Informed Consent: Background

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I. Purpose and Design of this Module

The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) conducts research and develops reports and other materials for public distribution in order to advise the President of the United States on bioethical issues that arise as a consequence of advances in biomedicine and related areas of science and technology. To support ethics education and facilitate the integration of bioethical analysis into existing curricula across traditional and nontraditional educational and professional settings, we have developed pedagogical materials designed to increase distribution of the Bioethics Commission’s work and to facilitate easy access to the material in its reports by professors, instructors, teachers, and professional leaders (collectively “instructors”).
This module was prepared for instructors who want to include in their teaching a discussion of informed consent in the research setting. It provides foundational information, ethical reasoning, applications, questions, discussion points, and additional readings that are designed to give the instructor enough information to plan lectures, discussions, or activities. These materials are not intended to be a lecture script or outline, but rather to support the instructor in developing his or her own presentation(s).

In addition to the background information provided here, further modules provide a guide for instructors to facilitate incorporation of the Bioethics Commission’s published reports as a resource for teaching and discussion. The featured Bioethics Commission reports illustrate relevant and current applications of informed consent in various contexts.

Instructors are invited to use these materials, or any portion of them, to integrate bioethics into coursework and professional development activities in all disciplines. Feedback is welcome, including insight into how the materials have been used and suggestions for how they might be improved for use in the future. (Send feedback to education@bioethics.gov.)

II. Introduction

Seeking and obtaining informed consent to participate in research or receive care is an integral part of the ethical treatment of individuals in both clinical and research settings. The clinical setting is focused on the care and treatment of individual patients, whereas the research setting is focused on experiments or clinical trials that will further the understanding of, for example, a medical condition, a diagnostic process, an educational practice, a behavior, or an intervention. Informed consent in the clinical setting involves clinicians seeking permission to treat patients, who, by consenting, agree to accept risks related to treatment in light of the anticipated benefits they might receive through treatment. Aspects unique to this setting include the existing legal and personal relationships between clinicians and patients. Informed consent in the research setting involves researchers from public or private organizations educating prospective research participants about a proposed study and prospectively seeking their consent to participate. In this context, consenting participants agree to accept risk for the benefit of others and not, generally, for their own benefit. In addition, risks and potential benefits might not be as well defined as they are in the clinical context. Further, in some cases risks might not be physical but rather “informational,” for example, if the research involves use of information obtained about an individual either as data or through analysis of blood or tissue obtained through clinical care.

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In both settings, informed consent refers to the process of informing the patient or participant about the planned procedure or protocol (research plan) and seeking their voluntary consent to proceed before the procedure or research begins.

This module focuses primarily on the informed consent process in the research setting, and does not address consent processes in the clinical or direct-to-consumer settings per se. However, in some studies clinicians and researchers work together or a clinician might be the individual conducting the research (e.g., a physician-scientist).

In research, the informed consent process primarily serves two purposes: to educate individuals about the risks and potential benefits of their possible participation in research, and to establish the voluntary willingness of the individual to participate. The informed consent process, which is outlined by investigators and must be approved by an institutional review board (IRB), can differ depending on the research project. In some situations the necessary information is provided via written documentation, a scripted conversation, or a video. Participants might have the opportunity to ask questions and typically are required to sign a form documenting that they have been fully informed about the research plan, the potential benefits and risks associated with participation, alternatives to the procedure, the right of participants to withdraw from the study at any time, and what level of privacy to expect. The participant might also receive information on the reporting and confidentiality of research results. In general, documentation of informed consent is a crucial piece of the process.

Federal regulations governing informed consent have been codified by the U.S. Department of Health and Human Services in the Code of Federal Regulations at 45 C.F.R. Part 46 (Subpart A of which is often referred to as the Common Rule [see Regulations section]). Informed consent is not required for all types of research; some studies are exempt from this requirement or a waiver of informed consent can be granted by an IRB. For example, research that is strictly observational and some historical studies might not require informed consent of participants. IRBs make this determination during their review and, in addition to determining whether informed consent is required, also have discretion to require additional elements in the informed consent process beyond what is specified in the federal regulations.

