SPAR “Changing the Narrative”

Institutional Review Board (IRB) Process

Presenter:
Dr. Jonathan Smalls, AVP of SPAR

IRB

- Brief History of IRB?
- What is an IRB?
- Who serves on IRB?
- IRB Protocols
- Completing an IRB Application

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IRB HISTORY

The history of Institutional Review Boards (IRBs) can be traced back to significant events and concerns in research ethics that emerged in the mid-20th century:

- **Nuremberg Code** (1947): The Nuremberg Code was established in response to the atrocities committed by Nazi physicians during World War II. It outlined principles for ethical medical research involving human subjects and emphasized voluntary informed consent, avoidance of unnecessary suffering, and scientific justification for research.
- **Tuskegee Syphilis Study** (1932-1972): The Tuskegee Syphilis Study, conducted by the U.S. Public Health Service, involved the unethical withholding of treatment from African American men with syphilis. The study raised awareness about the need for ethical oversight in research involving human subjects.
- **Declaration of Helsinki** (1964): The Declaration of Helsinki, adopted by the World Medical Association, provided ethical guidelines for medical research involving human subjects. It emphasized principles such as voluntary informed consent, beneficence, and respect for individuals.

In response to these events and growing concerns about the ethical conduct of research involving human subjects, the U.S. government implemented regulations to protect research participants:

- **Common Rule** (1981): The Common Rule, also known as the Federal Policy for the Protection of Human Subjects, was established to ensure consistency in the protection of human subjects across federally funded research. It requires institutions to establish IRBs to review and oversee research involving human subjects.

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IRB DEFINITION

IRB stands for Institutional Review Board. An IRB is a committee that is formally designated to review and monitor research involving human subjects. Its primary purpose is to ensure that the rights, safety, and well-being of human participants are protected in research studies. IRBs are typically composed of a diverse group of individuals, including scientists, ethicists, and community members, who evaluate research proposals to ensure that they adhere to ethical standards and regulatory requirements. Researchers must submit their study protocols to the IRB for review and approval before they can begin their research involving human subjects.

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IRB COMMITTEE

Scientists/Researchers: Individuals with expertise in various fields of research, such as medicine, psychology, sociology, biology, or other relevant disciplines.

Ethicists: Professionals with training in ethics, bioethics, or philosophy.

Community Members: Laypersons from the local community who represent the interests of the public.

Legal Experts: Individuals with expertise in relevant laws and regulations, such as healthcare law or research compliance.

Medical Professionals: Physicians or healthcare professionals who can provide expertise on medical procedures, participant safety, and medical ethics.

Statisticians/Data Experts: Professionals with expertise in statistics or data analysis who can evaluate the methodological and statistical aspects of research protocols.

IRB Administrators: Staff members responsible for the administrative management of the IRB, including protocol submission, review coordination, and documentation.

Non-Scientific Members: Individuals who do not have a scientific or medical background but provide valuable perspectives on the ethical and social implications of research.

Vulnerable Population Advocates: Advocates or representatives for vulnerable populations, such as children, elderly individuals, or individuals with disabilities.

Subject Matter Experts: Experts in specific areas of research or populations, such as oncology, pediatrics, mental health, or genetics.

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The Institutional Review Board (IRB) process typically involves several steps:

1. **Protocol Submission**: Researchers submit their research protocol to the IRB for review. The protocol includes detailed information about the study design, methodology, recruitment procedures, informed consent process, and measures to protect the rights and welfare of human participants.
2. **Initial Review**: The IRB conducts an initial review of the protocol to assess its compliance with ethical principles and regulatory requirements. This review evaluates the risks and benefits of the study, the adequacy of the informed consent process, the qualifications of the investigators, and the protections for vulnerable populations.
3. **Revisions**: If the IRB identifies any concerns or deficiencies in the protocol, the researchers may be required to revise their submission and address the IRB's feedback.
4. **Approval**: Once the IRB is satisfied that the protocol meets ethical and regulatory standards, it grants approval for the research to proceed. This approval may be contingent on certain conditions or requirements that the researchers must fulfill.
5. **Ongoing Monitoring**: Throughout the duration of the study, the IRB monitors the research to ensure continued compliance with ethical and regulatory standards. Researchers are required to report any adverse events or protocol deviations to the IRB, and the IRB may conduct periodic reviews of the study to assess its progress and safety.
6. **Continuing Review**: Research protocols approved by the IRB are typically subject to periodic review to ensure that they remain in compliance with ethical and regulatory requirements. Researchers must submit progress reports to the IRB at specified intervals, and the IRB may conduct continuing reviews to evaluate the ongoing conduct of the study and any changes to the protocol.
7. **Closure**: Once the research study is completed, the researchers must notify the IRB and submit a final report detailing the outcomes of the study and any significant findings. The IRB then closes the protocol and concludes its oversight of the research.

