IRB Member Training Session 2:
Refresher Training on the
Regulatory Criteria for Approval
Recap of Session #1

• Review key process changes and initiatives related to the IRB Efficiency Project

• Understand the tools and resources available to IRB members (“HRPP Toolkit”)

• Outline expectations for IRB members when reviewing research

• Walk-through of the relationship between new tools and templates and the regulatory criteria for IRB approval
SESSION #2 OBJECTIVES:

• Refresh IRB members’ knowledge of the regulatory criteria for the approval of human research, and how to apply them

• Review the additional considerations that inform IRB members’ reviews
Convened IRB Review

Worksheet: Evaluation of Quorum and Expertise (305)
Worksheet: Review Materials (301)
Template Letter to IRB Member Agenda Packet
Worksheet: Evaluation of Quorum and Expertise (305)
Worksheet: IRB Meeting Minutes (303)
Template Minutes (301)
SOP: IRB Records (070)
Worksheet: Calculation of Approval Intervals (302)
Worksheet: Communication of Review Results (303)
SOP: IRB Records (070)
Worksheet: Evaluation of Quorum and Expertise (305)
Worksheet: Criteria for Approval and Additional Considerations (314)
Worksheet: Advertisements (315)
Worksheet: Payments (316)
Worksheet: Short Form of Consent Documentation (317)
Worksheet: Additional Federal Agency Criteria (318)
Worksheet: Limited IRB Review and Broad Consent (319)
Worksheet: Criteria for Approval and Additional Considerations for HUD (323)
Worksheet: Scientific or Scholarly Review (320)
Worksheet: Review of Information Items (321)
Worksheet: Certificate of Confidentiality (333)

IRB Meeting Preparation (040)
Consultation to the IRB (051)
Conflicting Interests of IRB Members (050)
IRB Meeting Conduct (041)
Pre-Review (041)
Post-Review (052)

Checklist:
- Pre-Review (401)
- Waiver or Alteration of the Consent Process (410)
- Waiver of Written Documentation of the Consent Process (411)
- Research Involving Pregnant Women (412)
- Research Involving Non-Viable Neonates (413)
- Research Involving Neonates of Uncertain Viability (414)
- Research Involving Prisoners (415)
- Research Involving Children (416)
- Research Involving Cognitively Impaired Adults (417)
- Non-significant Risk Device (418)
- Waiver of the Consent Process for Emergency Research (419)

Review Outcomes:
- Approved
- Modifications required to secure approval, deferred, or disapproved

Send correspondence
Await resubmission
Protocol Review Guidelines
POND BALL

Created by Sicora Consulting, Inc.
Continually Improving Performance
www.sicoraconsulting.com
There are too many regulatory criteria for approval for most people to memorize and consistently track on their own.

Using worksheets and checklists to systematically consider and apply the regulatory criteria is much more effective.
### Criteria for Approval

#### 1. General Considerations
- **Check if “Yes” or “N/A”. All must be checked.**
- **The consent form is a signed legal document, or has obtained through consultation, adequate expertise.**
- **The study must be fully written up.**
- **All required information is complete.**

#### 2. Criteria for Approval of Research
- **Check if “Yes” or “N/A”. All must be checked!**

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#### Additional Considerations
- **Continuing review is required if any of the following are checked.** For expedited review, eligible research, documentation regarding continuing review requirements must be included in the Designated Personnel Form in IRRON.
  - Research is subject to the pre-2018 Rule and still meets the criteria for continuing review
  - Research is subject to the IRRON, which meet the criteria for continuing review
  - A review panel or continuing review committee is designated
  - Research is not ongoing and current review is not necessary
- **The IRR may require continuing review for research eligible for expedited review under the 2010 Rule requirements unless the risk is not normally required.** The following are circumstances that may justify the requirement of continuing review for these studies. Justification must be documented in the Designated Personnel Form in IRRON.
  - Unusual study results or progressing non-compliance determinations
  - Studies with additional regulatory oversight (e.g., conflicts of interest, international research setting)
  - Studies with new findings that require additional monitors (e.g., EPITECT dissemination)
  - Other (consult with IRB Lead or other IRB Office)
The Regulatory Criteria for Approval
Criterion for Approval #1 (45 CFR §46.111(a)(1)(i))

- Risks to subjects are minimized:
  
  (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

  (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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Two required criteria to minimize risk

• Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

• Can risks be reduced by changing the research procedures in a way that will still allow the research to get done and will not unnecessarily expose subjects to risk? (Risk = Physical, Social, Psychological, Economic, or Legal)
Two required criteria to minimize risk

• Examples:
  • Can less invasive/intrusive methods answer the question?
  • Can fewer procedures answer the question?
  • Can fewer subjects answer the question?
  • Are certain procedures needed at all?
  • Can additional procedures (e.g., monitoring) reduce risk?
  • Can different exclusion criteria reduce risk?
  • Is the research staff qualified?
Two required criteria to minimize risk

- Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes.
  - Are procedures that will answer the scientific question being done anyway?
  - If so, can the data from these procedures be used to reduce risks? (Risk = Physical, Social, Psychological, Economic, or Legal)
Criterion for Approval #2 (45 CFR §46.111(a)(2))

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result

1. What are the risks to subjects? (Physical, social, psychological, economic, legal)
2. What are the anticipated benefits to subjects?
3. What is the importance of the knowledge that may reasonably be expected to result?

