IRB Member Training Session 2:

Refresher Training on the Regulatory Criteria for Approval

IEP
IRB EFFICIENCY PROJECT

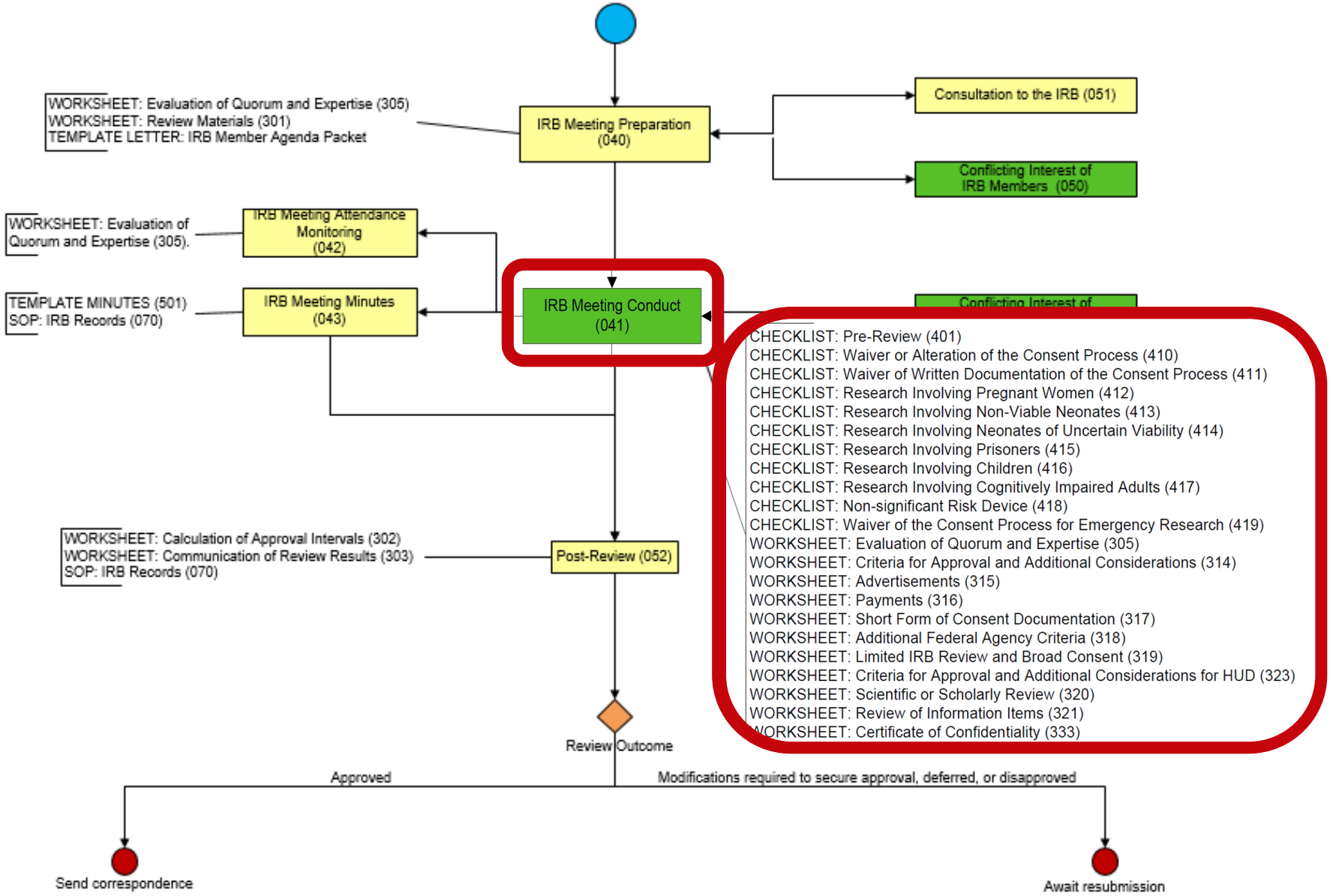
Recap of Session #1

- **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

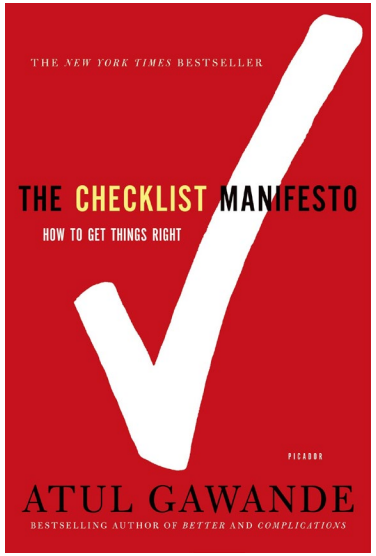


Protocol Review Guidelines

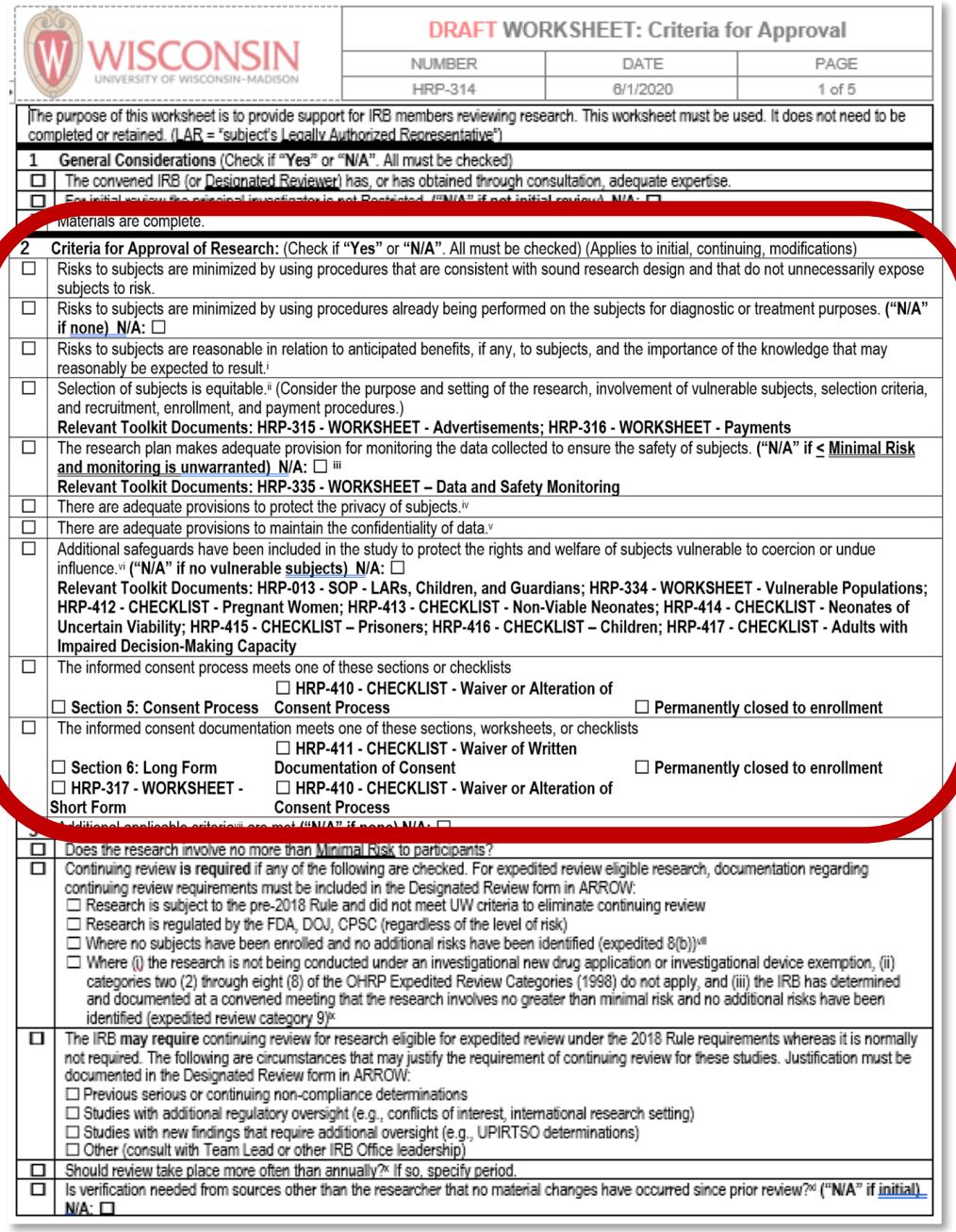

POND BALL
Created by Sicora Consulting, Inc.
Continually Improving Performance
www.sicoraconsulting.com

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



HRP-314 - WORKSHEET – Criteria for Approval



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DRAFT WORKSHEET: Criteria for Approval

NUMBER	DATE	PAGE
HRP-314	6/1/2020	1 of 5

The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")

1 General Considerations (Check if **"Yes"** or **"N/A"**. All must be checked)

- ☐ The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.
- ☐ For initial review the principal investigator is not Restricted. (**"N/A" if not initial review**) **N/A:** ☐
- ☐ Materials are complete.

