

SUNY New Paltz Summary of Human Subject Education Requirements

Institutional Signatory Official

OHRP module (1)

Human Protections Administrator

Belmont Report

OHRP Modules 1-3

NIH Human Participant Protections Education for Research Teams

CITI, Modules 1-13 (prior to Sept. 1, 2003)

Chadwick Workshop, March 9, 2001 a.m. and p.m. sessions

OHRP/Albany Workshop, April 24, 2001

Protecting Study Volunteers in Research by Dunn and Chadwick

IRB Manual

45 CFR 46

Institutional Review Board Guidebook – Introduction, Chapters I, II A, III, IV, V A & F, VI

CITI Social & Behavioral Research Modules 1-6 & 8-11, plus Biomedical Research Modules 14 & 15

IRB Chair

OHRP Modules 1-3

Chadwick Workshop, March 9, 2001 a.m. and p.m. sessions (previous requirement)

Belmont Report

IRB Manual

45 CFR 46

Protecting Study Volunteers in Research by Dunn and Chadwick

Institutional Review Board Guidebook – Introduction, Chapters I, II A, III, IV, V A and F, VI

CITI – Social and Behavioral Research Modules 1-6 & 8-11, plus Biomedical Research Modules 5, 6, 7, 9-11, 13, 14

IRB Members

*Belmont Report

*OHRP Module 1, HHS Regulations and Institutional Responsibilities

*Protecting Study Volunteers in Research by Dunn and Chadwick

(Every IRB member is provided with a personal copy of this book.)

*IRB Application Manual

*45 CFR 46

*OSP Human Subjects Website

Review the Forms for Investigators and Forms for IRB members' sections.

*SUNY New Paltz Policy on the Use of Human Subjects Research

*New Members: With an IRB mentor (can be done in an IRB meeting), discuss the review of 1 exempt and 1 expedited protocol

Chadwick Workshop, March 9, 2001 a.m. and p.m. sessions (previous requirement)

Participation in IRB 101 at the PRIMR conference is strongly recommended

* Note: Education program must be completed and documentation submitted to the Office of Sponsored Programs before IRB members may vote and independently review protocols.

IRB/Sponsored Programs Staff

Belmont Report

OHRP Modules (3) – Assistant VP for Sponsored Programs only

Chadwick Workshop, March 9, 2001 p.m. session (previous requirement),

OHRP/Albany Workshop April 24, 2001 (previous requirement), or

CITI modules 1-5, 7 & 9 (prior to Sept. 1, 2003)

CITI Social and Behavioral Research Modules 1-6 & 8, plus Biomedical Research Modules 7 and 14 (after Sept. 1, 2003)

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For all investigators and study team members on research projects with human subjects, training is required for all those who are involved in the design of the project or in the conduct of the human subjects portion of the project. Training is required even if the project is authorized as exempt by the IRB.
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Investigators

If taken or attended prior to October 1, 2001, the following meet training requirements:

NIH Human Participant Protections Education for Research Teams, or

Chadwick Workshop, March 9, 2001 p.m. session, or

OHRP/Albany Workshop April 24, 2001

Beginning Oct. 1, 2001 – Aug. 31, 2003: CITI modules 1-5, 7 & 9 plus 6, 8, 10, 11 as pertinent to research

Beginning Sept. 1, 2003: CITI Social & Behavioral Research Modules 1, 2, 4-6 & 8 required with 10 and/or 11 as pertinent to research and Biomedical Research module 7 required with 5, 6, 10, 11, 13 and/or 14 as pertinent to research (Refer to names of CITI modules on page 4 of this document).

Research Assistants and Study Team Members

For those involved in the design of the project or in the conduct of the human subjects portion of the project, training is required. For those working only with totally de-identified data, training is not required. For those working with identifiable data, even if it is coded, training is required.

Continuing Education

Certification is valid for three (3) years. If the CITI program was not taken initially, it is required for re-certification (refer to Sept. 1, 2003 requirements as stated above under the “Investigators” section.) If the CITI program was taken initially, then the CITI continuing education modules are required. (Modules 2,3,4,5,7,9, & 10. Refer to names of CITI modules on page 4 of this document.)

For consultants, external collaborators and external researchers, compliance with the continuing education requirements of their affiliated institutions will be accepted. If the affiliated institutions have no continuing education requirements, the SUNY New Paltz requirements apply. For investigators not affiliated with institutions, the continuing education requirements of SUNY New Paltz apply.

Continuing Education for IRB Members and IRB/Sponsored Programs Staff

Three CITI Social and Behavioral Research or continuing education modules (two for IRB/Sponsored Programs staff) or attendance at a PRIM&R/ARENA conference, OHRP workshop or other related human protections staff development program will be accepted as fulfilling continuing education requirements.

