CCR Orientation

CCR Orientation Requirements

The CCR orientation includes several activities:

- Review of orientation modules and SOPs
- Research orientation class
- Database training

If you have any questions at anytime, please don't hesitate to contact me at nesse@mail.nih.gov or at **240.858.3747**.

Thank you,
Elizabeth Ness, MS, BSN, RN
Director, Office of Education and Compliance
Office of the Clinical Director
Center for Cancer Research, NCI

Orientation Activity	Teaching Strategy
NCI Orientation *(Federal Employees)*	Three hour virtual session. To be arranged by your Administrative Officer (AO).
(Also on General NIH & CC orientation page) **Introduction to the Responsible Conduct of Research course** *(one time)* This module assists investigators to understand when they are engaged in human subjects research, and when review by an IRB or a determination by OHSRP(regarding the need for IRB review) is required before research may commence. *To be completed by all incoming Intramural Research Program (IRP) Investigators* *Note: for research nurses this needs to be completed as part of your credential packet.*	https://researchethics.od.nih.gov/
(Also on General NIH & CC orientation page) **Human Subjects Protection and Good Clinical Practice training: CITI Program Training** *(Triennial refresher required)* CCR requires that all clinical research staff take the CITI training courses for both human subjects protection (HSP) and Good Clinical Practice (US FDA Focus). You will first have the option to test out of the GCP course which requires a score of 80%. If you do not recieve the passing score, you will then be directed to complete the modules. The HSP course doesn't have a test out option. If you cannot complete training in one session, just complete the current module and return to the course at a later time. You will need to score an 80% for each module quiz in order to receive a Certificate of Completion for each module. Once a course is completed, you will receive an email from CITI. Please forward the CITI email to Liz Ness. **Also, please save a copy for records.** These courses are to be completed during the **first 4 weeks** of employment. *To be completed by all PIs, AIs, research nurses, data managers, and key research personnel.* *Note: for research nurses the Biomedical 101 and GCP need to be completed as part of your credential packet.*	Please review and follow the steps below to access the correct training courses: 1. Log into your CITI account via the NIH portal by clicking here, and then scroll down to *Required Training* and then click on CITI Training 2. When you create your account in the NIH CITI portal, you must be sure that the email used for this account matches your NED AD email in order for your training records to download to iRIS. To find your NED AD email, go to the NIH directory on the NIH home page and click on Staff Directory in the upper right. Towards the bottom of the page that then opens, locate your NIH AD Email and be sure this is the email you use in your NIH CITI portal account. 3. Select *NIH View Courses* 4. Scroll down to *Add a Course* 5. Select *Biomedical 101 (this is human subject protection training) and Good Clinical Practice (US FDA Focus).* a. NOTE: if you are involved with Social, Behavioral, or Education research, you will need to complete the course *Social & Behavioral Research* instead of the Biomedical 101 course 6. If you will be working with children, please take the optional course *Vulnerable Populations - Research involving Children*. 7. If you will be working on studies that have a genetic or genomic component, please take the optional course *Genetic Research in Human Populations*. 8. You may take any of the other courses. 9. Launch the required and any additional courses and complete 10. When you receive an email about completion with a link to your record and certificate, please forward to Liz Ness. Save a copy of your record and certificate for your files. These courses are to be completed during the **first 4 weeks** of employment. 11. Resource: FAQs

(Also on General NIH & CC orientation page) **NIH Technology Transfer Training** Course provides information related to the various types of agreements used with collaborators including Material Transfer Agreements (MTAs), Clinical Trial Agreements (CTAs) and Cooperative Research and Development Agreements (CRADAs). *To be completed by all Investigators, Fellows, non-FTE trainees and other non-FTE scientific contributors within 3 months of start date.* *Note: for research nurses this needs to be completed as part of your credential packet.*	Log into the LMS home page. Search for the *NIH Online Technology Transfer* course which should have a "current" box next to the version. Once completed, use the navigation bar, select *learning*, then *certifications*. Print/save your certificate and send a copy to Elizabeth (Liz) Ness.
Safe Shipping and Handling of Infectious and Biological Substances -Every 2-3 years, depending on where shipping to (i.e., U.S. or international)	One-day classes for all personnel involved in the shipping of infectious substances, diagnostic specimens, biological specimens and dry ice classified as "dangerous goods." Limited space is available in each class. To register for a class, please visit the following website: https://www.safetytraining.nih.gov
Independent review of NIH Clinical Center (CC) Medical Administrative Series (MAS) Policies	Review the NIH CC Policies: http://cc-internal.cc.nih.gov/policies/list_policies.asp?index=med_sub. Note: this site requires using an NIH computer to access.
Independent review of the NIH Intramural Research Program (IRP) Human Research Protection Program (HRPP) Policies	Review the current NIH IRP policies for human subjects protection: https://irbo.nih.gov/confluence/pages/viewpage.action?pageId=36241835. Note: NIH log-in required.
Independent review of CCR SOPs and related forms	Review the current CCR SOPs for clinical research from the CCR homepage for Clinical Research Operations: CCR Policies/Standard Operating Procedures (SOPs). Click on 'CCR SOPs and Related Forms'.
Clinical Trials Orientation **Web Modules** • Good Clinical Practice and Human Subjects Protection • Clinical Trial Design • Protocol Development Review and Approval • Responsibilities of the Research Team • Informed Consent • Documentation and Document Management • Adverse Events • Clinical Data Management • Clinical Trial Monitoring and Auditing • Drug Development: FDA and Sponsor Responsibilities of IND Trials	There are 10 clinical trials orientation modules which will provide a basic overview of clinical trials/research. The course is be completed during the **first 6 weeks** of employment or prior to the virtual classroom orientation.