III. Learning Objectives

*Students should be able to:*

1. Define and discuss informed consent.

2. Understand the content and purpose of informed consent procedures.

3. Understand the philosophical underpinnings of informed consent.
4. Explain how and why informed consent has developed historically.

5. Identify major informed consent regulations.

6. Explain how the informed consent process should differ among populations of research participants, for example, children or the mentally disabled.

IV. Background

A. Ethical Necessity

Informed consent is not only part of, but is arguably the cornerstone of the conduct of ethical human subjects research. The philosophical basis of informed consent lies in the concept of autonomy and the principle of respect for persons.

The *Belmont Report*, authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the National Commission) in 1978 and intended to serve as a guide for ethical human subjects research, set out three principles for ethical research: respect for persons, beneficence, and justice. Of primary importance to informed consent, respect for persons establishes that all individuals engaging in research should be respected as autonomous decision-makers or, if they are individuals with diminished autonomy, that they are entitled to protection.³ Autonomy refers to the capacity of an individual to make decisions freely. Autonomous decision-making is at the heart of informed consent.

There are three main goals to the informed consent process: to inform the participant of the required information, to document that the participant was informed, and to establish the participant’s voluntary (and autonomous) decision to participate in the research. In clinical research, proper informed consent processes should be sufficiently clear as to avoid what is known as the “therapeutic misconception,” which occurs when participants confuse study participation with the therapeutic benefit that one might expect from medical treatment in a clinical setting.

Another aspect of informed consent that is particularly important in the research setting is the fact that aspects of the research protocol can change in the course of a research project. If, during the course of a study, protocols change or are altered in any way, the changes must be reflected in the informed consent process. IRBs typically review ongoing research on an annual basis, so there is not a burden of additional approval, but changes must be approved in the annual review and implemented from that point forward. It is important that researchers use the proper and most current information regarding the study to be conducted in the informed consent process.

Informed consent also establishes protections against an unequal power relationship between participants and researchers by emphasizing the voluntary nature of participation and ensuring that the participant knows and understands that he or she can withdraw from the study at any time with no penalty or adverse effect. Moreover, the informed consent process serves to foster trust in research among the public by establishing standards of transparency in informing participants and demonstrating respect for participants’ wishes.4

B. Informed Consent with Persons with Diminished Autonomy

Respect for persons and beneficence require that ethically valid consent or its moral equivalent be obtained when those who might have diminished autonomy participate in research, for example prisoners, or children.5 These individuals might not have the capacity to freely and independently make decisions on their own behalf, or in some cases they might have limited cognitive or developmental capacity, and thus might be unable to fully understand the informed consent process or the implications of participating in research. As a result, their agreement to participate might not be considered valid. Vulnerable groups might also include others that are not explicitly mentioned in federal regulations—such as economically or educationally disadvantaged persons—who can be afforded protections and careful consideration through the informed consent process.

Ethical and legal standards for informed consent require that individuals with diminished autonomy be protected.6 An important first step in this process is assessing the capacity of potential participants to consent autonomously to participation. This necessary step precedes the informed consent process when working with populations that could be considered vulnerable (groups in which the individuals are unable to protect fully their own interests) because it determines how the informed consent process must proceed. For example, children have different capacities for autonomy based on their varying developmental stages. The federal regulations outlined in 45 C.F.R. Part 46, Subpart D contain specifications for research involving varying degrees of risk and potential benefit to children. Similarly, the autonomy of prisoners is diminished by their status in the penal system; prisoners have very little control or choice regarding their everyday lives and exist within the constraints of a significant power differential between them and detention officials. Prisoners are susceptible to coercion and their decisions whether to participate in research ought not be influenced by promises of better treatment, reduction of sentence, or other potential gain. Subpart C of the federal regulations stipulates additional considerations when research involves prisoners as participants.

