Institutional Review Board (IRB) 101 Workshop

WCU IRB Website: www.wcupa.edu/research/irb.aspx

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Fall 2015

Workshop Overview

1. Federal guidelines and regulations on the protection of human participants
2. Institution and individual investigator responsibilities
3. WCU-specific IRB guidelines and application form
4. Frequently asked questions
5. One-on-one Q&A with IRB members

Workshop Overview

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Historical Reasons for Protection of Human Participants in Research

- Past events unearthed research ethics concerns
  - Nazi Experimentation in Concentration Camps (1939-44) / Nuremberg Doctor Trial (1946)
  - Tuskegee Syphilis Study (1932-72)
  - Milgram Study (1961)
  - Stanford Prison Experiment (1971)

Tuskegee Study blood draw, '53

- In response to these events, The Belmont Report was authored by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979

The Belmont Report - 1979

- Report contains ethical principles and guidelines for the protection of human participants in research upon which the federal regulations (45 CFR 46) are based

- IRB requirements are based on the application of The Belmont Report's three basic ethical principles:
  - *Respect for Persons*
  - *Beneficence*
  - *Justice*

Respect for Persons

- *Definition:*
  - Respect individual autonomy
  - Protect individuals with reduced autonomy
- *IRB requirements:*
  - Informed Consent
  - Protecting privacy and maintaining confidentiality
  - Providing additional safeguards to protect participants vulnerable to coercion or undue influence
    - Such groups include: children, some mentally disabled, individuals with limited cognitive ability, and prisoners

Beneficence

- *Definition:*
  - Maximize benefits and minimize harm
- *IRB requirements:*
  - IRB assessment of risk/benefit analysis
  - Ensure that risks to participants are minimized
  - Risk justified by benefits of the research

Justice

- *Definition:*
  - Equitable distribution of research burden and benefits
- *IRB requirements:*
  - Ensure selection of participants is equitable

Health and Human Services (HHS) Regulations (45 CFR Part 46)

- In 1991, HHS published the Federal Policy for the Protection of Human Subjects (or the "Common Law")
  - 45 CFR Part 46: HHS Regulations for the Protection of Human Subjects at Title 45 Code of Federal Regulations Part 46
  - Institutional Review Boards (IRBs) are guided by the following subparts:
    - Subpart A – Basic HHS Policy for Protection of Human Research Subjects
    - Subparts B-D – Additional protections for vulnerable populations
      - Subpart B – Pregnant women, human fetuses, and neonates
      - Subpart C – Prisoners
      - Subpart D – Children
    - Subpart E – Registration of Institutional Review Boards

Basic Provisions of HHS 45 CFR Part 46 Regulations:

1. Institutional Assurances of Compliance

- Must have documentation of an institutional commitment to comply with regulations
  - OHRP-approved Assurance
  - Certifies to HHS that research has been reviewed and approved by an IRB
  - Research is subject to continuing IRB review

Basic Provisions of HHS Regulations: 2. IRB Review

- IRB committee:
  - Established to protect rights and welfare of human research participants involved in research activities
- IRB membership composition:
  - Must have at least 5 members with varying backgrounds (at least one scientist, one non-scientist, and one member non-affiliate)
    - Must be sufficiently qualified through experience/expertise and diversity of members (considering race, gender, and culture)
    - Must be knowledgeable about and experienced working with vulnerable participants such as children, prisoners, pregnant women, or handicapped or mentally disabled persons
  - WCU's IRB membership is located on our website

Basic Provisions of HHS Regulations: 2. IRB Review

- IRB Review of Research:
  - IRB must review all research activities covered by HHS regulations
    - Includes proposed revisions to previously approved IRB applications
  - IRB has the right to approve, require revisions prior to approval, or disapprove of any IRB application
  - Continued review of ongoing projects occur once a year
  - IRB can suspend or terminate approved research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants
    - Any suspension or termination of approval must be reported to the investigator, institutional officials and HHS and must include the reason for the action