Consultants

If involved in the design of the project or in the conduct of the human subjects portion of the project, training is required. If the consultant is also affiliated with an institution, that institution's approved training program will be accepted. If the consultant is not affiliated with an institution, but has received training, the consultant may request approval from SUNY New Paltz of that training by providing the certificate received in the course and a brief description of topics covered along with the date of completion of the training. If acceptable training has not been completed, the consultant will complete the SUNY New Paltz training program. Beginning Oct. 1, 2001 – Aug. 31, 2003: CITI modules 1-5, 7 & 9 plus 6, 8, 10, 11 as pertinent to research. Beginning Sept. 1, 2003: CITI Social & Behavioral Research Modules 1, 2, 4-6 & 8 required with 10 & 11 as pertinent to research and Biomedical Research module 7 required with 5, 6, 10, 11, 13, 14 as pertinent to research.

*All consultants must meet the continuing education requirements of institutions with which they may be affiliated or those of SUNY New Paltz if their institutions have no approved continuing education program or if they have no institutional affiliation. **Under no circumstances will training through the OHRP modules be accepted.***

External Collaborators/Investigators

On Subawards

Approved training program of subaward institution accepted. If affiliated institution has no approved training program, but collaborator/investigator has received training, approval of that training may be requested from SUNY New Paltz by providing the certificate received in the course and a brief description of topics covered along with the date of completion of the training. If acceptable training has not been completed, subaward employees and agents will complete the SUNY New Paltz training program (Beginning Oct. 1, 2001 – Aug. 31, 2003: CITI modules 1-5, 7 & 9 plus 6, 8, 10, 11 as pertinent to research. Beginning Sept. 1, 2003: CITI Social & Behavioral Research Modules 1, 2, 4-6 & 8 required with 10 & 11 as pertinent to research and Biomedical Research module 7 required with 5, 6, 10, 11, 13, 14 as pertinent to research.) The PI from the subaward institution must provide documentation of IRB approval of the research.

Not on Subawards, With Institutional Affiliation

Approved training program of collaborator's/investigator's affiliated institution accepted. If affiliated institution has no approved training program, but collaborator/investigator has received training, approval of that training may be requested from SUNY New Paltz by providing the certificate received in the course and a brief description of topics covered along with the date of completion of the training. If acceptable training has not been completed, the collaborator/investigator will complete the SUNY New Paltz training program (Beginning Oct. 1, 2001 – Aug. 31, 2003: CITI modules 1-5, 7 & 9 plus 6, 8, 10, 11 as pertinent to research. Beginning Sept. 1, 2003: CITI Social & Behavioral Research Modules 1, 2, 4-6 & 8 required with 10 & 11 as pertinent to research and Biomedical Research module 7 required with 5, 6, 10, 11, 13, 14 as pertinent to research.) IRB approval from collaborator's/investigator's institution is required.

Not on Subawards, Without Institutional Affiliation

If collaborator/investigator has received training, approval of that training may be requested from SUNY New Paltz by providing the certificate received in the course and a brief description of topics covered along with the date of completion of the training. If acceptable training has not been completed, the collaborator/investigator will complete the SUNY New Paltz training program (Beginning Oct. 1, 2001 – Aug. 31, 2003: CITI modules 1-5, 7 & 9 plus 6, 8, 10, 11 as pertinent to research. Beginning Sept. 1, 2003: CITI Social & Behavioral

Research Modules 1, 2, 4-6 & 8 required with 10 & 11 as pertinent to research and Biomedical Research module 7 required with 5, 6, 10, 11, 13, 14 as pertinent to research.)

External Researchers Conducting Research Utilizing SUNY New Paltz Subjects

These investigators will be affiliated primarily with higher education institutions as graduate students who are fulfilling degree requirements. SUNY New Paltz will accept the training program of the investigator's home institution. A copy of the training completion certificate or a letter from the institution's compliance officer, documenting completion of the program and providing the name of the program, a brief description and date of completion must be sent to the SUNY New Paltz Office of Sponsored Programs. (If acceptable training has not been completed, the investigator may complete either the home institution's program or the SUNY New Paltz program.)

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Under no circumstances will the SUNY New Paltz IRB serve to review and provide continuing oversight of another institution's human subject research. No other institution may operate under the Federalwide Assurance or under the human protections program of SUNY New Paltz.
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CITI Modules by name:

Social and Behavioral Research Modules:

- Module 1: History and Ethics
- Module 2: Defining Research
- Module 4: Assessing Risks
- Module 5: Informed consent
- Module 6: Privacy and Confidentiality
- Module 8: Research with Children
- Module 10: International Research
- Module 11: Research Using the Internet

Biomedical Research Modules:

- Module 5: Records Based Research
- Module 6: Genetics Research
- Module 7: Vulnerable Subjects – Overview
- Module 10: Vulnerable Subjects –
Women & Fetuses
- Module 11: Vulnerable Subjects –
Group Harms
- Module 13: Human Subjects Research
at the VA
- Module 14: HIPAA & Human Subjects Research

Continuing Education:

- Module 2: Regulations and Process
- Module 3: Informed Consent
- Module 4: Social & Behavioral Research
- Module 5: Records Based Research
- Module 7: Research with Protected Populations –
Vul. Subjects: A definition
- Module 9: Studies with Minors
- Module 10: Studies with Pregnant Women and Fetuses