5 Protection of Human Subjects, HHS. 45 C.F.R. Part 46.
6 For more information regarding informed consent with individuals who are mentally disabled, see Wendler, D., and K. Prasad. (2001). Core safeguards for clinical research with adults who are unable to consent. Annals of Internal Medicine, 135(7), 514-523.
The consent process with persons with diminished autonomy still involves both informing individuals of the various aspects of participation in research and obtaining permission for inclusion in research, but also can involve modifications to the process, including the recognition of assent or dissent, obtaining required consent from a legally authorized representative, or modification of the language of consent forms. Assent refers to agreement to participate, expressed verbally or nonverbally, while dissent is a verbal or non-verbal expression of a lack of desire to participate. Assent alone, however, is never an adequate substitute for informed consent. The scope of research that can be ethically conducted with these populations is limited because of the ethical and legal issues related to obtaining consent.

C. History of Informed Consent
The evolution of informed consent practices and regulations in the United States has occurred in tandem with the broader evolution of bioethics and ethical human subjects research. Advances in medicine and technology also have led to changes in research ethics, which continue to evolve as medicine and technology change.

Notable historical cases of research abuse have influenced the development and regulation of informed consent processes. The discovery of unethical research and the resulting public outcry contributed to the institution of informed consent policies in research.

In 1947, a panel of judges at the Nuremberg Medical Tribunal found 16 individuals guilty of abuses that occurred during the Holocaust under the guise of medical research. The trial included testimony addressing “ethical and legal conventions…for human experimentation.” One result of the trials was the 1947 establishment of the Nuremberg Code, which stresses the necessity of informed consent to research.

During the Syphilis Study conducted in Tuskegee, Alabama and sponsored by the U.S. Public Health Service from 1932 until 1972, participants were left untreated for syphilis infections despite the availability of penicillin, so that researchers could observe the natural progression of the disease. Informed consent was not obtained from those who were enrolled in the study. Participants voluntarily elected to be a part of the study but were not informed of the availability of treatment, provided with treatment, or made aware of the risks of lack of treatment.

From 1946 to 1948, the U.S. Public Health Service conducted studies in Guatemala that involved the intentional exposure and infection of research subjects from vulnerable populations with

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sexually transmitted diseases without obtaining informed consent. However, as these experiments were not revealed until decades later, they did not inform the development of federal regulations at the time.

In 1964, the World Medical Association issued the Declaration of Helsinki, which also emphasizes the centrality of informed consent. It has been revised multiple times and continues to serve as the foremost set of international guidelines for research with human participants.

In 1966, medical professional Henry Beecher published an exposé on unethical human subjects research in the New England Journal of Medicine that highlighted a number of studies that did not incorporate informed consent. Beecher’s publication is often cited as a seminal event in the field of bioethics.

The syphilis study in Tuskegee and other reported abuses led to the creation of the National Commission, which was charged with developing the principles that formed the basis of the Common Rule, which is the current set of federal regulations intended to protect research participants through regulating ethical human subjects research.

The following timeline provides a more complete historical picture of developments in U.S. research ethics and informed consent. Future developments in medicine and in bioethics will continue to guide informed consent practices. Developments such as the growing ease of sequencing entire genomes, as discussed in the Bioethics Commission’s report Privacy and Progress in Whole Genome Sequencing, exemplify the kinds of technological advances that necessitate evolving conceptions of informed consent.

**D. Timeline**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1900</td>
<td>Written contracts between researchers and participants are used in the Walter Reed Yellow Fever Experiment, an intentional exposure study of the mechanism of yellow fever transmission. This was the first documented instance of use of the informed consent process in a major research study.</td>
</tr>
<tr>
<td>1932</td>
<td>U.S. Public Health Service Syphilis Study in Tuskegee, Alabama begins.</td>
</tr>
</tbody>
</table>

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1946-1948  U.S. Public Health Service sexually transmitted disease studies are conducted in Guatemala (discovered in 2010).