- Is (1) reasonable in relation to (2) and (3)?
“...the importance of the knowledge expected to result...”

- Will any knowledge result?
  - Good scientific design*
  - Adequate resources
    - Research staff qualifications
    - Adequate time
    - Adequate personnel
    - Adequate participant pool

- What will be its importance?*

*Requires scientific or scholarly expertise
Scientific Review vs. Scientific Validity

• **Detailed** scientific review outside of IRB scope

• Emphasis is on **validity**:
  • Is the research protocol scientifically sound or does it have scholarly merit?
  • Does the protocol accurately describe the research in a clear, detailed way?
  • Is the research likely to answer its proposed question?
  • Does the protocol *fairly portray* the importance of the knowledge expected to result?
  • Is the available background information adequate to support the proposed research?
Criterion for Approval #3 (45 CFR 46.111(a)(3))

- **Selection of subjects is equitable.**

  - **In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.**

  - The IRB should be particularly cognizant of the special problems in research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

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Selection of subjects is equitable.

- Are any subjects unfairly shouldering the burdens of the research?
- Are any subjects unfairly getting the benefits of the research?
- Consider:
  - Purpose of the research
  - Setting of the research
  - Involvement of vulnerable subjects
  - Selection criteria
  - Recruitment, enrollment, and payment procedures.
Criterion for Approval #4 (45 CFR 46.111(a)(4))

- Informed consent will be sought from each prospective subject or a legally authorized representative (LAR), in accordance with, and to the extent required by 46.116 (Section 5: Consent Process).
- Obtain informed consent as required.
- Waive or alter informed consent process.

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The investigator will obtain the *legally effective* informed consent of the subject or LAR.

- Subjects are provided enough information.
  - *Will the elements in Section 7: Elements of Consent Disclosure be disclosed and explained?*
  - *Will subjects be given additional information when appropriate?*
- Subjects **understand** the consequences of a decision.
- Subjects are **able to make** a decision.
- Subjects are **able to communicate** that decision.
Information to be given to the subject or their legally authorized representative (LAR) will be in language understandable to them.

- “Readability” of the informed consent document, in and of itself, is neither strictly necessary nor sufficient: It is about **ALL** communications in the consent **process**

- Will the research team communicate with the subject in a way that the subject will understand the information?

- Consider:
  - What language do the subjects speak?
  - What is the educational level of the subjects?
  - Can the research team communicate in understandable language to the participants or representatives?
  - Will written information be in the language understandable to the participants or representatives?
Options for criterion for approval #4

• Obtain informed consent as required.

• Waive or alter informed consent process.
Mechanisms for Waiver of Consent

### Mechanisms

**Mechanism**

- DHHS FDA

**Demonstration projects**

- 45 CFR 46.116(c) N/A

**Research not practicable**

- 45 CFR 46.116(d) N/A

**Emergency exception**

- 21 CFR 50.23(a)-(c)

**Presidential waiver**

- 21 CFR 50.23(d)

**Planned emergency waiver**

- DHHS Waiver 21 CFR 50.24

**Anonymous tissue**

- N/A April 2006 Guidance

**FDA-regulated minimal risk research**

- N/A July 2017 Guidance

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**Checklist: Waiver or Alteration of Consent Process**

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45 CFR 46.116(c) and (d): An IRB may approve a consent procedure that omits some or all of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the elements described in 45 CFR 46.116(a).

1. **Presidential waiver**
   - The research must meet the criteria set forth in 21 CFR 50.23(d).
   - 

2. **Planned emergency waiver**
   - The research must meet the criteria set forth in 21 CFR 50.24.
   - 

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**April 2006 Guidance**

- Anonymous tissue

**July 2017 Guidance**

- FDA-regulated minimal risk research

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**NPRM: 21 CFR 50.22**
### Criterion for Approval #5 (45 CFR 46.111(a)(5))

- Informed consent will be appropriately documented or appropriately waived, in accordance with 46.117

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- Obtain written documentation of consent using the "long form" (a.k.a. standard informed consent template).

- Obtain written documentation of consent using the "short form."

