RESPONSIBLE CONDUCT OF RESEARCH WEBINAR

June 16, 2017
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Since 1984, APTR has partnered with CDC in a Cooperative Agreement to support training activities.

APTR is part of the Academic Partnerships to Improve Health (APIH) group, which focuses on strengthening academia's linkages to public health practice.

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Opening Remarks:
LaVonne Ortega, MD, MPH

Program Director
Academic Partnerships to Improve Health Division of Scientific Education and Professional Development Centers for Surveillance, Epidemiology, and Laboratory Services Centers for Disease Control and Prevention
Today’s Speaker:
Matthew L. Boulton, MD, MPH

Professor of Epidemiology & Preventive Medicine
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Research Ethics

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Presentation Outline

• Research ethics and shared values
• Historical events influencing research
• Research Regulations
  • Institutional review boards (IRB)
  • Informed consent
  • Vulnerable populations
  • Conflict of interest and conflict of commitment
• Research misconduct
• Reporting research and scholarship
  • Publication
  • Authorship
  • Peer review
Why Ethics is Important

We are concerned with normative ethics, asking questions such as: What should morality require? How should researchers behave? How should researchers not behave? What character traits should researchers cultivate as virtues? And, what character traits should researchers try to avoid?

There are many advantages to understanding research ethics. Concepts of research ethics:

- Provide us with a structure for analysis and decision-making
- Support and remind researchers to protect human subjects
- Provide workable definitions of benefits and risks, along with guidelines for evaluating and balancing the benefits and risks of our studies
Shared Values

Everyone engaged in research is expected to set high standards for integrity in their work. As researchers, research administrators, research staff, and students, we share a commitment to:

- be truthful and accurate in all aspects of research,
- avoid bias and appropriately manage conflicts of interest,
- adhere to all research regulations,
- be fair and honest in dealings with colleagues and staff, and
- use public resources efficiently.

In practice, conflicting obligations and the pressures that have become a routine part of research can sometimes make setting high standards for integrity a challenge. A personal commitment to integrity therefore needs to be coupled with a firm understanding of the practices that define the responsible conduct of research.

PEERSS is designed to help everyone who conducts, administers, or supports research learn about research and scholarly responsibilities.
Your Responsibilities

The public support of research rests on its trust of scientists, scholars and the institutions where research is conducted. Individual actions can bolster that confidence or, unfortunately in some instances, undermine it.

- Institutional research programs have been sanctioned for irresponsible behavior. In past years, New York University, University of Minnesota, University of Illinois at Chicago, University of Pennsylvania, University of California at San Diego, University of Washington and Johns Hopkins University were either fined and/or had to suspend much research activity while oversight systems were improved, often costing the institutions many millions of dollars and impeding research progress even for individuals who conducted themselves responsibly.

- Individual researchers have been penalized. The federal Office of Research Integrity publishes the results of formal investigations into research misconduct on their web site. As a minimum federal sanction, these individuals usually lose the right to apply for grant support for a specified time period.
Historical Events that Have Influenced Human Research

First Documented Human Subject Research

Research ethics has evolved. Among the first human subject research experiments to be documented were vaccination trials in the 1700's. In these early trials physicians used themselves or their family members as test subjects. For example:

- Edward Jenner (1749-1823) first tested smallpox vaccines on his son and on neighborhood children.
- Johann Jorg (1779-1856) swallowed 17 drugs in various doses to record their properties.
- Louis Pasteur (1822-1895) "agonized over treating humans," even though he was confident of the results obtained through animal trials. He finally did so only when he was convinced the death of the child, the first test subject, "appeared inevitable." [Rothman]
Historical Events that Have Influenced Human Research

First Documented Human Subject Research

The Era of Modern Science

Nuremberg Code

Society's high regard for the medical profession, however, was not to last. At the end of World War II, 23 Nazi doctors and scientists were put on trial for the murder of concentration camp inmates who were used as research subjects. Of the 23 professionals tried at Nuremberg, 15 were convicted, 7 were condemned to death by hanging, 8 received prison sentences from 10 years to life, and 8 were acquitted.