Basic Provisions of HHS Regulations: 3. Informed Consent

- Voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other relevant factors

- Unless specifically waived by the IRB, informed consent must be documented by a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative

Informed Consent Process

- *Information exchange* - inclusive of participant recruitment materials, oral instructions, written materials, Q&A sessions, and agreement documented by signature
- *Comprehension* - ensure a participant's understanding of the informed consent before and during the study
- *Voluntariness* - choice to participate or continue to participate is voluntary

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Institutional Responsibilities

- Responsibility for the protection of human participants is shared b/t the Institutional Official, the IRB, and the investigator
  - Institutional Official:
    - Designate IRB to review research
    - Provide sufficient resources for the IRB
    - Provide training/education opportunities for IRB and investigators
    - Ensure investigators fulfill their responsibilities
    - Serve as point of contact to OHRP
    - Develop policies and procedures for administration of the Human Research Protections Program (HRPP)
    - Ensure Assurances are in place and certifications of IRB review are submitted
    - Ensure institution and investigators engaged in HHS human participant research operate under an OHRP-approved Assurance for the protection of human participants

Investigator Responsibilities - I

- Primary responsibility for protecting the rights and welfare of human research participants and are responsible for complying with all provisions of their institution's Assurance
  - Expected to be knowledgeable about the requirements of HHS regulations, applicable state law, their institution's Assurance, and institutional policies and procedures for the protection of human participants

Investigator Responsibilities - II

- Conduct research according to IRB-approved protocol
  - Obtain and document the informed consent of each participant or legally authorized representative, unless the IRB waived the requirements
  - Ensure each potential participant understands the nature of the research and participation
  - Provide a copy of the IRB-approved informed consent document to each participant or representative
    - All signed consent documents are to be retained for at least 3 years after the completion of the research

Investigator Responsibilities - III

- Promptly report proposed changes in previously approved human participant research activities to IRB
  - Proposed changes (i.e., REVISION) may not be initiated without IRB review and approval (except where necessary to eliminate apparent immediate harm to participants)
- Report progress of ongoing approved research to IRB once every year
- Promptly report to IRB any unanticipated problems involving risks to participants or any non-compliance with HHS regulations