- Waive the requirement for written documentation of consent.
Criterion for Approval #5

- Obtain written documentation of consent using the “long form” (a.k.a. standard informed consent template).
  - See section #6 of WORKSHEET: Criteria for Approval
Options:

• Obtain written documentation of consent using the “short form”
  • See WORKSHEET: Short Form of Consent Documentation
Options:

• Waive the requirement for written documentation of consent. (45 CFR §46.117(c)(1))

• See CHECKLIST: Waiver of Written Documentation of Consent
Criterion for Approval #6 (45 CFR 46.111(a)(6))

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- Not needed if minimal risk
- If more than minimal risk:
  - Is someone looking at the collected data with enough frequency and depth to make sure that, if subjects as a group are at a greater risk than originally expected, something will be changed to address that risk?
- Consider:
  - Who reviews the data?
  - What data are reviewed?
  - When are data reviewed?
Criterion for Approval #7 (45 CFR 46.111(a)(7))

• When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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When appropriate, there are adequate provisions to protect the privacy of subjects

**Q:** When are provisions to protect the privacy of participants “appropriate”?

**A:** When participants have an expectation of controlling access to themselves.
Privacy interests refer to a person’s desire to control how, and with whom, they interact and communicate, particularly on issues that may be “sensitive” or “private.”

- Are the procedures in the research adequate to ensure that subjects’ expectations of privacy will be met?

- Consider:
  - Comfort with the procedures being performed.
  - Comfort with the research setting.
  - Comfort with the information sought.
When appropriate, there are adequate provisions to maintain the confidentiality of data.

- **Q:** When are provisions to maintain confidentiality “appropriate”?

- **A:** When confidentiality is pledged; OR when there are legal/ethical requirements.
Criterion for Approval #8

• Newly added, and specific only to new “Limited IRB Review” and “Broad Consent” requirements associated with Exempt category 7.
  
  • (Exempt #7: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).)
  
  • See HRP-319 - Limited IRB Review and Broad Consent
Criterion for Approval #9 (45 CFR 46.111(b))

• When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
How do you determine whether there is a vulnerable population?

• Is there a power differential?
• Are there communication issues?
• Are there decisional issues?
• Are there excessive motivating factors?
• Is the recruitment process acceptable?
• Are advertisements acceptable?
• Are payment arrangements acceptable?
IRB Members need to consider these general issues when reviewing research involving vulnerable populations.

• The research is of importance to the vulnerable population.
• The research question cannot be answered by using a non-vulnerable population.
• The risk-potential benefit relationship is appropriate to the vulnerable population.
• Additional steps will be taken to minimize coercion and undue influence of the vulnerable population, when appropriate.
Additional criteria for specific populations

- Children (HRP-416)
- Pregnant women (HRP-412)
- Prisoners (HRP-415)
- Adults unable to consent (HRP-417)
“Additional Applicable Criteria”

- Refers to the need to make Significant risk / Non-significant risk device determinations for certain kinds of investigational device research (HRP-418: Non-Significant Risk Device)
Additional Considerations When Reviewing Research
“Approval with Modifications”

OHRP “Guidance on IRB Approval of Research with Conditions”

• By IRB approval with conditions, OHRP means that at the time when the IRB reviews and contingently approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the investigator:
  a) make specified changes to the research protocol or informed consent document(s),
  b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or
  c) submit additional documents,

• such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations at 45 CFR 46.111 and, if applicable, subparts B, C, or D of 45 CFR part 46.

• Translation: IRB’s conditions result in a protocol that will meet the regulatory criteria for approval.
Unacceptable Examples of “Approval with Modifications”

- “Describe all risks of the study drug.”
- “Provide more information about the data and safety monitoring plan.”
- “Clean up the consent document to make it understandable.”
- “Justify why you are excluding children.”
- “Include additional protections for vulnerable subjects.”
Additional actions

• Initial and continuing review:
  • Should review take place more often than annually? If so, specify period.

• Continuing review:
  • Is verification needed from sources other than the investigator that no material changes have occurred since prior IRB review? (Are there questions about the veracity of the information provided is questioned.)

• Continuing review and modifications:
  • Is there information that needs to be provided to current or former subjects because it may affect their willingness to continue participation?
Designated Review

• The Toolkit draws a distinction between committee and non-committee review.

• Non-committee review is conducted by a Designated Reviewer.

• Certain worksheets are particularly useful for Designated Reviewers, in addition to HRP-314.
  • HRP-310: Human Research Determination
  • HRP-311: Engagement Determination
  • HRP-312: Exemption Determination
  • HRP-313: Expedited Review
IRB Member Questions?
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IEP Questions?
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IRB Member Training

• **Session 1**: HRPP Toolkit overview and crosswalk between templates and reviewer tools

• **Session 2**: Refresher training on the regulatory criteria for IRB approval

• **Session 3**: ARROW update overview and practical walk through of review processes in ARROW using HRPP Toolkit
Thank you!