Institutional Research Board

PROCEDURES FOR CONDUCTING RESEARCH

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Introduction

The Palm Beach State College (PBSC) Institutional Review Board (IRB) is charged with the responsibility to review and subsequently oversee research activities associated with PBSC. College personnel and outside researchers all must be aware of and comply with the ethical framework and regulatory requirements of the federal government and the College.

Research is defined, by Title 45 Public Welfare, U.S. Department of Health and Human Services (HHS), Part 46 Protection of Human Subjects (more commonly referred to as 45 CFR 46), as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (p.4). An IRB not only plays an important role by protecting participants but also in creating an opportunity for original research to be conducted and generate new information to add to the empirical literature on any range of topics.

Individuals should in all aspects of their research/study:

- demonstrate integrity and professionalism
- observe fairness and equity
- avoid conflicts of interests
- ensure the safety of those associated with the research/study

History of Research and Ethics

The Nuremberg Code, which was created in1947 by the Nuremberg Military Tribunal as standards with which to judge the Nazis experiments conducted on humans, is often viewed as the first modern document addressing protections of human participants in research (45 CFR 46). The Code continues to be referenced in subsequent documents as basic standards to guide ethical research with humans. In 1964, the Declaration of Helsinki produced similar standards by the World Medical Association (45 CFR 46). One of the most infamous experiments that occurred on US soil leading to the creation of IRBs was the Tuskegee Syphilis Study. The study enrolled 600 black men. The men were not informed of the exact nature of the study only that they would be treated for "bad blood" (Centers for Disease Control and Prevention, 2011, para. 2).

When the study began in 1932, there was no known cure for syphilis. However, in 1947, when penicillin was an accepted treatment for the illness, the medication was withheld from the men. They remained infected and infected their families, regardless that a viable treatment was readily available. The quest for scientific knowledge was placed above the consideration for the human lives that were and would continue to be lost until the study was shut down in the 1970's. While the subjects volunteered for the study, they were not provided the required information to genuinely consent to participate in the study

(National Public Radio, 2002). Because unethical research, like Tuskegee, was publicly criticized, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed. In 1979, they created the, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" or more commonly referred to as the Belmont Report (45 CFR 46).

The Belmont Report

The Belmont Report (1979) covers three main topics: Boundaries between Practice and Research, Basic Ethical Principles, and Applications. The first section, Boundaries between Practice and Research, explains the difference between research and treatment. Treatment is initiated for the sole purpose of enhancing the wellbeing of the client, whereas research tests a hypothesis, draws conclusions, and adds to generalizable knowledge. By drawing this distinction, it becomes clear which activities require review for the protection of research participants.

The second section of the Belmont Report (1979), Basic Ethical Principles, covers three tenets: Respect for Persons, Beneficence, and Justice. The first tenet, Respect for Persons, espouses a two-fold belief that individuals are "autonomous agents" and "persons with diminished autonomy are entitled to protection" (p.4). In other words, individuals need to enter into research on a voluntary basis, and research involving those who cannot traditionally consent to participate require additional scrutiny and protections. The second principle, Beneficence, focuses on two main points: "(1) do not harm and (2) maximize possible benefits and minimize possible harms" (p. 5). The first piece of this is clear. Individuals are not to be harmed. The second half requires researchers and reviewers of research to weigh and balance the opportunities for benefits, for the participants and society generally, and also the potential for risks. The last section of the Ethical Principles section, Justice, asks the question, "Who ought to receive the benefits of research and bear its burdens?" (p.5). Previously during the 19th and early 20th centuries, the poor, who were confined to wards, often served as research subjects. By contrast, private citizens were the ones to benefit from the research. This was an unjust practice.

The final section, Applications, covers three topics: Informed Consent, Assessment of Risks and Benefits, and Selection of Subjects. Informed consent looks to ensure that individuals are provided with the comprehensive information about the study, that they understand the information, and they are consenting voluntarily to participate in the research. Assessment of Risks and Benefits requires a systematic investigation that the research risks are justified by the potential benefits. The "risks must be 'balanced' and shown to be 'in a favorable ratio'" (p.8). Finally, Selection of Subjects looks to prevent injustices in the choice of participants based on things including but not limited to race, sex, socioeconomic status and other cultural biases. This is to ensure society is sharing both the benefits and risks associated with research (Belmont Report, 1979).