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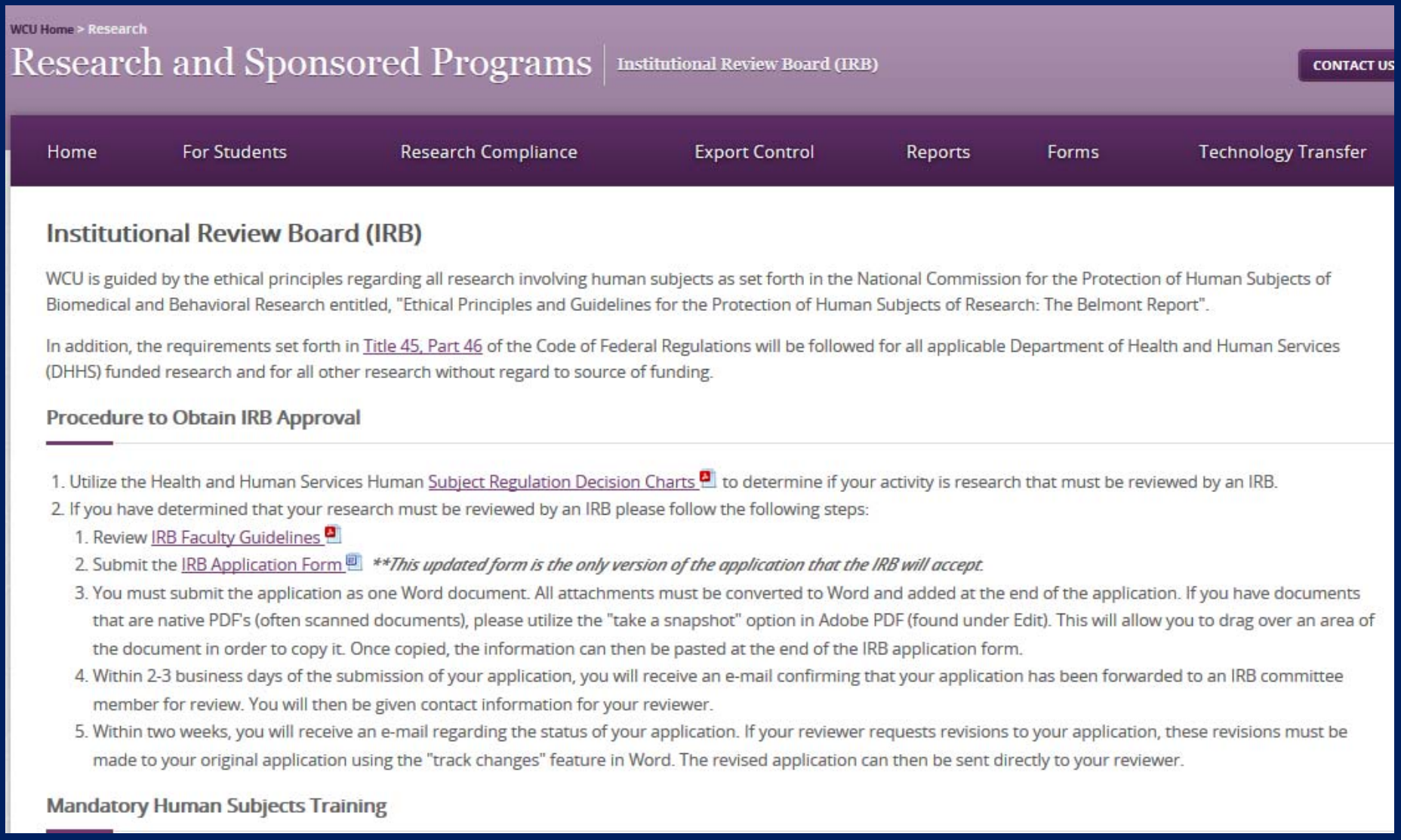
Does the Research Involve Human Participants?

- Human subject or participant – a living individual about whom an investigator conducting research obtains
  - data through intervention or interaction with the individual, or
  - identifiable private information

WCU IRB Guidelines and Forms

- Available at: www.wcupa.edu/research/irb.aspx



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Institutional Review Board (IRB)

WCU is guided by the ethical principles regarding all research involving human subjects as set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report".

In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations will be followed for all applicable Department of Health and Human Services (DHHS) funded research and for all other research without regard to source of funding.

