

NourishED Research Foundation (NRFi)

Responsible Conduct in Human Subjects Research Training and Compliance

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NourishED Research Foundation, Inc. (NRFi)
NOURISHING KNOWLEDGE, EMPOWERING HOPE



Table of Contents

<u>Section Number and Title</u>	<u>Page Number</u>
I. Welcome to NRFi’s Responsible Research Team.....	2
II. Introduction to Responsible Conduct in Human Subjects Research	3
A. The National Research Act (1974): Public Law 93-348	4
B. The Belmont Report (1978): Ethical Framework	4
C. “The Common Rule” (45 CFR 46) (1991): Legal Regulations.....	5
D. HIPAA (45 CFR 160-165)(1996): Legal Regulations	7
i. The HIPAA Privacy Rule.....	7
ii The HIPAA Security Rule.....	9
iii HITECH	9
E. FDA’s ICH Good Clinical Practices: Legal Regulations	10
F. CITI: The Collaborative Institutional Training Initiative.....	10
III. NRFi’s CITI Training & Certification Instructions	11
IV. Registering for you CITI Trainings & Certifications.....	12



I. Welcome to NRFi's Responsible Research Team

Welcome to NRFi's Research Team! We are excited to have you onboard!

NRFi requires that all research volunteers, faculty, employees, and staff uphold and comply with a high standard of legal and ethical regulations and guidelines when conducting **human subjects research (HSR)**, e.g., research in which humans are the subjects).

These standards serve to protect the safety, confidentiality, and overall rights and welfare of HSR participants, researcher investigators, and research institutions and affiliations alike.

This document provides a brief outline of the minimum level of ethical and legal standards that all NRFi research and researchers are required to comply with in order to ensure the safety, ethics, legal and ethical compliance, and welfare of all NRFi research (including researchers and participants alike).

Section II provides a brief overview of some **ethical and legal standards and regulations all NRFi research upholds** and complies with.

Sections III-IV provide instructions on how you can begin receiving your formal trainings and certifications in **responsible conduct in human subjects research**. This will enable you to be added to a research protocol at NRFi and – upon review and approval from our **Institutional Review Board (IRB)** – begin contributing to NRFi research.

NOTE: The CITI trainings and certifications that you will receive as part of your standard NRFi Research Training and Onboarding (outlined in Section III) are standards that most IRBs require of all research staff. Thus, these trainings can be added to your resume/CV and can help identify you as a competitive applicant for any subsequent or additional research positions you may seek.

Please feel free to reach out to your direct supervisor and/or Dr. Bray (nourished@nourishedrfi.org) with any questions, comments, concerns, or any other feedback you have. We appreciate your contributions to NRFi. We are here to support you and your dreams, and we value any and all feedback!



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II. Introduction to Responsible Conduct in Human Subjects Research

Welcome again to NRFi's Research Team! We are excited to have you onboard!

This section provides a brief outline of the better-known ethical and legal standards that all NRFi research and researchers are required to comply with in order to ensure the safety, confidentiality, overall rights and welfare of all of NRFi's HSR participants, investigators, and research institutions and affiliations.

These standards include:

- A. **The National Research Act** (1974: Public Law 93-348).
- B. **The Belmont Report** (1978: Ethical Framework).
- C. **"The Common Rule"** (45 CFR 46)(1991: Legal Regulations).
- D. **HIPAA** (1996: Legal Regulations).
- E. **Good Clinical Practices** (Legal Regulations).
- F. CITI Training & Certification (Institutional Compliance).



II. A. The National Research Act (1974, Public Law 93-348)

The National Research Act (Public Law 93-348) was signed into law in 1974, leading to creation of a commission to consider a set of boundaries and guidelines for ethical human subjects research, including:

- i) The boundaries between:
 - a. Biomedical and behavioral research AND
 - b. Acceptable and routine practices in medicine.
- ii) The role of assessing the risk-benefit criteria when determining the appropriateness of human subjects research.
- iii) Appropriate guidelines for human subject selection and participation in research.
- iv) The nature, definition, and minimum requirements of administering, obtaining, and ensuring continued **informed consent** of all research participants in various research settings.

(Office of Human Research Protections, 2018).