[Nitscherlich & Mielke] Included in the legal judgment and sentences handed down at the culmination of the trial were ten points describing required elements for conducting research with humans. These points became known as the Nuremberg Code.

In summary, the Nuremberg Code includes the following guidance for researchers:

- Informed consent is essential
- Research should be based on prior animal work
- The risks should be justified by the anticipated benefits
- Only qualified scientists must conduct research
- Physical and mental suffering must be avoided
- Research in which death or disabling injury is expected should not be conducted

Effect of the Nuremberg Code

Declaration of Helsinki

Beecher Article
Research Ethics since the 1970s

The Public Health Service (PHS) Syphilis Study is among the most influential in shaping public perceptions of research involving human subjects. After media reports on the PHS Syphilis Study, Congress formed an Ad Hoc Panel. The Panel determined that the PHS Syphilis Study should be stopped immediately and that oversight of human research was inadequate. The Panel recommended that federal regulations be designed and implemented to protect human research subjects in the future. Subsequently, federal regulations were enacted including the National Research Act, 45 Code of Federal Regulations 46, and 21 Code of Federal Regulations 50.

The National Commission

In 1974 Congress authorized the formation of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, known to most people in research ethics as The National Commission. Congress charged the National Commission to identify the basic ethical principles that underlie the conduct of human research—not look at the writings and discussion that had taken place up to this time and to ask, "What are the basic ethical principles that people are using to judge the ethics of human subject research?" Congress also asked the National Commission to develop guidelines to assure that human research is conducted in accordance with those principles.

The Belmont Report

The National Commission met and in 1979 published the Belmont Report. The Belmont Report is "required reading" for everyone involved in human subject research. The Belmont Report identifies three basic ethical principles that underlie all human subject research. These principles are commonly called the Belmont Principles. The Belmont Principles are respect for persons, beneficence, and justice.
Research Ethics and Regulations

Federal regulations are derived from all of these ethical concerns. Federal regulations provide three basic protections to human subjects involved in research.

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<td>Review by an IRB</td>
<td>Institutional assurances are a mechanism to apply federal regulations to all human subject research. When institutions sign federal assurances, they may also elect to apply the Health and Human Services regulations and terms of the assurance to all research of the institution, regardless of the source of funding.</td>
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**Institutional Assurances**

**Review by an Institutional Review Board**

Review by the IRB is the glue that holds the evaluation process together. IRB review is guided by the ethical principles described in the Belmont Report and asks the following questions when evaluating a study:

**Respect for persons**

- Does the consent process maximize autonomy?
- Does the protocol maximize autonomy?
- What additional protections have been put in place for vulnerable populations?
- Does this study maximally protect subject privacy and confidentiality?

**Beneficence**

- Is the research design adequate? Can it be improved?
- What are the risks? Have they been minimized? Is the subject informed?
- What are the benefits? Have they been maximized? Is the subject informed?

**Justice**

- Does recruitment for the study target the population that will benefit from the research?
- Does the recruitment unfairly target a population?
- Are the inclusion/exclusion criteria fair?

Ethical principles and federal regulation provide a framework for IRBs to evaluate research involving human subjects. However each research study is unique and thus a comprehensive review may be a complicated process.
Role of the IRB

An Institutional Review Board (IRB) is a review committee established to help protect the rights and welfare of human research subjects. Regulations require IRB review and approval for research involving human subjects if it is funded or regulated by the federal government. Most research institutions, including the University of Michigan, professional organizations, and scholarly journals apply the same requirements to all human research. Although federal regulations refer to IRBs, an institution may have chosen a different name for this committee.
**Investigator-Subject Relationship**

The investigator must place the subject's rights, welfare, and safety above all other personal and scientific concerns. The relationship between researcher and subject is similar to a physician-patient relationship, but different in the following ways:

- **Informed consent is required for participation in research.**
- **Withdrawal from a study is at the discretion of the subject.**
- **Investigators should be sensitive to power relationships.**
- **The investigator has a moral fiduciary relationship with the subject.**

Example: A healthy research subject enrolls in a pharmacokinetic study of a drug that is known to cause anxiety and feelings of distrust. After receiving two doses, the subject declares he no longer trusts the researchers and says he will leave. The investigator says, "It's the drug talking" and tries to continue the procedure.