It is difficult to fathom returning to such an archaic time in which research was unregulated to ensure the ethical treatment of participants. Today, an IRB's main job is to protect research participants' rights and well-being through drawing on the tenets of the

Belmont Report (APA, 2009). They are composed of at least five members including at least one scientist (an individual who is well-versed in areas of research that will be reviewed, e.g. a math professor), at least one non-scientist (an individual who is not well-versed in areas of research that will be reviewed, e.g. a student life employee), and at least one member who is not affiliated with the institution (e.g. a member of the surrounding community who is not employed by the College) (HHS, n.d.). Board members are additionally required by PBSC to possess a working knowledge of 45 CFR 46. All records associated with the IRB, including its communications, meeting minutes, and decisions will be housed in the Department of Institutional Research & Effectiveness under the supervision of the IRB Chair.

Terms and Procedures

The terms and procedures section details relevant terminology, definitions, and the procedures for obtaining IRB approval, exemption, continuing approval, or termination of a study.

The IRB

The purpose of an IRB is to ensure research involving human participants complies with ethical guidelines. Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects (more commonly referred to as 45 CFR 46 or The Common Rule) is the federal policy that grants permission and guides the creation and implementation of IRBs. The regulations are based upon the principles detailed in the Belmont Report. Researchers must submit an overview of their study for IRB review and approval or exemption prior to engaging in research at PBSC.

Research that falls within this policy must meet the three main characteristics of human participants research. They include: (1) the study involves people or information about people; (2) it is an orderly exploration and gathering of information; and (3) it will be shared with an audience outside of PBSC.

Many classroom assessments do not constitute research because they only fulfill the first two parts of the definition of human participants research, but do not contribute to the literature via publication or generalizable knowledge via presentation at a conference. For example, professor evaluations are not considered human participants research. However, anyone, who plans ultimately to publish or present data about people at PBSC that is gathered at or from PBSC needs to seek IRB approval first.

Types of IRB Review

There are three types of IRB review: Exempt, Expedited, and Full Board Review. A brief overview of each, with examples, is provided below.

Exempt Review

Exempt review is appropriate for research involving low or very minimal risk in which participants cannot be identified. Studies that fit into the exempt category need to be submitted for IRB review. The IRB can officially determine if the research is exempt. The researcher cannot. A certificate of exemption will be issued to the researcher by the IRB. The six categories of exemption can be viewed within 45 CFR 46.

Examples of exempt research include anonymous surveys, an investigation in publicly observable behavior without the collection of identifying information, or the analysis of previously collected, de-identified data.

Expedited Review

Expedited review is appropriate for research involving no more than minimal risk and if the true identities of participants were exposed it would not harm them in a criminal, civil or stigmatizing manner. The nine categories of expedited review can be viewed on the OHRP Categories of Research website.

Examples of expedited research include maintaining records of the personally identifiable information of participants (i.e. real names, email addresses), multiple interviews conducted over a period of time with follow-up meetings, or studies that include a signed informed consent form.

Full Board Review

Full board research includes research involving more than minimal risk and may include participants from a vulnerable population. Vulnerable populations include, "children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons" [45 CFR 46, §46.111(a)(3)].

Examples of full board research include the following when the participants are identifiable: interviews with faculty about their perceptions of administration, surveys for students actively using illicit substances, or a study focusing on individuals who live with chronic and persistent mental health issues.

Unsure of Review Type

If you are still unsure which category of review is appropriate for your research, you may contact the IRB or choose the "unsure" option on the IRB Protocol form.

Researcher Training

As of September 2018, the National Institute of Health (NIH) is no longer offering its Protecting Human Research Participants course.

All individuals who wish to conduct research at PBSC or are interested in Board membership must have certification or have completed Ethics and Human Subjects Protection training. The following organizations all provide training:

Protecting Human Research Participants Online Training
The first organization offering training is Protecting Human Research Participants (PHRP) Online Training. PHRP Online Training offers an affordable, high quality, interactive online course to meet requirements for education in the protection of human research. Protecting Human Research Participants Online Training is available for $39.99 USD for all individual learners. There website is https://phrptraining.com/#!/.

