Wellesley College
Mandatory Research Integrity Training

Wellesley College expects faculty, staff, and students to conduct their work, including sponsored projects and research, with the highest degree of integrity. Likewise, federal sponsors are increasingly imposing requirements for grantee institutions to demonstrate the proficiency of their investigators in the ethical considerations inherent in research. These requirements reflect a shared societal concern for the proper stewardship of public dollars in support of research, the ethical treatment of human subjects, and the humane care and use of animals in research. Wellesley College shares these commitments and therefore puts forward the following training requirements. This policy constitutes minimum standards set forth by Wellesley College. Specific sponsors may have more stringent training requirements, in which case investigators supported by those sponsors are required to adhere to those requirements. There are four areas of research integrity training covered by this institutional policy:

I. Responsible Conduct of Research (RCR) Training
II. Institutional Review Board (IRB) Protection of Human Subjects Training
III. Institutional Animal Care and Use Committee (IACUC) Training
IV. Institutional Biosafety Training

I. Responsible Conduct of Research (RCR) Training

Applicability: This RCR training requirement applies only to externally sponsored research. This requirement applies to all individuals (faculty, staff, and students) supported under externally sponsored research projects. For the purposes of this policy, the term “supported” means receiving payment for personal services or for participation in research or training programs (e.g., salary, wages, or stipends). This RCR training policy is in effect for all externally sponsored awards received on March 1, 2015 or after.

The policy does not apply to other types of externally sponsored projects, such as projects that are primarily creative or artistic in nature, or grants supporting instruction or equipment. This policy also does not apply to internally funded research.
**Requirement:** All faculty, student, and staff researchers supported under externally sponsored research projects are required to complete one of the following two options: 1) the Responsible Conduct of Research Workshop offered by the Science Center in the summer, or 2) the CITI RCR online training course. Instructions for new CITI users are available on the [Office of Sponsored Research (OSR) website](#). Either the workshop or the online training course must be completed at least once every three years.

To complete the CITI RCR course, individuals should register on the CITI site, affiliate themselves with Wellesley College, and choose the appropriate RCR course based on the individual’s discipline (e.g., Humanities, Social & Behavioral Sciences, Physical Sciences, etc.). Upon completion of the course, OSR will automatically receive a completion notification for the individual that can be made available to external sponsors by request. Training certifications are valid for a period of three years, after which time it is the individual’s responsibility to complete a “refresher” CITI module.

For new awards, sponsor funds will not be released to the Principal Investigator of a sponsored project until documentation of his/her completion of the RCR course is received. It is the Principal Investigator’s responsibility to ensure each current or future member of his/her research team supported by sponsor funds (including students) also completes the training course.

Faculty, staff, and students conducting research activities not supported under externally sponsored projects are not required to complete this training, but are strongly encouraged to do so. Wellesley College has purchased a campus-wide membership to the CITI training site and all members of our community are encouraged to utilize this resource.

Additionally, faculty are encouraged to consider ways in which the training course may be incorporated into their coursework to enhance student understanding of research ethics.

**II. Institutional Review Board (IRB) Protection of Human Subjects Training**

**Applicability:** This IRB training requirement applies to all key personnel (faculty, staff, or students) on proposals funded by HHS or NIH.

This IRB training policy is in effect for all human subjects research protocols submitted to the IRB as of March 1, 2015 or later.
**Requirement:** According to guidance from the Office for Human Research Protections, “The HHS regulations for the protection of human subjects (45 CFR part 46) do not require investigators to obtain training in the protection of human subjects in research. However, an institution holding an OHRP-approved Federal-Wide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects.” In addition, since October 1, 2000, the National Institutes of Health (NIH) has required all key personnel on funded NIH proposals involving human subjects to complete an educational course on the protection of human subjects.

At Wellesley College, key personnel who plan to participate in research funded by HHS or NIH must (in addition to reviewing these guidelines), complete the responsible conduct of research training provided by the Wellesley College Office of Sponsored Research. To complete the training, all key personnel should go to this link and set up an individual account to complete their training [http://www.citiprogram.org](http://www.citiprogram.org). On completion a certificate will be automatically sent to the Office of Sponsored Research. You cannot receive IRB approval until the certificate is on file.

Other researchers (faculty, students or research staff) are expected to review the written IRB guidelines. Additional training will be provided by the IRB chair, as indicated.

Faculty, staff, and students are reminded that no funded research involving human subjects may be conducted without the advance review and approval of the Wellesley College IRB.

**III. Institutional Animal Care and Use Committee (IACUC) Training**

**Applicability:** This IACUC training requirement applies to all faculty, staff, or students conducting research with vertebrate animals, regardless of whether those activities are externally funded, internally funded, or unfunded.

This IACUC training policy is in effect for all animal research protocols submitted to the IACUC as of March 1, 2015 or later.