III. B. The Belmont Report (1978, Ethical Framework).

The National Research Act of 1974 led to the formation of the National Commission for the U.S. Department of Health, Education, & Welfare in 1978, which published a set of Ethical Principles and Guidelines for the Protection of Human Subjects Research that are known as The Belmont Report.¹²³

Thus, The Belmont Report was written in accordance with the National Research Law (93-348) and provides a statement of basic ethical principles and guidelines for human subject research that serves as the foundation for legal requirements related to ethical research.

The Belmont Report centers around three core principles:

- 1) Respect for Persons.
- 2) Beneficence.
- 3) Justice.

To ensure these three minimum principles, the Belmont Report provides guidance on the following topics:



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- i) Obtaining **informed consent** from all research participants.
- ii) Identifying specific **vulnerable populations** whose safety, rights, and welfare require additional consideration, protection, and monitoring in order for these populations to be included in research.
 - a. The Belmont Report identifies the following vulnerable populations in the context of ethicolegal human subjects research:
 - i. **Children.**
 - ii. **Prisoners.**
 - iii. **Individuals with HIV serostatus.**
 - iv. **NOTE:** These are certainly not the only vulnerable populations who require additional consideration and protection. Can you think of any other vulnerable populations who you might encounter in research?
- iii) Guidelines for **resolving ethical problems** that may arise in human subjects research.
- iv) A variety of additional ethical and legal guidelines.

II. C. “The Common Rule” (45 CFR 46)(1991, Legal Regulations)

In 1991, the **U.S. Department of Health and Human Services (DHHS)** used the ethical framework provided in the Belmont Report to identify several legal regulations that must be upheld when conducting human subjects research. These regulations are outlined in **Title 45 in the Code of Federal Regulations, Part 46 (45 CFR 46)**, also referred to as **“The Common Rule.”**

The Common Rule (45 CFR, Part 46) provides federal legal regulations and guidelines for ethical conduct in human subjects research that remain to this today.

The Common Rule includes five (5) main subparts that are described briefly below.

- 1) **Subpart A** provides regulations and requirements that **protect the safety, rights, and welfare** of all human research subjects, including:
 - a. Guidelines for ethical conduct in human subjects research.
 - b. Requirement for all research conducted by federal departments or agencies, including those that receive federal support (e.g., colleges and universities). These requirements include:



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- i. Criteria for formation, conduct, and operations of an **Institutional Review Board (IRB)** that will review, decline, revise, or approve, and monitor all human subjects research protocols for ethical and legal compliance.
 - ii. Administering, ensuring, obtaining, and maintaining **informed consent**.
 - iii. Assurance of ethical and legal compliance by the IRB.
 - iv. Criteria for **exempt or expedited IRB review** and approval processes.
- 2) **Subparts B - D** provide additional protection requirements that pertain to three specific populations identified as **vulnerable populations**:
- a. **Pregnant women and fetuses (Subpart B)**.
 - b. **Prisoners (Subpart C)**.
 - c. **Children (Subpart D)**.
- 3) **Subpart E** provides requirements for reviewing, approving, and monitoring the ethical and legal compliance of all human subjects research by an **Institutional Review Board (IRB)**.
- a. These regulations require all human subjects research be reviewed, approved, and monitored by an IRB that is formed and maintained at an institutional level (e.g., at the level of a research institution) and has been reviewed, approved, and registered at a federal (legal) level.
 - b. Subpart E provides requirements for the formation, components, roles, regulations, and registration of all IRBs, as well as for the IRB review, approval, compliance, and maintenance of all human subjects research.

The Common Rule has been revised in recent years (specifically, in 2018 when Subpart A was significantly revised). The most recent revisions can be found here:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>.



II. D. HIPAA (45 CFR 160-165)(1996): Legal Regulations

The **Health Insurance Portability and Accountability Act (HIPAA)** is the first set of national standards (and violations standards) that exist to **protect the privacy and security of individually identifiable health information.**

HIPAA was first enacted in 1996 by the Department of Health & Human Services' Office of Civil Rights (DHHS OCR) to reform health care laws and prevent insurance companies from accessing and using patients' past medical history to inform future health care access, coverage, and rates.

HIPAA now serves to protect individually identifiable health information more broadly, including in research use.

Since its enactment in 1996, HIPAA has undergone several revisions. Three primary components of HIPA are outlined and addressed further below.

- The 2003 HIPAA **Privacy Rule.**
- The 2005 HIPAA **Security Rule.**
- The 2009 Health Information Technology for Economic and Clinical Health (**HITECH**).