The Association of Clinical Research

The Association of Clinical Research also offers a course with or without contact hours. If you take the course without contact hours, it is offered with a certificate at no cost to you. While open to all, this is an organization with a clinical perspective that may influence course design. There website is https://acrpnet.org/courses/ethics-human-subject-protection/.

CITI Program

A third organization is the CITI Program. CITI Program's human subjects research training fulfills the requirements if the learner completes the basic modules for either the Biomedical (Biomed) or Social-Behavioral-Educational (SBE) track. Check the website for costs.

PBSC Sponsors

Certain individuals require a Sponsor in order to conduct research at PBSC (see Outside Researchers and Students as Researchers sections). The Sponsor must be employed full-time at PBSC in a supervisory or faculty role at the college. They must also be both agreeable and qualified to oversee the research process. Examples of Sponsors include but are not limited to Vice Presidents, Deans, Directors, Managers, and Faculty members.

Outside Researchers

Individuals who are not full-time employees at PBSC and want to conduct a study at PBSC are considered outside researchers. These individuals must secure a Sponsor for their research in order for their protocol to be reviewed by the IRB (see Section 1 of the IRB Protocol Application).

Additionally, if outside researchers are affiliated with another institution for the purposes of the research, they need to secure approval from their "home" institution IRB prior to submitting a protocol to the PBSC IRB.

PBSC Student Researchers

Any PBSC students who wish to conduct research must have a Sponsor. The Sponsor must be secured prior to review of the student's protocol and the Sponsor's information must be included in Section 1 of the IRB Protocol Application.

Class Assignments

Generally, class assignments do not meet the federal definition of research. The purpose of research focused class assignments are to teach students research methods or to assist in the acquisition of course concepts through experiential learning. Research focused class assignments are conducted to meet the requirements of a course typically within one semester. They are not systematic investigations that generate new knowledge, and they

pose little to no risk to participants. These types of class assignments therefore may not require an IRB application. However, faculty who require students to complete research focused class assignments are responsible for the oversight of such projects and to ensure that little to no risk is posed to those who participate in the activities.

Additionally, if a student class assignment is a systematic investigation that will add to generalizable knowledge or it involves high risk activities (i.e. asking questions about drug or sexual activity) or a vulnerable population (i.e. minors), it does require IRB review.

Informed Consent

The informed consent process is salient to conducting ethical research. Informed consent indicates that the participants have been educated about the risks and benefits of participating in the study, that they understand their participation is voluntary, that they can withdraw from the study at any time, and that they agree to take part in the research. The consent process must meet the minimum requirements as detailed in 45 CFR 46.116.

Informed consent forms may include a signature; however, in some cases this requirement may be waived. Per 45 CFR 46.117(c), the research must meet one of the following two criteria in order to forego the signature on an informed consent form:

> (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
> (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Whether participants sign the informed consent form or not, a consent procedure is required of all projects at PBSC. The consent procedure may consist of a consent form with the participant's signature or a consent statement may be read to participants or participants may be provided with a hard copy of the consent statement depending on which might be feasible for the study protocol. Both the consent form and consent statement require the same types of information. The only difference is the inclusion or foregoing of the signature. See the sample informed consent form in this packet for an example.

IRB Decisions

Once protocols are received by the IRB, they will be formally categorized for the type of review. Per 45 CFR 46.110(b), a review of expedited research:

> … may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.

The same procedure will be followed for exempt review. However, full board reviews will be conducted monthly as needed during the Fall and Spring semesters only.

