studies (SOCRA Source: 12 CE):

You may complete the SOCRA **Source Self Study articles** included in the quarterly journal. Each self-study article gives 1 CE credit. You may submit up to **12** Self Studies from your current certification period. If you are in need of any past Self Studies, the PDF's can be emailed to you. These CEs would count in the regulatory section.

You can collect **3** additional CEs of this type *i.e.*, from nursing/clinical research journals of your choice, to make a total of **15** continuing education for self-study.

Other No Cost CE Information:

SOCRA offers no-cost basic GCP and Research Protections on-line education through CITI (10 CE):

<http://www.citiprogram.org/default.asp?language=english>

SOCRA became a member of **The Collaborative Institutional Training Program (CITI)** to offer SOCRA members free entry-level Basic Courses in the Protection of Human Research Subjects including Biomedical Focus, Social and Behavioral Focus, and Refresher Courses, as well as the basic course on GCP (Good Clinical Practice course).

SOCRA will accept two courses from the Citi Program, **Basic GCP and Research Protections**. Please visit the link above or click here. You will need to choose **SOCRA** under Institutions for this to be at no cost to you.

This will take you to the CITI Welcome Page. Click onto the CITI Welcome Page (see below). Then click onto "New Users Register Here." Complete instructions 1-7. For the Participating Institution click onto SOCRA. Create your user name and password. Use Last Name for User name and SOCRA member ID# as password. Hit submit. See sample CITI welcome page below.

You can take (1) the **Good Clinical Practice GCP Course** which is **4 credits** (completing all the modules) and (2) the **Basic Human Subjects-Biomedical Research Investigators** which is **6 credits** (completing all the modules). You will need to print the **History of completion** for your records. There is no fee for that. These modules would count toward the Regulatory continuing education units for a total of 10 CEUs. You can only claim this one time in your 3-year period.



FDA Training and Continuing Education (various trainings):

<http://www.fda.gov/Training/>

See individual CEs for specific modules:

BIMO Part 5b Strategies for Clinical Investigators to Build Quality into Device Research (19 minutes, .5 CEUs)

<http://fda.yorkcast.com/webcast/Viewer/?peid=b618186c8c9c488f8d951013adf0b635>

Overview of Regulatory Requirements: Medical Devices (48 minutes, 1 CEU)

<http://fda.yorkcast.com/webcast/Viewer/?peid=040308365ec8405bad39b06de8561bdc>

Quality System Regulation 20 CFR Part 820 Basic Introduction (105 minutes, 2 CEUs)

<http://fda.yorkcast.com/webcast/Viewer/?peid=dd2d4823b14a4e4ca6d60eae43c5ac9c>

BIMO Part 1a Good Clinical Practice 101: An Introduction (28 minutes, .75 CEUs)

<http://fda.yorkcast.com/webcast/Viewer/?peid=477af877491747379c36c4ab1c7421b9>

BIMOPart 1b Introduction to the Bioresearch Monitoring Program (15 minutes, .5 CEUs)
<http://fda.yorkcast.com/webcast/Viewer/?peid=96f1ee7896ee4a70876b601f533b4a9c>

BIMOPart 2b The Clinical Investigator: Responsibilities in Medical Device Trials (14 minutes, .5 CEUs)
<http://fda.yorkcast.com/webcast/Viewer/?peid=29b55c1dd3f64d8fa74ca2227df14b39>

BIMOPart 4b Preparing for an FDA Clinical Investigator Inspection (30 minutes, .75 CEUs)
<http://fda.yorkcast.com/webcast/Viewer/?peid=2c785eeadc754baab704a351a0e5cc19>

These CEUs include time for a brief quiz. Therefore CEU equals the time of presentation and approximately 15 min per quiz

NIAID GCP Learning Center (Total 4 CE):

For the GCP learning center link below, each of the four modules is approximately 1 hour of material. This would be 1 CE for each module. Print the certificate for each module completed.

<https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx>

Please contact recertification@SOCRA.org if you have additional questions.