II. D. i. The HIPAA Privacy Rule

HIPAA's Privacy Rule provides a national set of *privacy standards* for protecting **individually identifiable health information.**

These standards typically addresses when, where, why/what for, how, and by whom individually identifiable health information may be used, disclosed, and requested.

HIPAA defines **Health information** as “*any information ... whether oral or recorded in any form or medium that: (1) is created or received by a health care provider [or other health care organization or entity, including research entities]; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual,*” (U.S. DHHS, 45 CFR 160.103 “Definitions”).



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Individually Identifiable Health Information is defined by HIPAA as a subset of health information that includes:

“demographic information collected from an individual, and: ...(i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual,” (U.S. DHHS, 45 CFR 160.103 “Definitions”).

Health information that is regulated, protected, and enforced by HIPAA with regards to the privacy and security of its use and disclosure is called **Protected Health Information (PHI)**.

HIPAA defines PHI as individually identifiable health information that is “transmitted or maintained in any other form or medium...” (U.S. DHHS, 45 CFR 160.103 “Definitions”).

Thus, essentially all individually identifiable health information qualifies as PHI and its use and disclosure must comply with HIPAA’s Privacy and Security Rules.

Examples of PHI include: name, address, employer information, telephone number or email address, social security number, medical record number, patient identification number, and any date associated with a health-related event (e.g., birth date, date of a medical appointment, intervention, referral, inpatient intake, or prescription).

Exclusions in which individually identifiable health information is not considered PHI include: *“(i) Education records covered by the Family Educational Rights and Privacy Act ..., (iii) Employment records held by a covered entity in its role as an employer,”* (U.S. DHHS, 45 CFR 160.103).

All identifiable health information used in research is considered PHI and must comply with HIPAA Privacy and Security Rules.

The HIPAA’s basic policy on **PHI use and disclosure** specifically addresses when, where, why/what for, how, and by whom PHI can and cannot be requested, collected, disclosed, handled, used, stored, and shared is commonly referred to as **“The Minimum Necessary Rule,”** outlined in 45 CFR §§ 164.502, “Uses and disclosures of PHI.”

As its name suggests, the **“Minimum Necessary Rule”** states that any healthcare or research organization that has access to PHI may only use, disclose, or request the **minimum PHI necessary** “to accomplish the intended purpose of the PHI” (HIPAA Privacy Rule).



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Furthermore, when a healthcare or research organization or business associate is permitted or has express authorization to access, use, or disclose PHI, they must only access, use, or disclose the **minimum amount that is necessary to fulfill his/her duties**.

Moreover, healthcare and research organizations are responsible for implementing and enforcing policies and procedures that reasonably restrict PHI access based on employee responsibilities to the patient.

II. D. ii The HIPAA Security Rule

HIPAA's Security Rule provides a national set of *security standards* for protecting **individually identifiable health information // PHI**.

These standards typically address when, where, why, and how PHI can be stored and/or transmitted, with specific attention to the safety and security of **electronic PHI (ePHI)** storage and transmission.

HIPAA requires that all healthcare and research organizations that are permitted to request, use, store, and/or access PHI develop and implement "the necessary safeguards" to protect PHI and ePHI.

The HIPAA Security Rule provides guidelines on the administrative, physical, and technical safeguards that must be implemented by any organization requesting, using, accessing, storing, and/or transmitting PHI and/or ePHI.

II. D. iii The Health Information Technology for Economic and Clinical Health Act (HITECH)

The **Health Information Technology for Economic and Clinical Health Act (HITECH)** was enacted into law in 2009 as part of the **American Recovery and Reinvestment Act (ARRA)**.

ARRA was and remains an economic stimulus package that included laws regarding health care. As part of ARRA, HITECH's main purpose was to **promote the adoption and meaningful use of health information technology (HIT)**.



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In 2009, the ARRA provided monetary incentives for healthcare organizations and providers to adopt meaningful use (MU) of health information technology under HITECH.

HITECH included several key amendments to the HIPAA Security Rules, including:

- Creation of four categories of HIPAA violations, based on culpability.
- Four corresponding tiers of penalties, based on type of violation.
- New HIPAA breach notification requirements.
- Setting a maximum penalty of \$1.5 million for all violations of an identical provision.
- Applying direct penalties against Business Associates for violating HIPAA.