For all types of review, once a decision has been rendered which may include exemption, approval, approval with modifications, tabled, or disapproval, the primary investigator will be notified in writing of the decision and appropriate next steps to take. A brief overview of each type of IRB decision is as follows:

> *Exempt*: The study has been determined by the IRB to be exempt from additional IRB review. Once a study has been deemed exempt, research may commence. Exempt status does not expire. However, if a researcher makes any changes to the protocol, a new application for review must be submitted to the IRB.
>
> *Approval*: Expedited or full board review may result in an approval decision. Studies are typically approved for one year at a time. Once a study is approved, the research may begin.
>
> *Approval with modifications*: Expedited or full board review may result in an approval with modifications decision. In these cases, the researcher must make any modifications requested by the IRB prior to commencement of the research. If the researchers believe the modifications cannot be made, they may provide the IRB with additional information. Again, the researchers need to receive approval prior to beginning the research. The research is typically approved for one year at a time.
>
> *Tabled*: A full board review may result in a tabled decision. If the committee members do not believe they have sufficient information in order to reach a final decision, they will table the protocol. The IRB Chair will request additional information from the researcher. In some cases the primary investigator may be invited to the next IRB meeting in order to provide additional information and answer committee members' questions.
>
> *Disapproval*: A full board review may result in a disapproval decision. The researcher will be notified in writing of the decision and the committee's reason for the decision. Per 45 CFR 46.109(d) the researcher has the opportunity to respond to this in writing (see Appeals section).

The committee does not assess the methodological rigor of a study; rather it concentrates on the health and well-being of the participants. The committee's decisions are made focusing on the rights of the participants and considering the potential risks of the research. The committee also considers the potential benefits of the study, and the

potential participant fatigue caused by a population being over studied. Pursuant to 45 CFR 46, although the IRB committee is housed within PBSC, it reports to the federal government. IRB decisions cannot be overruled by any other entity.

Appeals

A researcher, whose research has been denied, has the right to appeal the IRB's decision. A researcher who wants to appeal needs to submit a letter explaining the justification for the appeal and provide any additional information to address the IRB's concerns. However, the IRB has the final authority on the type of research that may or may not be conducted.

Amendment

Once a protocol has been approved, no modifications may be made without additional approval by the IRB. An amendment must be submitted to the IRB via email and approved prior to implementation of any deviations in the originally approved or exempted study procedures.

Adverse Events

Adverse events are any abnormal or unfavorable reactions in participants during their participation in the study, even if seemingly unrelated to the research, or the discovery of additional risks to participants. Some examples include unanticipated issues with the research protocol, threats to confidentiality, or participant injury requiring medical or psychological treatment. These events must be reported to the IRB Chair as soon as possible, once they are discovered. Further guidance about unanticipated problems and adverse events is available on the OHRP website.

Once the IRB Chair has been alerted of an adverse event, the Chair may suspend the research while the IRB is consulted and the risks to participants are considered. If a research study is suspended, the IRB will alert the researcher of the steps needed to resume research. The IRB may also terminate the approval and the research would need to be permanently halted. In all of these cases, a formal report will be created by the IRB Chair and provided to all IRB members and the Head Official of record who is responsible for overseeing IRB activities.

Continuing Review

Research is approved for no more than one year at a time. If the research is not complete, a researcher must earn approval to continue the study annually prior to the study's expiration. If a study's approval expires, the research must stop until approval is again granted. This could mean the researcher needs to complete the entire review process again.

In order to avoid a study's approval expiring, researchers must email the IRB Chair with an update 30 days prior to the expiration explaining: (1) which phase the study is in (2) the number of individuals who have participated in or are currently active participants in the study (3) any adverse events or that no adverse events have occurred. The IRB's decision on the continuation of the research will be provided to the researcher in writing.

Closing Report

When researchers are ready to terminate their study, they must complete a closing report via email. A study is typically ready to be terminated when researchers are no longer collecting data or handling personally identifiable data. Please note, if a master code list linking participants' real names to their data exists, even if the researcher is only analyzing the data, a study may not be terminated.

Within 30 days of the conclusion of the study, an email that serves as the closing report must be sent to the IRB Chair detailing: (1) the number of individuals who participated in the study (2) any adverse events or that no adverse events occurred (3) a brief summary of the student results (4) a statement certifying that the study is complete.