(Virtual) Classroom Orientation	Classroom orientation is based on your role. For content and room information, see the agenda. **For Physician Investigators (including staff clinicians)**: Classroom orientation consists of 2 half-day classes (in person) or 4 virtual classes offered twice a year. Please contact Liz Ness to register. • **Session 1 (virtual)**: February 19, 2021, February 26, 2021, March 5, 2021, March 12, 2021; See agenda for times and WebEx url. Agenda • **Session 2 (virtual):** October 8, 2021; October 15, 2021; October 22, 2021; October 29, 2021; See agenda for times and WebEx url. Agenda **For ALL non-Physician Investigators, federal employees and contractors** (e.g., RNs, NPs PAs, data managers, PCCs, CCR sponsor staff, post-bacs): Classroom orientation is a 1-day in-person class or 3 virtual classes offered 3 times a year. Please contact Liz Ness to register. • **Session 1 (virtual)**: March 11, 2021; March 15, 2021; March 17, 2021; See agenda for times and WebEx url; Agenda • **Session 2 (Virtual)**: July 15, 2021; July 21, 2021; July 26, 2021; See agenda for times and WebEx url; Agenda • **Session 3 (virtual):** November 4, 2021; November 8, 2021; November 10, 2021; See agenda for times and WebEx url; Agenda **For ALL Research Nurses**: In addition to the classes above, there are additional classes offered 3 times a year. In-person classes are offered Classroom orientation is 3 half-day classes in person or 4 virtual classes. Agenda includes times and room numbers or WebEx link. • **Session 1 (virtual)**: April 12, 2021; April 22, 2021; May 5, 2021, May 14, 2021: Agenda • **Session 2 (virtual):** August 4, 2021; August 16, 2021; September 9, 2021; September 20, 2021; Agenda • **Session 3 (virtual):** December 9, 2021 December 15, 2021; January 10, 2022; January 28, 2022; Agenda
Protocol Analysis Worksheet	The Protocol Analysis Worksheet is to be completed by all Research Nurses, NPs, PAs, Clinical Data Managers, and any other staff members who would like to do so. Select a protocol that you will be working with, complete the worksheet, and then email the worksheet to Liz Ness, who will then set up a time to meet with you and review the worksheet. This activity needs to be completed within the **first 4 weeks** of employment. ***Note:*** *Clinical Data Managers will have the review done by a member of the DM team lead*.
Orientation to Adult Day Hospital (3SE-S)	For MDs, DOs, Research Nurses, NPs, and PAs: This 2 hour orientation will provide an overview of the Adult Day Hospital on 3SE-S. Please contact Legna Hernandez to schedule. This activity needs to be completed within your **first 4 weeks** of employment.
Integrated Research Information System (iRIS) Training & Account Registration	**iRIS Training:** NIH iRIS training sessions are offered by the NIH iRIS training team. For upcoming training classes, visit the training website and send an email to the iRIS team using the link at: https://irbo.nih.gov/confluence/display/ohsrp/IRBO-iRIS-Training. You may access the NIH iRIS "Training Site" to independently explore at https://irb-training.nih.gov. The NIH iRIS Training Site can be accessed using your existing NIH login credentials. **iRIS account registration**: 1. Please register for an iRIS account. Log into the website using your NIH credentials: https://iris.helpdesk.nih.gov/jira/servicedesk/customer/portal/3/user/login?destination=portal%2F3 2. Once logged in, select iRIS accounts in the left column, then request account (NIH User). 3. Complete the form. Your iRIS account manager, if a required field, is Stacie Jeter.
C3D and J-Review Training	C3D (Cancer Central Clinical Database) is the central database (i.e., electronic case report forms) used for the majority of CCR clinical trials. Click here to view class dates, times, locations and agenda. ***REGISTRATION IS REQUIRED.***

Telework	NCI Telework Program: https://mynci.cancer.gov/topics/nci-telework-program Review policy: https://mynci.cancer.gov/sites/mynci.cancer.gov/files/field/file/NCI%20Telework%20Program%20Policy.pdf. Discuss telework capablity with supervisor. If cleared to telework, complete training: https://hr.od.nih.gov/workingatnih/telework/training.htm. Complete telework agreement in ETS: https://telework.nci.nih.gov/ets/ProcessSteps.action.
Accessing shared drives remotely	Review and request remote access: https://ncs.cancer.gov/basic-services/network-access/nci-remote-apps