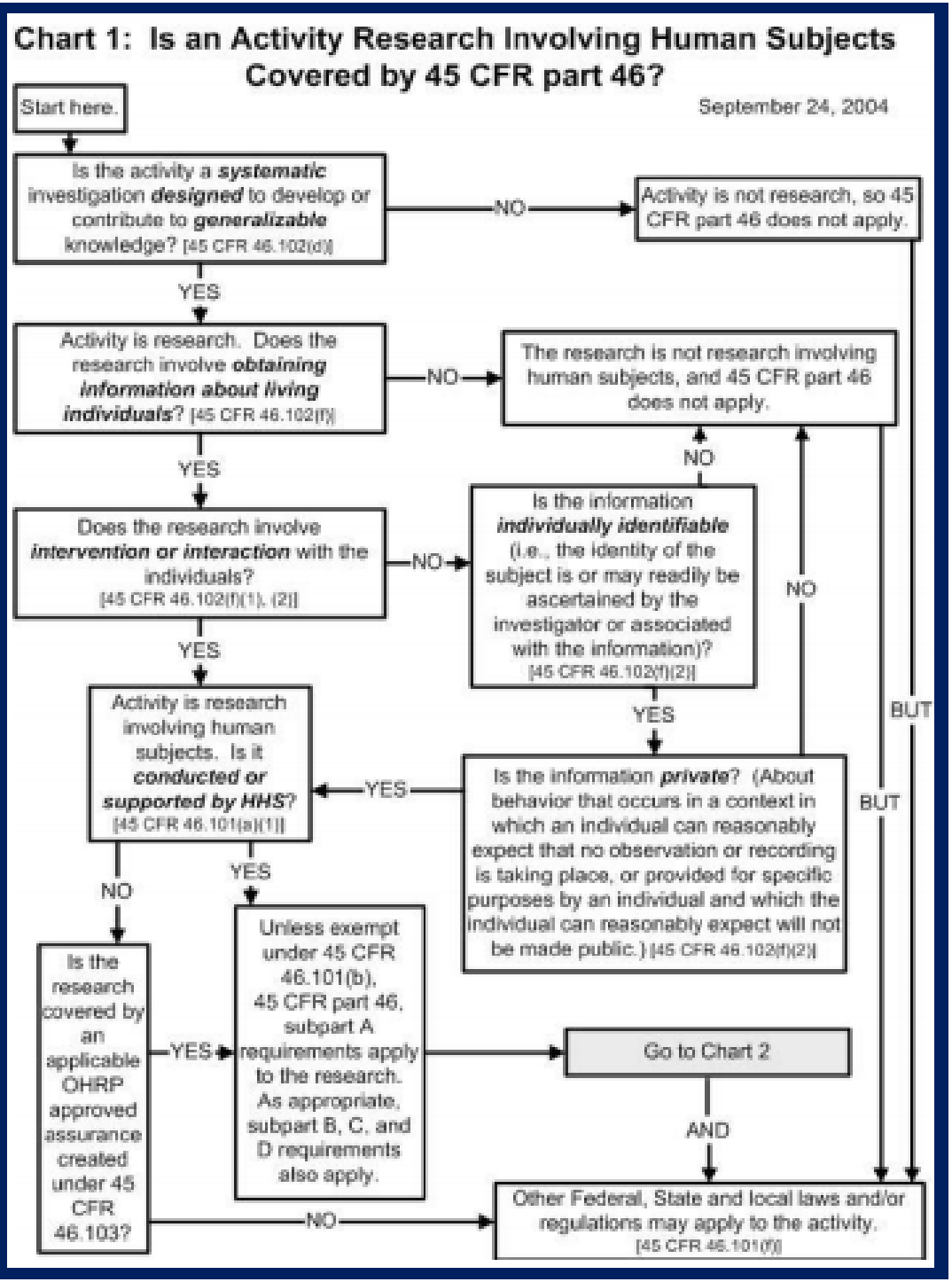
Procedure to Obtain IRB Approval

1. Utilize the Health and Human Services Human Subject Regulation Decision Charts to determine if your activity is research that must be reviewed by an IRB.
2. If you have determined that your research must be reviewed by an IRB please follow the following steps:
   1. Review IRB Faculty Guidelines
   2. Submit the IRB Application Form ***This updated form is the only version of the application that the IRB will accept.*
   3. You must submit the application as one Word document. All attachments must be converted to Word and added at the end of the application. If you have documents that are native PDF's (often scanned documents), please utilize the "take a snapshot" option in Adobe PDF (found under Edit). This will allow you to drag over an area of the document in order to copy it. Once copied, the information can then be pasted at the end of the IRB application form.
   4. Within 2-3 business days of the submission of your application, you will receive an e-mail confirming that your application has been forwarded to an IRB committee member for review. You will then be given contact information for your reviewer.
   5. Within two weeks, you will receive an e-mail regarding the status of your application. If your reviewer requests revisions to your application, these revisions must be made to your original application using the "track changes" feature in Word. The revised application can then be sent directly to your reviewer.