An ethical researcher will permit subjects to withdraw for whatever reason or for no reason. Of course, a researcher must do what is needed for subject safety; in the example above, the investigator should ensure the subject's emotional equilibrium returns to normal.
Criteria for IRB Approval

Federal policy lists Basic Criteria that the IRB must apply [45 CFR Part 46.111 and 21 CFR Part 56.111] when reviewing research involving human subjects. To approve a research project, the IRB must determine that:

- The risks to subjects are minimized.
- The risks are reasonable in relation to any anticipated benefits to the subject, and to the advancement of knowledge.
- The selection of subjects is equitable.
- Informed consent will be sought.
- Informed consent will be documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

In addition, there are specific requirements regarding the informed consent process. The IRB must determine that these conditions exist at the time of initial review and at each subsequent review conducted by the IRB.
Consequences

If IRB regulations are not followed, consequences could include:

- Suspension of research project.
- Suspension of all of a PI's research projects.
- Inability to use data or publish results.
- Notification of sponsors, regulatory agencies and funding agencies of noncompliance.
- Debarment by FDA from using investigational products.
- Inability to receive funding from federal grants.
- Additional monitoring and oversight by the IRB and/or third party monitoring of research activities.
- Termination of employment.
- Loss of licenses.
- Immediate shut-down of ALL research at an organization.

These are not theoretical consequences. Some or all of these consequences have occurred at sites where human subjects research was conducted improperly or without IRB approval.
Informed Consent

There is consensus regarding the importance of informed consent. Informed consent is how you show respect to research subjects, and it is mandated by the Code of Federal Regulations (CFR) to:

- Protect human subjects/volunteers.
- Ensure that potential study subjects clearly understand the benefits and risks associated with their participation in a study.
- Provide the potential study subjects with all information needed to reach a decision on whether or not to participate in a research study.

The Code of Federal Regulations (CFR) is published in the Federal Register, a publication of the Federal Government that codifies the general and permanent rules of executive departments and agencies. There are 50 titles that represent broad areas subject to federal regulation. The CFR is updated once each calendar year and is issued on a quarterly basis.

Informed Consent Section Content Author:

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Requirements

The framework for informed consent can be found in The Code of Federal Regulations 45 CFR 46.116(a) and 21 CFR Part 50.25(a). Legally appropriate informed consent will include the following elements.

General Requirements

1. Information that the study involves research.
   - An explanation of the purposes of the research.
   - The expected duration of the subject’s participation.
   - A description of the procedures to be followed.
   - Identification of any procedures that are experimental.

2. A clear description of the risks or discomforts to the subject. Such description must:
   - Be accurate and reasonable.
   - Review any risks related to procedures and tests relating solely to research and any tests that carry a risk of morbidity/mortality.
   - Inform the subject of previously reported adverse events.

3. A description of the benefits to the subject or to others.

4. A disclosure of any alternative procedures or treatments that may be advantageous to the subject, thus giving the subject a full range of available options. When appropriate, a statement that supportive care with no additional disease specific treatment is an alternative.

General requirements are continued on the next page.
Research with Protected Populations - Vulnerable Subjects

The concept of subject vulnerability is important to research ethics and to regulatory compliance. DHHS regulation 45 CFR 46.111(b) and FDA regulation 21 CFR 56.111(b) require that “when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.” The DHHS and FDA regulations, and International Conference of Harmonization (ICH) guidelines provide partial lists of subjects who should be considered vulnerable, but they do not provide a definition of vulnerable subjects or an explanation of the causes of vulnerability.

Examples from DHHS and FDA Regulations

DHHS regulation 45 CFR 46.111(b) and FDA regulation 21 CFR 56.111(b) provides the following list of examples of vulnerable subjects: “children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.” ICH guideline 1.61 provides the following list of vulnerable subjects:

- Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

- Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention.

- Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
To What Are Vulnerable Subjects Vulnerable?

Subjects who are vulnerable are more likely to have their rights abused in the following ways:

- Physical Control - Vulnerable subjects have been physically forced to participate in research at times. This represents a complete lack of voluntariness. A classic example is the use of prisoners of the Nazi Holocaust camps in research with an endpoint of subject death, such as the hypothermia studies. The subjects had no choice about whether or not to participate, and were under the complete physical control of the investigators. A recent example is a surgeon in California who kept a subject under anesthesia to perform research after clinically-required surgery, despite the subject’s prior refusal to participate in the research.

- Coercion - The use of a credible threat of harm or force to control another person. An example of coercion is a nursing home resident who was forced to choose between participating in a research study or leaving the nursing home, as reported in the June, 2000, Office of the Inspector General Report OEl-01-97-00195, "Recruiting Human Subjects."

- Undue Influence - The misuse of a position of confidence or power to lead another to make a decision he would not otherwise have made. An example would be a physician’s affirmative response to a patient’s inquiry of whether the patient should enter a research study, when in fact the physician knows that participation in the study is not in the patient’s best interest.

- Manipulation - Deliberate management of conditions or information in such a way as to lead another to make a decision he would not otherwise have made. Examples of information manipulation include lying, withholding information, and exaggeration.
Conflict of Interest (COI):

...a situation where a faculty or staff member is in a position to influence the business, research, or other decisions of the University in relationship to an outside organization that could lead directly or indirectly to financial gain for that individual or the family of that individual, or give improper advantage to others to the detriment of the University.

Conflict of Commitment (COC):

...a situation where the commitment to external activities of a faculty or staff member adversely affects his or her capacity to meet University responsibilities. Frequently, time devoted to external activities is referred to as "professional commitment" or "consulting."

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<th>COI/COC situations can impact areas related to your responsibilities, including:</th>
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<td>· Mentoring of graduate students, post-doctoral fellows, and junior faculty</td>
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<td>· Human subjects enrollment</td>
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<td>· Purchasing decisions</td>
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<td>· Acceptance of gifts</td>
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<td>· Technology transfer</td>
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<td>· Use of University resources</td>
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Recognizing COI - Guiding Principles

Unsure whether a situation represents a conflict of interest or commitment between your obligation and an outside interest, activity, or relationship? Ask yourself if the relationship could:

1. Lead to personal gain
2. Give improper advantage to someone other than your institution
3. Negatively impact your research
4. Unduly influence the business of your institution
5. Negatively affect your institution or other professional obligations

Some COI situations (e.g., financial interests) require a formal disclosure to your unit and/or COI Committee. Others (e.g., influence upon procurement decisions) rely on your knowledge of policies and your conscience to behave ethically as opposed to formal disclosure.

Other Resources: Human Research Protection Program (HRPP): http://research-compliance.umich.edu/operations-manual-conflicts-interest-and-commitment
Disclosing Outside Interests

Remember, having an outside interest does not necessarily mean you have a conflict of interest or commitment. Conflicts are also not inherently bad or prohibited. However, **failure to properly disclose** an outside interest that relates to your institutional responsibilities can lead to problems. All investigators on a sponsored project must evaluate if they have financial or management interests to disclose.

**What do I disclose?**

- **Time** (i.e. length of a relationship and estimated professional effort spent on the outside interest)

- **Type of relationship** with the outside entity (e.g., consultant, honoraria speaker, board member, etc.)

- **Equity interest in** and/or **compensation from** the outside entity and its **value**

- **Travel** paid by the outside entity (PHS or unit-specific policy)

- **Association** (e.g., sponsor, product use, licensed inventions, subcontract with) with your research
Research Misconduct

The working Federal definition of misconduct in research singles out three unacceptable practices: Fabrication, Falsification, and Plagiarism. To be considered misconduct, actions must be:

- a significant departure from accepted practices of the relevant research community; and
- committed intentionally, knowingly, or recklessly; and
- proven by a preponderance of evidence.