1947  Nuremberg Code is implemented.\textsuperscript{14}

1962  Kefauver-Harris amendments to the Federal Food, Drug and Cosmetics Act is passed and signed into law in response to the thalidomide tragedy; from this point forward, clinical drug testing requires informed consent.\textsuperscript{15}

1964  *Declaration of Helsinki* is published.\textsuperscript{16}

1966  Henry Beecher’s *New England Journal of Medicine* article, “Ethics and Clinical Research,” is published, identifying 22 cases of unethical research.\textsuperscript{17}

1974  Congress passes the National Research Act, which establishes the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to consider and provide guidance for ethical human subjects research.

1978  National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research publishes the *Belmont Report*.\textsuperscript{18}

1980-1983  President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research publishes reports including *Protecting Human Subjects* (1981), which specifically addresses informed consent.

1981  The Department of Health and Human Services and the Food and Drug Administration regulations are substantially revised in light of the *Belmont Report*.

1982  Council for International Organizations of Medical Sciences publishes *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (revised in 1993 and 2002).\textsuperscript{19}


\textsuperscript{15} Kefauver-Harris Drug Amendments. 21 U.S.C. 301.

\textsuperscript{16} World Medical Association, op cit.

\textsuperscript{17} Beecher, H.K., op cit.

As of 1982, 30 states have implemented informed consent legislation.\textsuperscript{20}

1991 The U.S. Department of Health and Human Services issues the “Federal Policy for the Protection of Human Subjects,” the “Common Rule,” which 18 federal agencies have adopted.\textsuperscript{21}

### E. Federal Law and Regulations

Federal regulations govern research with human participants. As mentioned previously, these regulations are referred to as the Common Rule, and were codified by the U.S. Department of Health and Human Services in 1991 as 45 C.F.R. Part 46, Subpart A.\textsuperscript{22} Eighteen federal agencies have adopted the Common Rule. In addition to the Common Rule, the U.S. Food and Drug Administration, has codified its policy for the Protection of Human Subjects, at 21 C.F.R. Parts 50 and 56, which regulate research involving human subjects in the clinical trials of the products the agency regulates.\textsuperscript{23}

**Figure 1**: Federal Protection of Human Subjects in Research


\textsuperscript{20} Blacksher, E., and J.D. Moreno, op cit.

\textsuperscript{21} Protection of Human Subjects, HHS. 45 C.F.R. Part 46, Subpart A.

\textsuperscript{22} Ibid.

The 18 agencies that have adopted the Common Rule are:

- Agency for International Development
- Central Intelligence Agency
- Consumer Product Safety Commission
- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Homeland Security
- Department of Housing and Urban Development
- Department of Justice
- Department of Transportation
- Department of Veterans Affairs
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation
- Social Security Administration

The Common Rule applies to research involving human participants supported or conducted by these 18 federal departments or agencies. It establishes general requirements for informed consent including, but not limited to, an explanation of the research study, a description of expected benefits and potential risks, an explanation of confidentiality, a description of any available medical care and compensation for research related injury, and a statement of voluntariness specifying that participants can withdraw from the study at any time with no penalty. Some agencies have adopted additional regulations or policies concerning research with pregnant women, human fetuses, neonates, prisoners, and children.

1. State Regulations

In addition to federal regulations, all 50 states have adopted some form of informed consent law, and many have adopted additional regulations as well, but there is wide variation among state laws regarding both clinical and research settings.²⁴

²⁴ For example, “a few states (e.g., Vermont), have enacted patients’ rights laws requiring informed consent and notice when hospital patients are also subjects of human research studies. Others, like Maryland, Oregon, and Minnesota, specify the form and content of the patient authorization required for disclosure of health information.” Hakimian, R., et al. (2004, November). National Cancer Institute Cancer Diagnosis Program: 50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research.
Maryland and Virginia, for example, extend the Common Rule beyond federally funded research to any human subjects research, regardless of funding source. Similarly, New York and California have public health statutes that include a provision requiring informed consent for studies that do not fall under federal regulations.

There is also variation in state regulations in more specific cases, such as the informed consent process when tissue samples or genetic information are generated and stored as part of a research protocol. States also have varied definitions of “genetic information,” leading to differences in how informed consent laws are interpreted.