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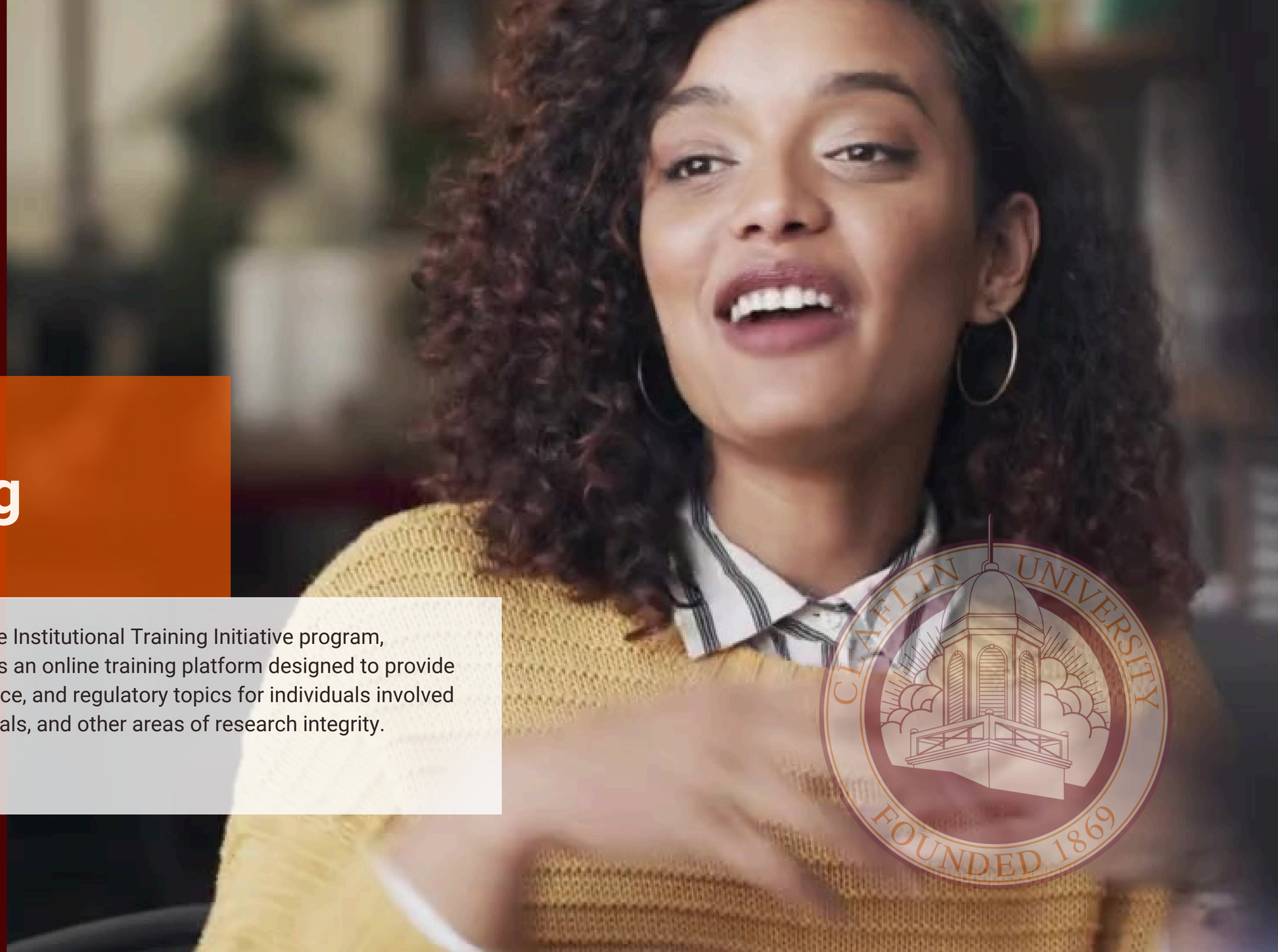
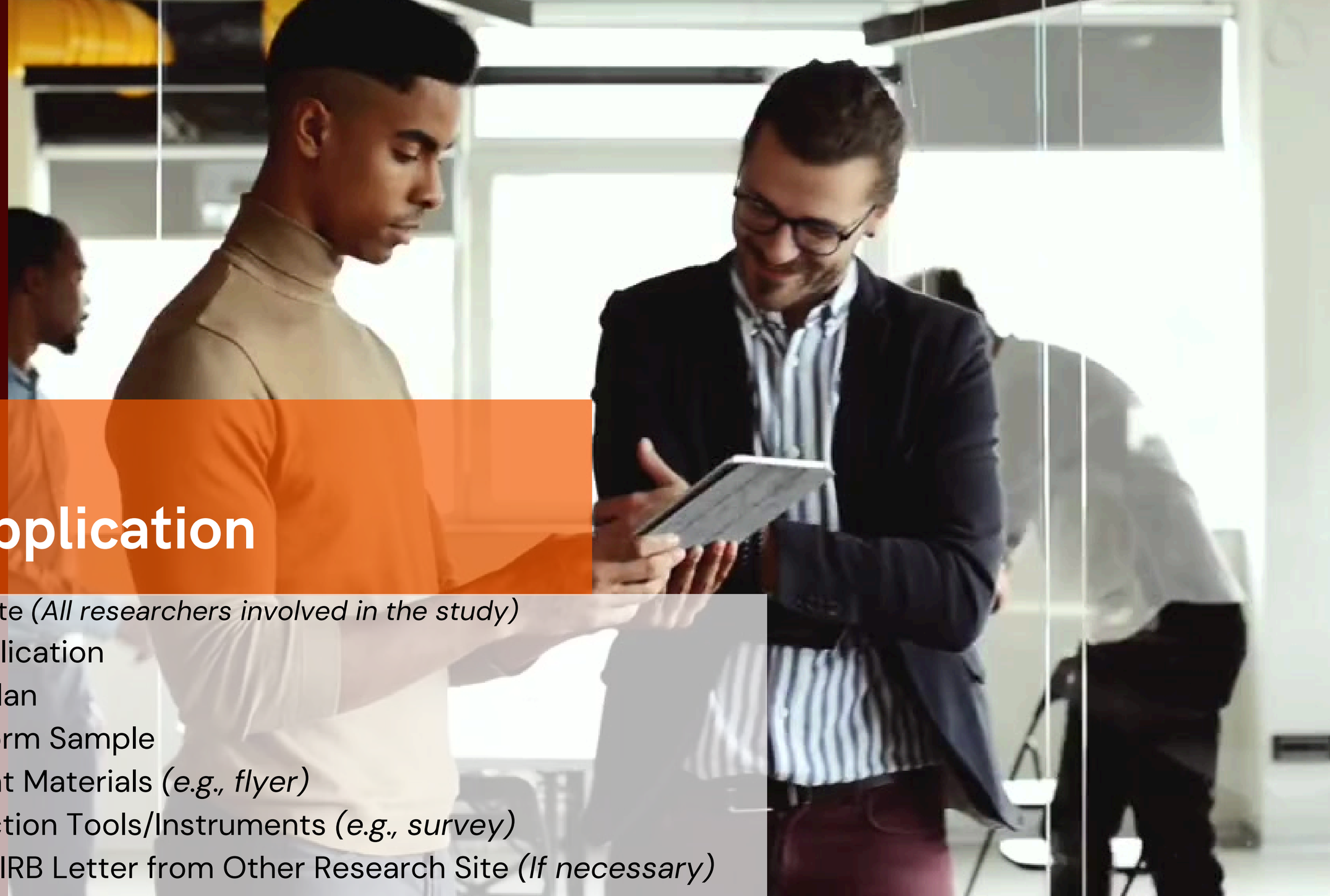
CITI Training