Data Fabrication refers to the “artificial” generation of data and then presenting it as actual data from a genuine observational system or process. In other words, presenting “fake” data as real. Data fabrication can be as simple as “pulling numbers out of a hat” and using them to bolster an argument or prove a hypothesis, or as elaborate as a complicated simulation involving instruments and computers.

An example of the latter was chronicled in Science [297(5578) 5 Jul 2002, pp. 34-37] in an article describing the rapid rise and later fall of wunderkind, Jan Hendrik Schön, who was able to “demonstrate” possibilities in atomic physics that had eluded researchers for many years. The result of an investigation concluded he had committed data fabrication.

Data Falsification usually refers to “intentionally changing or editing” data, usually to better suit an expectation or a proposed hypothesis. Data falsification may include altering the values of results, deleting data altogether, or any form of modification applied to a set of data that cannot be justified by standard methods of inquiry.

Plagiarism refers to claiming someone else’s intellectual property (IP) as one’s own. In academia, most IP is in the form of published works, but may also include software or work products disseminated through other media.

Learn more...

Reporting Misconduct

After careful consideration, anyone who has reasonable suspicions of misconduct in research has two fundamental obligations:

- report the suspected misconduct, and
- do so in a responsible, appropriate manner, meaning a) in confidence; b) in writing with supporting evidence, unless there are unusual mitigating circumstances; and c) to someone who has responsibilities for the research in question, such as a lab director, principal investigator, department chair, dean, or the Office of the Vice President for Research.

Once an allegation of misconduct has been reported, the University will conduct an investigation. In situations where the agency funding the research under suspicion learns of the allegation first, it will contact the University to begin the investigation and report back before the agency takes further steps.

Important:

- Failure to report misconduct in research is itself misconduct in research.
- Both the accused and the accuser (whistleblower) have rights, which must be protected.
- Being accused of misconduct in research is a serious charge that should not be discussed in public or shared with anyone other than an appropriate University officer prior to a decision about the merits of the charge.
- Reporting someone who may have committed misconduct takes moral courage and can involve personal risks, particularly if the whistleblower works for the person being accused of misconduct. For this reason, Federal and state laws protect whistleblowers from retaliation. Anyone who reports misconduct in good faith and in appropriate ways cannot be fired or in other ways penalized for their actions.
Reporting Research and Scholarship

While most academic work is reported in the form of peer-reviewed publication, several options exist for the reporting of academic research.

These options include:

- research conferences within and outside of the institution;
- abstracts resulting in poster presentations or oral communications at meetings;
- press releases;
- presentations at job interviews;
- journal publications, as peer reviewed articles or review articles;
- monographs or books, and
- invention disclosures and patent applications.

Each mode of reporting research findings has its own value. For instance, the presentation of the work at a national meeting may result in speaking invitations and job interviews.

Results reported through the public media may generate interest among donors who wish to support the research or investors who might wish to see the work translated into marketable products. On the other hand, peer reviewers may be alienated if they know that research findings have been prematurely reported to the public press, and some journals may not publish an article that has already appeared in the media. Furthermore, some forms of reporting research findings may preclude or limit the value of other forms of communication. For example, United States patents will not be awarded for inventions that have been disclosed at public conferences or through publications appearing more than one year prior to the filing date. In Europe, prior reporting in any form is not permitted prior to filing a patent application.
Guiding Principles: Publication, Authorship and Peer Review

- Respect for the ideas and work of others is important.
- Be careful to give credit when credit is due and respect the confidentiality of works that are under review.
- The norms for who gets credit (or not) for a particular contribution can vary by discipline. (Norms Vary. There are no universal definitions for how and when to provide credit to colleagues. A researcher is advised to find out the norms of his/her specific discipline. Journals and the societies that publish them may also provide useful guidelines.)
- When in doubt, put yourself in the other person’s shoes and ask whether under the circumstances, you would want credit for the contribution in question.
Guiding Principles: Importance of Authorship for the Academic Community

While publications may differ in form and format between disciplines, three principles transcend these differences and apply to all members of the University community.