II. E. The FDA’s Good Clinical Practices (Legal Regulations)

The **U.S. Food and Drug Administration (FDA)** provides a variety of recommendations, guidelines, and regulations that serve to protect and support a high standard of legal and ethical conduct in HSR. These recommendations, guidelines, and regulations are made available publicly in the FDA’s **International Conference on Harmonization (ICH) Document**.

The ICH includes a variety of guidelines for maintaining ethical and scientific standards when designing, conducting, recording, and reporting on HSR (e.g., ICH guidelines for **Good Clinical Practice (ICH GCP)**).

II. F. The Collaborative Institutional Training Initiative (CITI)

At NRFi, we deeply value responsible research conduct and take a variety of measures to ensure that all NRFi research complies with a high standard of legal and ethical regulations and guidelines.

NRFi complies with the National University of Natural Medicine (NUNM)’s Institutional Review Board (IRB) standards and asks all NRFi research volunteers, interns, and staff members to undergo a set of basic trainings and certifications on the responsible conduct of human subjects research.

These trainings are offered by the **Collaborative Institutional Training Initiative (CITI Program)**, considered the “Trusted Standard in Research, Ethics, Compliance, and Safety Training.”

Instructions for accessing these trainings are provided in section III below.



IV. NRFi's CITI Training & Certification Instructions

At NRFi, we deeply value responsible research conduct and take a variety of measures to ensure that all NRFi research complies with a high standard of legal and ethical regulations and guidelines.

NRFi complies with the National University of Natural Medicine (NUNM)'s **Institutional Review Board (IRB)** standards and asks all NRFi research volunteers, interns, and staff members to undergo a set of basic trainings and certifications on the responsible conduct of human subjects research that are required by NUNM's IRB.

These trainings are offered by the **Collaborative Institutional Training Initiative (CITI Program)**: <https://about.citiprogram.org/en/homepage/>), considered the "Trusted Standard in Research, Ethics, Compliance, and Safety Training."

The [CITI trainings](#) we ask all NRFi research volunteers, interns, and staff to receive certification in are:

- Responsible Conduct in Research (RCR).
- Human Subjects Research, (HSR, which includes HIPAA Compliance).
- Good Clinical Practices (GCP; FDA or ICH version; **FDA is recommended**).

Together, these three trainings provide an adequate introduction to the ethical and legal standards that exist regarding responsible human subjects research. They also provide a sufficient introduction to the regulations and standards outlined in the Belmont Report, The DHHS' "Common Rule" (45 CFR 46), HIPAA and HITECH, and the FDA's Good Clinical Practices.

CITI trainings are offered for-pay in two different ways:

- 1) CITI trainings are publicly available for-pay, so any individual can pay to access CITI trainings **independently (out-of-pocket)** at any time.
- 2) An institution can purchase a subscription//access to CITI trainings that enables its **affiliates to access these trainings for free**.

NRFi's partnership with the National University of Natural Medicine (NUNM) enables NRFi volunteers and staff to access select CITI trainings for free (through identifying affiliation with NUNM).



NourishED Research Foundation, Inc. (NRFi)
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You can find instructions on how to register for these courses here: <https://nunm.edu/research/resources/citi/>.

V. Registering for you CITI Trainings & Certifications

As per the instructions provided at <https://nunm.edu/research/resources/citi/>, you can create a CITI account using your **personal email address**.

Once you create an account, you'll be asked to select your institution/affiliation(s). You'll want to select "**National University of Natural Medicine.**"

You may also be asked if you'd like to receive CE credits; you will select "**no.**"

Altogether, these training courses can take up to 10-20 hours to complete, since the material will likely be new for you. They're not necessarily exciting, but they will provide you with a very informative foundation for understanding the basics of how human research works; they will also enable you to participate in human research at any institution until they expire, which will look most impressive on college resumes and applications (as per above).

NOTE: The CITI trainings and certifications that you will receive as part of you standard NRFi Research Training and Onboarding (outlined in Section III) are standards that most IRBs require of all research staff. Thus, these trainings can be added to your resume/CV and can help identify you as a competitive applicant for any subsequent or additional research positions you may seek.

Please feel free to reach out to your direct supervisor and/or Dr. Bray (nourished@nourishedrfi.org) with any questions, comments, concerns, or any other feedback you have. We appreciate your contributions to NRFi. We are here to support you and your dreams, and we value any and all feedback!