**Requirement:** Individuals conducting research with vertebrate animals are required to complete the [CITI Lab Animal online training course](http://www.citiprogram.org).
Individuals must register on the CITI site and affiliate themselves with Wellesley College. Upon completion of the course, OSR and the Chair of the Wellesley College IACUC will automatically receive a completion notification for the individual that will be made available to external sponsors (if applicable) by request. Training certifications are valid for a period of three years, after which time it is the individual’s responsibility to complete a “refresher” CITI module. Please go to this link and set up an individual account to complete the training course: http://www.citiprogram.org. On completion, a certificate will automatically be sent to the Office of Sponsored Research.

Faculty, staff, and students are reminded that no research with vertebrate animals may be conducted without the advance review and approval of the Wellesley College IACUC. IACUC protocols will not be approved without documentation of the completion of the required training by the Principal Investigator. It is the Principal Investigator’s responsibility to ensure each current or future member of his/her research team (including students) engaged in animal research also completes the training course.

Additionally, faculty are encouraged to consider ways in which the training course may be incorporated into their coursework to enhance student understanding of the ethical considerations involved in the use of animals in research.

IV. Institutional Biosafety Training

Mandatory as of March 1, 2015

Wellesley College expects all investigators (faculty, students and staff) to conduct their work, including sponsored projects and research, with the highest degree of integrity. Likewise, federal sponsors are increasingly imposing requirements for grantee institutions to demonstrate the proficiency of their investigators in the ethical considerations inherent in research. All investigators supported under externally sponsored research projects are required to complete mandatory research integrity, CITI Responsible Conduct of Research Basic Biosafety training. This policy, effective March 1, 2015, constitutes minimum training standards set forth by Wellesley College. Specific sponsors may have more stringent training requirements, in which case investigators supported by those sponsors are required to adhere to those requirements.
Basic BioSafety Training

At Wellesley College, the Biosafety training requirement applies to all faculty, staff, or students teaching or conducting research with hazardous biological material at biosafety level 1 and biosafety level 2, and recombinant or synthetic nucleic acid molecules, regardless of whether those activities are externally funded, internally funded, or unfunded. This program has three courses available depending upon program involvement.

This Institutional Biosafety training policy is in effect for all research protocols submitted to the Institutional Biosafety Committee (IBC) as of March 1, 2015 or later.

1. Biosafety training for Level 1 and Level 2

All key personnel involved in biological teaching or research with hazardous biological material are required to set up an individual account and affiliate themselves with Wellesley College to complete the CITI Basic Biosafety (14 modules) certificate course: http://www.citiprogram.org.

Upon completion of the course, the Office of Sponsored Research (OSR) and the Chair of the Wellesley College IBC will automatically receive a completion notification. The training certificate for faculty and staff is valid for three years after which time it is the individual's responsibility to complete a "refresher" CITI module. The certificate can be made available to external sponsors by request. You can not receive approval until the certificate is on file.

Students in research laboratories are required to take annual training. Classroom based training is provided by the Environmental Health and Safety (EHS) Office each semester for students with Wellesley specific information. If more advanced training is appropriate, students may take the CITI training as well.

Before any hazardous biological material may be ordered or research conducted, you must have the advanced review and approval of the Wellesley College IBC and CITI training certificate. Protocols involving the use of hazardous materials will not be approved without documentation of the completion of the required training by the Principal Investigator.

It is the Principal Investigator's responsibility to ensure each current or future member of his/her research team (including students) engaged in research that involves Biosafety material completes the CITI training course.
2. National Institutes of Health (NIH) Recombinant DNA Guidelines

All Individuals working with recombinant or synthetic nucleic molecules are required to comply with the NIH Guidelines (http://osp.od.nih.gov/office-biotechnology-activities/biosafety/ NIH-g uidelines) and complete CITI Basic Biosafety (see above) and NIH rDNA Guidelines (3 modules) certificate course (www.citiprogram.org) as a condition of receiving funding. Even if only one research project involving recombinant or synthetic acid molecules at an institution benefits from NIH support, all such projects at the institution must comply. The NIH Guidelines promote the safe and responsible practice of this type of research and provides the public confidence that safety matters.

Upon completion of the course, the Office of Sponsored Research (OSR) and the Chair of the Wellesley College IBC must receive a copy of the completion notification. The training certificate for faculty and staff is valid for three years after which time it is the individual’s responsibility to complete a “refresher” CITI module. Students are required to take annual training. The certificate can be made available to external sponsors by request. You can not receive IBC approval until the certificate is on file.

It is the Principal Investigator’s responsibility to ensure each current or future member of his/her research team (including students) engaged in research that involves recombinant or synthetic nucleic molecules completes the CITI training course.

3. Institutional Biosafety Committee Member Training:

All IBC members are required to complete CITI Basic Biosafety (8 modules) certificate course: (www.citiprogram.org) prior to sitting on the committee. The training course covers, among other items, current IBC requirements, basic information on rDNA and Biosafety. The IBC has several mandates as required by NIH. One is to ensure that the IBC has the working knowledge and tools to fully participate in reviewing and providing oversight for applicable research protocols.

Non-compliance

Wellesley College considers instances of non-compliance with institutional policies, including those pertaining to sponsored research, to be serious events. Consequences for individuals not in compliance with this Mandatory Research Integrity Training policy will be determined by the Provost, in consultation with other institutional officials as appropriate to the case.