These principles are as follows.

- Authors must guarantee the originality of their work.
- Authors must provide credit for the ideas of others upon which their work is built.
- Authors must assume responsibility for the accuracy and fairness of the presented information.
  - If there are multiple authors, the primary should be able to identify the specific contribution of each author.
  - Each author should be able to defend the methods and data pertinent to their specific contributions and agree with the general conclusions and interpretations presented by the paper.
  - Each author should have sufficient familiarity with the work to be sure it is accurate and was conducted in accordance with the rules for good science.
Guiding Principles: Assignment of Authorship

- Authorship is important because it establishes priority, reputation, and standing within an academic community.
- Authorship constitutes a stepping-stone to promotion.
- Published articles are research products and authorship denotes responsibility.
- Individuals included as authors will usually have provided significant contributions in one or more of the following areas:
  - conception and design of the research
  - data acquisition
  - data analysis vital to the conclusions of the project
  - drafting the manuscript
  - revisions to the manuscript related to important intellectual content

- Individuals are not included as authors for contributions limited to:
  - providing workspace, instrumentation, or funding
  - consulting or materials for a fee
  - routine technical work or patient care
  - proofreading or editing manuscripts
Improper Practices in Authorship

Because publishing is inherently valuable, individuals have occasionally engaged in improper practices in both the content of their publications and the assignment of authorship.

Misconduct in the pursuit of scholarship and research is well defined by the University. Misconduct and the procedures for investigating misconduct are outlined in the UM “Policy Statement on Integrity of Scholarship” (see Learn More for link). Major offenses include the following (select link for definition):

- Fabrication of data: Dishonesty in reporting results, improper adjustment of results, and gross negligence in collecting or analyzing data. Included is the selective reporting or omission of conflicting data for deceptive purposes.
- Plagiarism: Taking credit for someone else’s work and ideas, stealing others’ results or methods, copying the writing of others without proper acknowledgment, or otherwise falsely taking credit for the work or ideas of others.
- Abuse of confidentiality: Taking or releasing the ideas or data of others that were shared with the legitimate expectation of confidentiality.
- Falsification in research: Deliberately misrepresenting research, including progress of research to a sponsor.
- Dishonesty in publication: Knowingly publishing material that will mislead readers, such as misrepresenting data, research progress, or adding the names of authors without their permission.
**Guiding Principles: Authorship Practices**

- Misconduct in the performance and reporting of scholarship and research is a serious matter that may result in disciplinary action by an institution and/or the federal government.

- Serious lapses in integrity, including the falsification of results, plagiarism, and the abuse of confidentiality are easily recognized across disciplines as serious offences. Such offenses may result in dismissal from an institution.

- Less serious practices serve to undermine the quality of the research and the significance of authorship. While practices designed to maximize the number of publications and to use authorship as a reward for more senior faculty or others may not be considered as egregious, these practices erode the quality of scholarship at an institution.
Guiding Principles: Peer Review

- Manuscripts and grants should be considered to be privileged communications and the intellectual property of the submitting authors.
- Reviewers should refrain from sharing the contents of manuscripts and grants with anyone, except to obtain limited assistance on the review of technical points.
- If the reviewer believes that a colleague is more qualified to assess a grant or manuscript, then the reviewer should obtain the permission of the study section chair or administrator or the journal editor prior to sharing the contents of the work.
- Reviewers should submit their assessments within a timely fashion.
- If a reviewer perceives that he or she has a conflict of interest in the review of a manuscript or grant, then the reviewer should return the work promptly.
- If a reviewer believes that he or she may be perceived as having a conflict of interest, then the reviewer should disclose this to the funding agency or journal editors either prior to or at the time he or she submits his review.
Thank you for attending today’s webinar

- Slides & a recording of the webinar will be available soon on APTR’s website.
- Your feedback in the evaluation form will help us measure the impact of our event.
- If you are a CDC Public Health Fellow, you are expected to complete the evaluation in its entirety.