F. Common Challenges to Implementation of Informed Consent

1. Information Provided and Comprehension

One of the challenging aspects of the informed consent process is ensuring that the information provided to potential participants is both comprehensive and clear enough for the reader to understand fully. Researchers must be mindful both of the ethical imperative of informed consent, and of the applicable regulations and laws that enforce the ethical requirements.

Additionally, different research protocols and populations of research participants can necessitate alternate processes and the inclusion of additional information. For example, content might need to be translated into another language or written for a lower-literacy audience. Forms might need to include in-depth information about obtaining tissue samples, risky procedures, or specifically include information pertaining to alternative treatments. The informed consent process must provide enough information for research participants to understand the proposed study and its risks and potential benefits without overwhelming them with cumbersome or overly technical information. To be effective, informed consent documents must strike a balance between too much information and too little information.

There are several possible options for the delivery of information in the informed consent process, as described above. Regardless of the mechanism chosen, some participants will comprehend the information better than others.


26 Ibid.


2. Undue Inducement
The informed consent process must ensure that participation is voluntary and protect against undue inducement. Undue inducement refers to ways that the researcher might influence potential participants’ decisions about taking part in the study.\(^{30}\) Undue inducement diminishes voluntariness. Examples include excessive monetary payment, feelings of obligation to a researcher, or other influential power dynamics; influential factors can vary from community to community.

3. Incidental and Secondary Findings
Traditionally, incidental findings have been defined as results that arise that are outside the original purpose for which the test or procedure was conducted.\(^{31}\) The Bioethics Commission further specifies the term “incidental finding” to include two categories: incidental findings that are “anticipatable” and those that are “unanticipatable.” An anticipatable incidental finding is one that is known to be associated with a test or procedure, and an unanticipatable incidental finding is one that could not have been anticipated given the current state of scientific knowledge.\(^{32}\)

A secondary finding is a finding that is not the primary target of the test or procedure, but that is actively sought by a practitioner. For example, a clinician who conducts large-scale genetic sequencing to diagnose a patient’s disease might deliberately seek other variants underlying other traits.\(^{33}\) Since anticipatable and unanticipatable incidental findings and secondary findings are beyond the scope of the procedure or study, ethical questions focus on when it might be acceptable or necessary to report incidental findings to a research participant.

When it is applicable to their investigation, researchers should anticipate that incidental findings are a possibility, and “convey to participants the scope of potential incidental or secondary findings, whether such findings will be disclosed, the process for disclosing these findings, and whether and how participants might opt out of receiving certain types of findings.”\(^{34}\) This will alert participants to the potential for discovering incidental findings and indicate whether or not those findings will be shared with them.

V. Discussion Questions
The following questions are based on the information provided in the “Background” section above and are intended to reinforce important aspects of the informed consent process and


\(^{33}\) PCSBI. (2013, December). op cit, p. 28.

\(^{34}\) PCSBI, (2013, December), op cit, p. 87.
regulations that govern that process. Important points are noted with each question to help the instructor guide a group discussion. The “Additional Resources” section will be helpful in answering these questions.

1. **Why is informed consent referred to as a “process” and more than “just reading and signing a form?”**

Starting points for discussion:

   a. Informed consent includes the process of informing and educating the potential participants about the research on an ongoing basis.

   b. This language comes from the Office for Human Research Protections, the federal agency with regulatory oversight over a majority of federally funded research.

   c. Informed consent is an ethical and legal obligation, not just a method for dispensing information.

   d. Additionally, regarding informed consent as a process reminds investigators of the complex issues that might arise and how changes to research protocols might require changes to the informed consent process.

2. **The requirements of the informed consent process are summarized as part of the Common Rule at 45 C.F.R. § 46.116, “General Requirements for Informed Consent.” Discuss the rationale for including: purpose of the research, a description of risks and potential benefits, a description of confidentiality, compensation for injury, and freedom to withdraw from the study.**

Starting points for discussion:

   a. *Explanation of the purposes of the research:* A prospective participant should understand what a researcher is trying to learn in order to make a personal assessment of the merits of the research.

   b. *Description of risk and potential benefits:*

      i. Prospective participants have a choice whether to engage in research that might carry some risk. In order for the decision to be truly autonomous, the choice must be fully informed.

      ii. Research risks can be considered alongside potential benefits (to others or to self).