Checklist

Researchers need to complete the following requirements:

1. _____ Receive approval by your "home" IRB (only applicable if the researcher's "home" institution is not PBSC)

2. _____ Complete the NIH Protecting Human Research Participants training

3. _____ Submit in one email to irb@palmbeachstate.edu the following items:

    - PBSC IRB Protocol Application (*required of all researchers*)
    - Certificate of Completion of the NIH training (*required of all researchers*)
    - Other study supplemental materials (as applicable):
        - Consent/Assent forms or statements
        - Copy of other IRB approval letters
        - Data collection instruments
        - Recruitment materials
        - Other supplemental materials

4. _____ Wait for the PBSC IRB's decision before conducting the research

Sample Informed Consent Template

Title of Research Study:

List the title of the study in this section.

Purpose of the Research:

This section should answer why the research is being conducted and the study's purpose should be briefly described in layperson terms.

Study Procedure:

This section should answer what will happen in this study. It should include a description of the procedures, the length of time the participant will be involved, identification of any experimental procedures, how many people will participate in the study overall, and any locations in which the study is occurring.

Risks and Benefits Associated with the Study:

This section must describe any foreseeable risks, discomforts, direct, and indirect benefits to participants if they choose to participate in the study.

Confidentiality:

This section should describe the ways in which the researcher will maintain the confidentiality of the data and protect participants identifying information, if this is being collected. It should also describe who will have access to the data and under what circumstances.

Voluntary Participation:

This section needs to include a statement that the participant's participation in the research is voluntary and that the participant may withdraw from the study at any time without penalty.

Contact Information:

This section should detail who the participant can contact if they have additional questions or concerns about their rights or if they incur a research related injury. Therefore it needs to include the PI's contact information, as well as, the PI's supervisor or chair contact information if appropriate.

This section should include the following statement if PBSC is the researcher's "home" institution "Please contact Palm Beach State College's IRB if you have questions,

complaints or concerns regarding your rights as a research participant. The IRB can be reached by phone at (561)868- or by email irb@palmbeachstate.edu."

If the researcher has another institution as their "home institution," a similar statement directing participants to the "home" institution IRB needs to be included.

Statement of Consent:

I have read this information or it has been read to me. All of my questions have been answered about the study and I have received a copy of this consent form. I understand that by signing this form I am voluntarily agreeing to participate in this study.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Signature of Participant Authorizing Audio/Video Recording (if applicable)

_____
Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

Frequently Asked Questions

When does the IRB meet?

The IRB convenes monthly as needed during the Fall and Spring semesters to review protocols. During the Summer semester, select IRB members review exempt and expedited protocols, but no full board reviews are conducted. Please plan accordingly.

What if my research is exempt? Do I need to submit a protocol to the IRB?

Yes. While researchers are requested to categorize the type of review they believe is appropriate for their research, ultimately the IRB determines the type of review. As noted previously, IRBs can determine and provide an exemption for a study, not researchers.

How do I receive a letter of cooperation from PBSC for my university?

If the research being conducted is a dissertation or thesis at another institution and you need a letter of cooperation, you must first submit a brief description of the research procedures as they pertain to human participants and provide the name of the PBSC sponsor (see PBSC Sponsors section in this document for more information).

Who should I contact if I have additional questions?

You can email PBSC's IRB if you have additional questions irb@palmbeachstate.edu

References and Additional Resources

American Psychological Association (2009). The institutional review board (IRB): A community college planning guide. Retrieved from: http://www.lakemichigancollege.edu/Default.aspx?DN=3bc70785-8efa-4bf9-8c3d-952b5d1c81d5

Centers for Disease Control and Prevention. (2011, June 15). U.S. public health service syphilis study at Tuskegee: The Tuskegee timeline. Retrieved from: http://www.cdc.gov/tuskegee/timeline.htm

Department of Health, Education, and Welfare. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Washington, DC: OPRR Reports. Retrieved from: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

HHS Protection of Human Subjects, 45 C.F.R. 46 (2009).Retrieved from: http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf

National Public Radio. (2002, July 25). Remembering Tuskegee: Syphilis study still provokes disbelief, sadness. Retrieved from: http://www.npr.org/programs/morning/features/2002/jul/tuskegee/

Office for Human Research Protections. (1993). *IRB Guidebook*. Retrieved from: http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

U.S. Department of Health & Human Services. (n.d.). IRB registration process – FAQs. Retrieved from: http://answers.hhs.gov/ohrp/categories/1565