Mandatory Human Subjects Training

Procedure to Obtain IRB Approval

1. Determine if your activity is research that must be reviewed by the IRB.
   - Examine the HHS Human Subject Regulation Decision Charts



Procedure to Obtain IRB Approval

2. If you determined your research must be reviewed by the IRB, then follow these steps:
   - Review the *IRB Faculty Guidelines*
   - Complete and submit the IRB Application Form to irb@wcupa.edu
     - Application must be submitted as one Word document
     - Include all scanned/pdf documents in the body of the application:
       - Use the Print Screen key to copy a document on your screen and paste it into the Word IRB app or use the "Edit > take a snapshot" option in Adobe pdf, copy a portion of the pdf, and paste it into your Word IRB app
     - Upon submission of your IRB application, you will receive an email confirming your application was forwarded to an IRB committee member for review. Your reviewer will be Cc'd on that initial email for future contact.
     - Within two weeks, you will receive an email regarding your application status. If your reviewer request revisions to your application, these revisions must be completed and sent directly to your reviewer.

WCU IRB Application Form

- Assemble in one Word document in the following order:

1. Section I: Project information (including review category)
2. Section II: Detailed protocol
3. Completed checklist
4. Section III: Signatures
5. Appropriate informed consent forms
6. Research instruments used
7. Letters of approval from participating institutions
8. External support proposal
9. Evidence of computer-based IRB training (CITI)

1. Section I: Project Information

- Investigators (including faculty sponsor if PI is student)
- Project title
- Project period
- Revision or renewal status for previously approved IRB applications
- Review category (exempt, expedited, or full board review)
- Involvement of vulnerable populations as participants
- Participating non-WCU organization(s)
- External support

Review Categories – Exempt

- The HHS Human Subject Regulation Decision Charts will help you to decide if your IRB application is of exempt, expedited, or full board review status.

- Applications with exempt status present with the lowest amount of risk to potential participants.

- Exempt does not mean you are not required to go through IRB review.
  - You will still go through IRB review, but it requires less rigorous review.
    - Only requires review from one IRB member
    - Does not require completion and submission of a *Continuing Review* form to irb@wcupa.edu one year post-approval *(NOTE: renewals of ongoing projects beyond one year still apply)*

Review Categories – Exempt

- To qualify as *Exempt Research*, your application must fall into one of the 6 categories:

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior – unless identified and sensitive
3. Research on elected or appointed public officials or candidates for public office
4. Research using existing data, if publicly available or recorded w/o identifiers
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

Review Categories – Expedited Review

- Expedited review includes research that presents no more than minimal risk to human participants.
  - *Minimal risk* means that the probability and magnitude of the anticipated harm/discomfort in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - *At risk* means the participant is anticipated to be placed in a position with greater potential for physical, mental, social, or financial harm than would be expected for that individual in his or her normal occupation or daily activities.

Review Categories – Expedited Review

- Expedited Review Categories include:
  - Collection of blood samples
  - Prospective collection of biological specimens by noninvasive means
  - Collection of data through noninvasive procedures routinely employed in clinical practice
  - Research involving materials that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or dx)
  - Collection of data from voice, video, digital, or image recordings made for research purposes
  - Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies (*NOTE:* some research in this category may be exempt)

Review Categories – Full Board Review

- If exempt nor expedited review does not apply, then full board review is required.

- A full board review IRB application presents with more than minimal risk to human participants which cannot be minimized with reasonable procedural safeguards.

  NOTE: Both expedited and full board review applications require more rigorous review:

  - Expedited requires review from two IRB members, while full board review requires review from all IRB members
  - Both require completion and submission of a *Continuing Review* form to irb@wcupa.edu one year post-approval

What Review Category is it?

- Scenario
  - The investigator wishes to study if a verbal subliminal persuasive message (Danger!) will influence the physiological behavior (change in galvanic skin response, heart and respiratory rates) of the undergraduate students.

What Review Category is it?

- Scenario
  - The investigator wishes to study if a verbal subliminal persuasive message (Danger!) will influence the physiological behavior (change in galvanic skin response, heart and respiratory rates) of the undergraduate students.