2 Criteria for Approval of Research: (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)

- ☐ Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
- ☐ Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
- ☐ 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.[i]
- ☐ Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)
  Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments
- ☐ The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii]
  Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring
- ☐ There are adequate provisions to protect the privacy of subjects.[iv]
- ☐ There are adequate provisions to maintain the confidentiality of data.[v]
- ☐ Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐
  Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity
- ☐ The informed consent process meets one of these sections or checklists
  ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
- ☐ The informed consent documentation meets one of these sections, worksheets, or checklists
  ☐ **Section 6: Long Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **Permanently closed to enrollment**
  ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
- ☐ Additional applicable criteria[vii] are met (**"N/A" if none**) **N/A:** ☐
- ☐ Does the research involve no more than Minimal Risk to participants?
- ☐ 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 Review form in ARROW:
  ☐ Research is subject to the pre-2018 Rule and did not meet UW criteria to eliminate continuing review
  ☐ Research is regulated by the FDA, DOJ, CPSC (regardless of the level of risk)
  ☐ Where no subjects have been enrolled and no additional risks have been identified (expedited 8(b))[viii]
  ☐ Where (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified (expedited review category 9)[ix]
- ☐ The IRB **may require** continuing review for research eligible for expedited review under the 2018 Rule requirements whereas it is normally not required. The following are circumstances that may justify the requirement of continuing review for these studies. Justification must be documented in the Designated Review form in ARROW:
  ☐ Previous serious or continuing non-compliance determinations
  ☐ Studies with additional regulatory oversight (e.g., conflicts of interest, international research setting)
  ☐ Studies with new findings that require additional oversight (e.g., UPIRTSO determinations)
  ☐ Other (consult with Team Lead or other IRB Office leadership)
- ☐ Should review take place more often than annually?[x] If so, specify period.
- ☐ Is verification needed from sources other than the researcher that no material changes have occurred since prior review?[xi] (**"N/A" if initial**) **N/A:** ☐

IEP IRB EFFICIENCY PROJECT

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.

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii] **Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring**
☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **Permanently closed to enrollment** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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 [redacted] legal)
2. What are the [redacted]
3. What is the in[redacted]d to result?

- Is (1) reasonab[redacted]

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii] **Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring**
☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
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☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

“…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 m… …the purp… …h will be con…*
  - *The… …ems of rese… …able to coe… …viduals with… edu…*

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii] **Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring**
☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
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☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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 inf**
- Waive or a

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
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☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
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☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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

Mechar	FDA
Demonstration pro	N/A
Research not prac	N/A
Emergency excep	CFR 50.23(a)-(c)
Presidential waive	1 CFR 50.23(d)
Planned emergen	21 CFR 50.24
Anonymous tissue	il 2006 Guidance
FDA-regulated mi research	y 2017 Guidance RM: 21 CFR 50.22

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CHECKLIST: Waiver or Alteration of Consent Process

NUMBER	DATE	PAGE
HRP-410	6/1/2020	1 of 3

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 – WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

Use a separate checklist for each waiver or alteration determination for a study.

IRB Number:	
Study Title:	
Short Title:	
Investigator:	

The research must meet one of the following six sets of criteria

1 Waiver or Alteration of Consent Process[1] (Check if "**Yes**". All must be checked)

- ☐ The research is **NOT** FDA-regulated.
- ☐ The research does **NOT** involve non-viable neonates.
- ☐ The research involves no more than Minimal Risk to the subjects.
  Provide protocol specific findings justifying this determination:
- ☐ The research could **NOT** practicably be carried out without the waiver or alteration
  Provide protocol specific findings justifying this determination:
- ☐ If the research involves using Identifiable Private Information or Identifiable Biospecimens, the research could **NOT** practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research does not use identifiable private information or biospecimens, or if the research is not subject to the 2018 Rule) ☐ N/A**
  Provide protocol specific findings justifying this determination:
- ☐ The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.
  Provide protocol specific findings justifying this determination:
- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  Provide protocol specific findings justifying this determination:
- ☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[2]. **(N/A if waiving informed consent, or if the research is not subject to the 2018 Rule) ☐ N/A**

2 Waiver or Alteration of Consent Process[3] (Check if "**Yes**". All must be checked)

- ☐ The research **IS** FDA-regulated.
- ☐ The clinical investigation involves no more than Minimal Risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.
  Provide protocol specific findings justifying this determination:

[1] 45 CFR §46.116(f)
[2] An IRB may approve a consent procedure that omits some, or alters 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 requirements described in 45 CFR 46.116(a).
[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk.