CITI Training refers to the Collaborative Institutional Training Initiative program, commonly known as CITI Program. It is an online training platform designed to provide education in research ethics, compliance, and regulatory topics for individuals involved in research with human subjects, animals, and other areas of research integrity.





IRB Application

- CITI Certificate *(All researchers involved in the study)*
- CU IRB Application
- Research Plan
- Consent Form Sample
- Recruitment Materials *(e.g., flyer)*
- Data Collection Tools/Instruments *(e.g., survey)*
- Provisional IRB Letter from Other Research Site *(If necessary)*

IRB

REVIEW OF THE APPLICATION

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IRB DECISION CATEGORIES

Exempt: Research projects that pose minimal risk to participants and meet specific criteria outlined in federal regulations may be eligible for exempt status. Exempt research typically involves minimal interaction with participants and minimal privacy or confidentiality risks. Examples include anonymous surveys, educational tests, and certain types of secondary data analysis.

Expedited: Research projects that involve minimal risk but do not qualify for exempt status may be eligible for expedited review. The expedited review allows for a quicker approval process compared to a full board review. Examples of research eligible for expedited review include certain types of surveys, interviews, and observational studies.

Full Board Review: Research projects that involve more than minimal risk to participants or raise complex ethical issues typically require full board review by the IRB. This review involves the entire IRB committee and may require multiple meetings to assess the protocol, discuss ethical concerns, and determine whether the research meets regulatory requirements. Examples of research that may require full board review include clinical trials, studies involving vulnerable populations, and research with greater potential for physical or psychological harm.

Conditional Approval: In some cases, the IRB may grant conditional approval to a research protocol, subject to certain conditions or modifications. Researchers must address these conditions before final approval is granted and the study can proceed.

Deferred Approval: If the IRB determines that additional information or revisions are needed before a decision can be made, they may defer approval of the research protocol until these issues are addressed. The researchers must address the IRB's concerns and resubmit the protocol for further review.

Not Approved: If the IRB determines that the research protocol does not meet ethical or regulatory standards or poses unacceptable risks to participants, they may withhold approval for the study to proceed. Researchers may have the opportunity to revise and resubmit the protocol for further review, or they may need to abandon the study altogether.

Not Research: Focus groups, surveys or interviews with faculty or students intended only to evaluate and improve program(s) or service(s) provided by the institution or to assess its needs and does not result in publication or submitting the results to granting agency for funding.

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BURNING QUESTIONS

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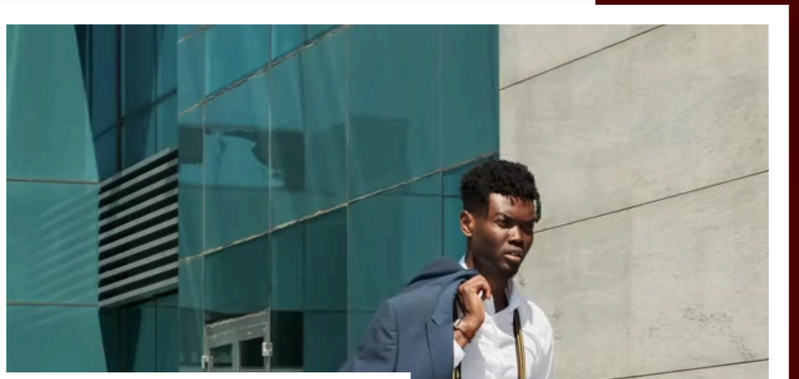

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