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c. **Description of confidentiality:** The level of confidentiality that the participant can expect must be made clear. If confidentiality is not assured, participants must consider this fact along with risks and benefits.

d. **Compensation for injury:** Whether compensation is provided might affect a participant’s assessment of risk.

e. **Freedom to withdraw from study:** Understand that once involved, participants are not obligated to continue. In most cases, participants are free to remove themselves from a study at any point in time with no penalty or loss of benefits.

3. **Discuss what events might have had the most impact on the development of informed consent policies.**

   Starting points for discussion:

   a. This discussion will depend on students’ points of view. Students may have interest in exploring the opinions of historians in the field.

   b. Some might point to public outcry over events like the Syphilis Study in Tuskegee, Alabama as the major impetus for action, while others might point to legal or regulatory actions; and still others might argue that a combination of public awareness and public action fostered the creation of new ethical standards.

**VI. Exercises**

**Exercise A.** Access Protection of Human Subjects. 45 C.F.R. Part 46 on the Internet and answer the following questions. [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (last accessed on Sept. 3, 2013)].

1. **How do the regulations for obtaining informed consent differ when children are involved?**

   a. To conduct research with children, researchers must generally obtain the permission of parents or guardians and children’s meaningful assent. See 45 C.F.R. § 46.408 of the regulations.

2. **How and in what situations must consent be physically documented?**

   a. Informed consent must be physically documented, unless waived by an IRB; a copy of the consent form should be given to the person signing the form. Consent
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Informed consent should be documented in a written document or a short form indicating informed consent has occurred orally. See 45 C.F.R. § 46.117 of the regulations.

3. What resources can you find for researchers engaging in projects that involve informed consent?

   a. Try to find resources from public and private institutions, such as: guides to writing informed consent documents and procedures, and guides for submitting informed consent documents to an IRB.

   b. Students can access educational materials from academic institutions, government bodies, or private institutions that provide guidance to researchers. Students should try searching for “IRB,” “informed consent,” and the name of a local research hospital or biomedical company.

   **Exercise B.** *Use the Internet to learn more about the specific informed consent requirements at your academic institution.*

1. How does your institution compare to others in terms of informed consent requirements?

**VII. Glossary of Terms**

**Anticipatable incidental finding:** A finding that is known to be associated with a test or procedure. Anticipatable incidental findings need not be common or likely to occur; rather, the possibility of finding them is known.

**Autonomy:** The capacity to direct the course of one’s own life or to live according to one’s own values and beliefs.

**Common Rule:** Current federal regulations that protect research participants, codified by the U.S. Department of Health and Human Services in the Code of Federal Regulations at 45 C.F.R. Part 46, Subpart A. Also known as “Human Subjects Regulations.”

**Confidentiality:** A set of rules or a promise to restrict access to certain information.

**Informed consent:** The process of informing and obtaining permission from an individual before conducting medical or research procedures or tests.

   In the clinical setting, this involves clinicians seeking permission to treat patients who, by consenting, agree to accept risk in anticipation of potential benefit to themselves through treatment.
In the research setting, this involves researchers educating prospective research participants about the risks and potential benefits of a proposed study and prospectively seeking their consent to participate.

In the direct-to-consumer setting, this involves practitioners of direct-to-consumer testing providing consumers with sufficient information about their services to enable consumers to make informed decisions about purchasing their product.

**Institutional review board (IRB):** A specially constituted review body established or designated by an entity to protect the welfare of individuals recruited to participate in biomedical or behavioral research. The duties and responsibilities of IRBs are described in the federal regulations.

**Protocol:** A plan for the conduct of a research project, including all aspects of the project from recruitment to obtaining informed consent to dissemination of results.

**Secondary finding:** A finding that is actively sought by the practitioner but is not the primary target of the test being conducted.

**Unanticipatable incidental finding:** A finding that could not have been anticipated given the current state of scientific knowledge.

**VIII. Additional Resources**