- Why is this an expedited review?
  - This study presents *no more than minimal risk* as per the criteria listed in 45 CFR 46.101(b)(4) and is included in one of expedited review categories: prospective collection of biological specimens for research purposes by noninvasive means. Checking heart and respiratory rate is noninvasive as is the attachment of monitors on the finger tips to measure galvanic skin response.

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- Scenario
  - The investigator wishes to study the effects of an over-the-counter herbal supplement with no FDA approval on muscular strength following an exercise intervention on healthy adults.

What Review Category is it?

- Scenario
  - The investigator wishes to study the effects of an over-the-counter herbal supplement with no FDA approval on muscular strength following an exercise intervention on healthy adults.

- Why is this a full board review?
  - There is *more than minimal risk*, as per the criteria listed in 45 CFR 46.101(b)(4). The use of an herbal supplement and the implementation of the exercise protocol indicates this study would need to be reviewed by the full IRB board to determine level of risk for the participants.

What Review Category is it?

- Scenario
  - The investigator wishes to determine the differences in taste, texture and visual appeal of two identical cookies, sans one ingredient; baking soda vs baking powder in students in a college level research class. The goal is to publish these results in a pedagogy journal.

What Review Category is it?

- Scenario
  - The investigator wishes to determine the differences in taste, texture and visual appeal of two identical cookies, sans one ingredient; baking soda vs baking powder in students in a college level research class. The goal is publish these results in a pedagogy journal.

- Why is this an exempt review?
  - As per the criteria listed in 45 CFR 46.101(b)(4), studies of taste evaluation qualify for exempt status only if (1) wholesome foods without additives are consumed; or (2) if a food is consumed that contains a food ingredient at or below the level of and for a use found to be safe. The federal exemption category 46.101(b)(6) applies to these studies.

2. Section II: Detailed Protocol

A. Provide a brief summary of the proposed research in lay terms. Include major hypotheses (if appropriate), research questions and research design.

B. Describe the source(s) of subjects and the selection criteria. Specifically, how will you obtain potential subjects, and how will you contact them? Will any compensation or incentives be given for participation? If so, what?

C. Informed consent: Describe the consent process, or if you are applying for a waiver of consent, provide detailed justification for the requested waiver. Attach a copy of all consent documents after Section III, Signatures Page.
(see 45 CFR 46.116(c) and/or 45 CFR 46.116(d) for waiver guidelines.

D. Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.

E. How will confidentiality of the data be maintained? Include the exact location of the signed originals of the Informed Consent Forms, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. Specify the date for destruction of data (surveys, disks, etc)?

F. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.

G. Describe the anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Checklist and
4. Section III: Signatures

- Checklist:

  Checklist to be used as a guideline and completed prior to submission

- Signatures:

  Signatures required for all investigators and faculty sponsor if Principal Investigator (PI) is a student

  NOTE: typed PI, co-PI, faculty sponsor signatures accepted

5. Appropriate Informed Consent Forms - I

- No investigator may involve a human being as a participant in research covered by HHS regulations unless the investigator has obtained the legally effective informed consent of the participant or the legally authorized representative of the participant

- The Consent Process:
  - Not a single event or just a form to be signed; it is an ongoing process b/t investigator and participant
  - Basic concepts include:
    - Full disclosure of nature of the research and participation, adequate comprehension on part of the potential subject, and the voluntary choice to participate

5. Appropriate Informed Consent Forms - II

- Informed Consent Requirements:
  - Language understandable to participant (7th – 8th grade level)
    - Tips: avoid multisyllabic words (limit to 2 if possible), create short simple sentences, increase white space on form and avoid long blocks of text, use second person ("you") wording instead of third person ("the participant")
    - Resources on creating a readable form:
      - http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_ii.html
      - http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage16.html
      - https://www.ttuhsc.edu/research/hrpo/irb/files/informed_consent_article.pdf
  - Withdrawal notice
  - Contact info for WCU Office of Sponsored Research (610-436-3557)
  - 8 bolded headings containing study purpose, procedures, confidentiality, risks/benefits, etc. (see next slide)