Criterion for Approval #5 (45 CFR 46.111(a)(5))

- Informed consent will be appropriately documented or appropriately waived, in accordance with 46.117
  - Obtain w… m" (a.k.a. standard…
  - Obtain w… rm."
  - Waive th… t.

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
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☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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.

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii] **Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring**
☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **Permanently closed to enrollment** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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.
  - Priv
    - A
    - I
    - I

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
☐	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("N/A" if ≤ Minimal Risk and monitoring is unwarranted) N/A:** ☐ [iii] **Relevant Toolkit Documents: HRP-335 - WORKSHEET – Data and Safety Monitoring**
☐	There are adequate provisions to protect the privacy of subjects.[iv]
☐	There are adequate provisions to maintain the confidentiality of data.[v]
☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

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.

2	**Criteria for Approval of Research:** (Check if **"Yes"** or **"N/A"**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
☐	Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("N/A" if none) N/A:** ☐
☐	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.[i]
☐	Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) **Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments**
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☐	Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence.[vi] **("N/A" if no vulnerable subjects) N/A:** ☐ **Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-334 - WORKSHEET - Vulnerable Populations; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST – Prisoners; HRP-416 - CHECKLIST – Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**
☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **Permanently closed to enrollment**
☐	Additional applicable criteria[vii] are met **("N/A" if none) N/A:** ☐

How do you determine whether there is a vulnerable population?

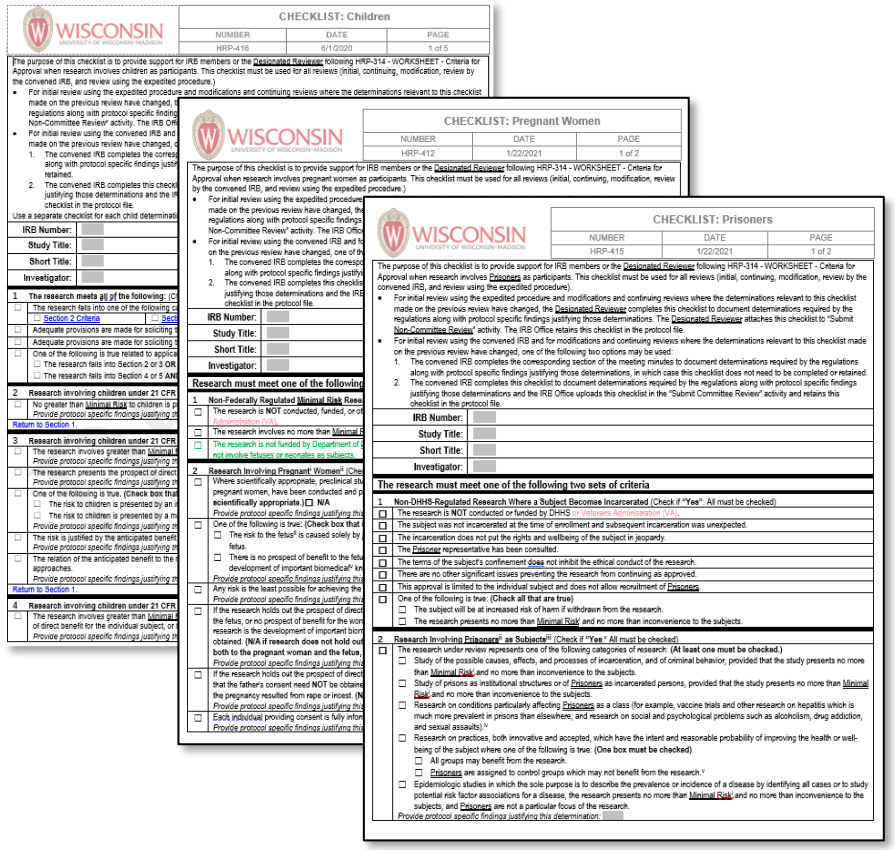
- Is there a power differential?
- Are there communication issues?
- Are there decisional issues?
- Are there excessive motivating factors?
- Is the recruitment process acceptable?
- Are advertisements acceptable?
- Are payment arrangements acceptable?

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”

2	**Criteria for Approval of Research:** (Check if **“Yes”** or **“N/A”**. All must be checked) (Applies to initial, continuing, modifications)
☐	Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
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☐	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.[i]
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☐	The informed consent process meets one of these sections or checklists ☐ **Section 5: Consent Process** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	The informed consent documentation meets one of these sections, worksheets, or checklists ☐ **Section 6: Long Form** ☐ **HRP-317 - WORKSHEET - Short Form** ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent** ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process** ☐ **Permanently closed to enrollment**
☐	Additional applicable criteria[vii] are met **(“N/A” if none) N/A:** ☐

- 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!