5. Appropriate Informed Consent Forms - III

- The 8 bolded headings must be included and explained on each informed consent form:

1. Nature and Purpose of the Project
2. Explanation of Procedures
3. Identification of Any Experimental Medical Treatments or Procedures
4. Discomfort and Risks
5. Benefits
6. Confidentiality
7. Explanation of Compensation, if any
8. Name of person to contact in case of research-related injury

*** See Sample Informed Consent Form on Page B-3 in the IRB Faculty Guidelines document.*

5. Appropriate Informed Consent Forms - IV

- Obtaining assent from children/minors under age 18:
  - Parents or legal guardians must sign the informed consent form permitting minors to participate in research projects prior to gaining the child/minor's assent.
    - Child/Minor Assent Form must be completed by the minor. Language required to be simplified and appropriate for the age group.
    - If a minor is unable to read/sign a written assent form, a verbal script should be submitted.

***The IRB Faculty Guidelines document includes sample assent forms on page B-4 and a sample parental/guardian informed consent form on page B-5.*

6. Research Instruments

- Include copies of all instruments, surveys, focus group, or interview questions
  - For focus groups or interviews, please include a script of intended conversations/instructions with participants.
  - For surveys or instruments, omit identifying information on published surveys if not necessary (such as social security number, name, birthdate, address, etc.)

7. Letter(s) of Approval from Cooperating Organizations

- Request and obtain letters of approval from cooperating organizations
  - Letters must be signed by a person-in-authority and printed out on their organization's letterhead
    - Typed person-in-authority signature not accepted
    - Approvals written in the body of an email not accepted
  - What to include?
    - Project title
    - Confirmation they reviewed your study procedures and agree to cooperate
    - Their specific role in the study
    - Person-in-authority's title, organization name, and hand signature
  - Scan letter and copy/paste into IRB application

8. External Support and 9. Evidence of Computer-Based IRB Training

- External Support:
  - Attach external support proposal, if any

- Evidence of Computer-Based IRB Training:
  - WCU is a subscribing institution with The Collaborative Institutional Training Initiative (CITI Program) at the University of Miami. CITI provides comprehensive online training in *Human Subjects Research*.
  - All PI's, co-PI's, faculty sponsors, research assistants, and any researcher on the project are required to create a CITI account and complete the *Human Subject Research* Training at https://www.citiprogram.org/
  - Training must have been completed within 3 years from the date of the IRB application.

CITI Human Subject Research Instructions

- For instructions, see the WCU IRB website or follow these instructions to complete the *CITI Human Subject Research* Training:
  - Register to take the course at: https://www.citiprogram.org/
  - Under Institutional Affiliation type in *West Chester University of PA*
  - Provide contact and other relevant information
  - Under the *Human Subject Research* training course, you will have two modules to choose from: *Biomedical* or *Social-Behavioral-Educational*. Select the module most closely related to your research.
    - The module will present info followed by quizzes. You can retake quizzes in order to pass.
    - There are other optional trainings you could complete, but are not required for the WCU IRB.
  - The product is a completion report ~ include this report in your IRB application.

NOTE: If you have a previously approved IRB application prior to August 26, 2015 and are applying for a revision, renewal, or continuing review, NIH training certificates will continue to be accepted until the 3 year window runs out. New applications require CITI training.

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FAQs

1. Do I need to include my recruitment flyers or email/verbal recruitment scripts in the IRB application?

   YES – Attach and refer to these included recruitment materials in the IRB application's Section II. Detailed Protocol, Part B. Selection and Source of Subjects.

FAQs

2. I'm on a university wide task force that is looking at academic advising. We would like to implement a faculty perception survey and will be using the data internally to improve and better understand the campus culture around advising. Do I need to go through IRB approval?

   NO – A project is not considered research if there is *no intent to generalize the knowledge* through conference presentations (even WCU Research Day) or publications. Internal quality improvements projects are not considered research.

FAQs

3. My research project is just an anonymous survey with non-sensitive questions. I plan to send a Qualtrics link to adult participants (18 years of age and older) asking them about their attitudes towards physical activity. Do I need to obtain the traditional informed consent where they sign the form?

Depends. As long as your study meets exempt status, you can follow the Letter of Consent template on page B-5 in the IRB Faculty Guidelines. Completion of the online survey will be considered their consent to participate and no signed hardcopy of an Informed Consent will be necessary. This waiver of the standard informed consent form, however, must be deemed appropriate and approved by an IRB reviewer. *NOTE*: This waiver may apply to online and in-person exempt surveys.

FAQs

4. I teach a research methods course. All students undertake a survey research project as part of a class assignment. Do my students need to obtain IRB approval?

   Depends. Certain types of survey research, conducted as part of a specific course, do not require IRB approval. This includes research where the responses of participants are anonymous (not identifiable by name/description) and where the survey is seeking opinions about various topics. If a participant is not asked to reveal personal experiences or behaviors then IRB approval is not necessary.

   If survey research is conducted as part of a class where participants are asked to disclose identifying information (or a project is of expedited or full board review status), then IRB approval is necessary. Also, research involving vulnerable populations and/or sensitive topics require IRB approval.

   All student project protocols must be reviewed and approved by the course instructor prior to implementation.

Student Course-Based Research Projects

- Course faculty members are responsible to review course-based research project methods prior to implementation.

- If there is any thought about possibly presenting or publishing the work (i.e., generalizing knowledge), regardless of review status, the student (and faculty member) must obtain IRB approval prior to project start.
  - Once research has been conducted without a protocol, future use of data is not permitted.
  - This includes publication and presentation, including at Research Day. It is ideal to obtain IRB approval prior to the start of any research.

Student Internship-Based Research Projects

- Student Course-Based Research Project guidelines also apply to students conducting a research/evaluation project while at internships, field placements, practica, or applied learning experiences at agencies within the community.
  - The supervising faculty member is responsible to review research/evaluation project methods prior to project start.
  - If the project is of exempt status and there is no intent to generalize knowledge by student and/or agency in future, then proceed without formal WCU IRB approval.
  - If there is intent of disseminating knowledge at conferences or in publications, regardless of review status, it must be reviewed and approved by the WCU IRB.

FAQs

5. I will be doing research involving individuals who speak a foreign language. If the IRB approved the English version of the consent form do I have to submit a translated version for approval?

YES. The IRB must approve all translated documents that will be presented to participants, i.e. the informed consent form, surveys, and any recruitment materials/scripts.

FAQs

6. I will have graduate assistants working with my data from a previously IRB-approved research protocol. Do I need to have them do the CITI Training and must I submit a revision with their CITI completion reports to my already approved IRB application?

   YES, any person having access to the data or informed consent forms will need to complete the CITI training. If you only wish to add the GA CITI completion reports to your previously approved IRB, you must formally submit a revision to your application.

Steps to Applying for a Revision to a Previously Approved IRB Application

- Complete the IRB application form:
  - Check off Yes to I.F. and provide the approximate date of review.
  - Check off Revision to I.G. and provide the Protocol ID# of the original submission.
  - Highlight the revisions in the body of the application. Unchanged portions of the application can be cut and pasted from your original application.

- E-mail the completed form (in Word format only) to irb@wcupa.edu
  - In the subject line of the e-mail, clearly indicate that this is a revision application.
  - In the body of the e-mail, clearly list your revisions by application section (number/letter of section, or appendix documents)

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4. Common questions
5. ***One-on-one Q&A with IRB members***

Please stay to have your individual questions answered by IRB members!

If you have any further questions, please contact:

- The IRB office at irb@wcupa.edu,
- Dr. Stacie Metz, IRB co-chair, at smetz@wcupa.edu, or
- Dr. Gautam Pillay, IRB co-chair and AVP of Research at gpillay@wcupa.edu.