The Common Rule Delay, PittPRO System and Other HRPO News

HRPO Seminars: January 25, 2018

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Things to Talk About

- Delay of Revised Common Rule Effective Date
- Status of PittPRO
- Revised Effective Date and PittPRO Dates
- Other HRPO News
Long Time Coming…And Yet…

Advance Notice of Proposed Rulemaking (ANPRM) published July 22, 2011

Notice of Proposed Rulemaking (NPRM) published September 5, 2015

January 18, 2017
Final Rule published with effective date of January 19, 2018

NIH Policy on Single IRB Review for Multi-Site Research effective January 25, 2018

Final Rule Single IRB Requirement effective January 20, 2020

January 18, 2018
Final Rule effective date delayed

July 19, 2018
New Effective Date of Final Rule

Delay Announcement – January 17, 2018

- [DHHS and 15 other departments delay] the effective date and general compliance date to July 19, 2018, providing regulated entities additional time to prepare to implement these revisions.
- …Until July 19, 2018, regulated entities will be required to comply with the pre-2018 Common Rule
- [Unless the change] does not conflict with the pre-2018 rule

https://www.hhs.gov/ohrp/interim-final-rule-common-rule.html

Human Research Protection Office
What’s Out?

- New and Revised Exempt Categories
- Release from Continuing Review (unless non-federally funded)
- Release from Screening and Recruitment Waivers
- Public Posting of Consent Form

What’s In?

- Single IRB Review for Multi-Site Studies
  - January 25, 2018 – NIH funded
  - January 20, 2020 – other Common Rule Agency funded
- Required and Additional Elements of Consent
- Key Information Consent Summary (sort of)
**Requirement for Single IRB Review**

U.S. institutions engaged in cooperative research must rely upon a single IRB for review

- Reviewing IRB named by the Federal Agency supporting the research or proposed by the lead institution
- May not be required if supporting Federal Agency or agency deems a single IRB inappropriate in a particular context
- Effective January 20, 2020

http://www.hrpo.pitt.edu/reliance-agreementssingle-irb-review

**NOTE:** NIH Single IRB requirement is effective January 25, 2018

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**General Requirements for Informed Consent**

1. A clear statement of research, purpose, duration, and procedures;
2. A description of any risks or discomforts to the subject;
3. A description of any benefits to the subject or to others;
4. Alternative procedures;
5. A statement describing how confidentiality will be maintained;
6. Compensation for injury (> min risk);
7. Research subjects' rights, and whom to contact in the event of a research-related injury;
8. A statement that participation is voluntary
Additional Elements, When Appropriate

1. A statement that there may be unforeseeable risks to the subject, embryo or fetus
2. When participation can be ended by the investigator
3. Any costs the subject may incur
4. Consequences of early withdraw and procedures for early termination
5. A statement that subjects will be told of new findings that may affect willingness to continue
6. Approximate number of subjects to be enrolled

New Elements Not In Conflict with Pre–2018 Rule

<table>
<thead>
<tr>
<th>When your project will involve...</th>
<th>Include in the informed consent:</th>
</tr>
</thead>
</table>
| The collection of identifiable private information or biospecimens | A statement whether:
  * Identifiers may be removed, and
  * if the de-information or biospecimens **may or may not** be used for future research or shared with other investigators [46.116 (b)(9)] |
| Use of biospecimens | A statement that the subject’s biospecimens (**even if identifiers are removed**)
  * may be used for commercial profit and
  * whether the subject will or will not share in the commercial profit [46.116 (c)(7)] |
| Clinically relevant research results | A statement regarding whether the clinically relevant research results, including individual research results, will be disclosed to subjects, and if so under which conditions [46.116 (c)(8)] |
| Whole genome sequencing | A statement indicating that the research will (if known) or might include whole genome sequencing [46.116 (c)(9)] |
Key Information Consent Summary

Informed consent must begin with a concise and focused presentation of the key information that would assist a potential subject in deciding whether to participate:

- No guidance given beyond Preamble recommendations:
  - Statement that the project is research & participation is voluntary
  - A summary including:
    - Purpose
    - Duration
    - Procedures
  - Reasonable, foreseeable risks or discomforts
  - Reasonable, expected benefits
  - Alternative procedures or treatment, if any

NOTE: HRPO is not encouraging implementation at this time but will consider and approve well-articulated versions.
PittPRO to Replace OSIRIS

• Streamlined submission system
• Testing and improving with staff
• Beta Testing expected in March
• “Go Live” expected in April

The Common Rule delay will allow PittPRO to be up and running at July effective date

Why is this good?
Entering projects in PittPRO will ensure compliance with the New Rule
Study Scope

1. Will any of these populations be recruited?
   - Children under the applicable law of the jurisdiction in which the research will be
   - Wards of the State
   - Employees or Students of the University of Pittsburgh
   - Adults with impaired decision-making capacity
   - Non-English speakers
   - Nursing home patients in the state of Pennsylvania
   - Neonate of uncertain viability
   - Non-viable neonate
   - Pitt Medical Students as primary research group
   - Pregnant women
   - Prisoners

2. Will this study involve any of the following FDA Considerations?
   - Drug
   - Biologic
   - Food or Dietary Supplement
   - Device

3. Involve any Waivers?
   - Waiver of Consent
   - Waiver to Document Consent
   - Waiver of IRBRA Authorization
   - Exception from consent for emergency research

4. Involve any of the following Data/Specimens?
   - Banking specimens/data
   - Data only, no human subject interaction
   - Honesty Broker to provide data/specimens
   - Return of Results to Subjects or Others
   - Fetal Tissue

5. Involve use of Protected Health Information?
   - UPMC medical records
   - Pitt medical records
   - Other institutions' medical records

6. Involve any of the following Technologies be used to collect or record data?
   - Mobile App
   - Web-based site, survey, or other tool
   - Wearable device (also select mobile app if it will be used with the device)
   - Electronic photo, photographic, or video recording or conferencing
   - Text messaging
   - Identifiable or coded data will be used with one or more of the listed technologies

7. Other?
   - Placebo Arm
   - Withdraw from usual care
   - Deception (also requires waiver of consent)
   - Emergency Use Request

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View Study

Basic Information

1. * Title of study: Full Board Study - Do Not Touch
2. * Short title: FF (5)
3. * Brief description: This is a multicenter phase I trial evaluating the intravenous administration (IV) of LMP744 over 1 hour on days 1, 5 followed by 23 days. The study design includes both dose escalation and expansion. Dose escalation will follow design 3 of the Simon accelerated titration designs for each patient cohort, with a standard 3+3 design with a 'stop decision is taken'. Dose escalation will proceed initially with single patient 100% increments in dose level for the next single patient cohort. Once a 'stop decision is taken' to reroute to the 3+3 dose-escalation cycle, the next increment is the dose until a maximum dose is reached. In the 3+3 dose-escalation phase, 3 patients will be treated at the first dose level, the MTD is the dose level at which no more than 1 in 6 patients experience DLT, and the dose below that have DLT as a result of the drug. Once the MTD is identified, an additional 15 patients will be treated at the MTD on an expansion cohort.
4. * Principal investigator: Tom Edwards (ph2)
5. * Does the investigator have a financial interest related to this research? ☑ Yes ☐ No
6. Determining Scientific Review
   - Organizational Scientific Review (ODS requires departmental review)
   - Choose the appropriate organization to conduct the scientific review:
     - U of Pitt | School of Medicine | Medicine
What to Expect

• Additional testing and testers needed
• Limited roll-out extended to certain groups
• Full Roll Out to University community

• Will include Common Rule updates when they are effective
• Will include a Single IRB Interface

What you can do to prepare

• All existing non-exempt studies, regardless of status will have to convert to PittPRO
• Review existing studies and close if possible
  • Data analysis only with de-identified data
  • Studies which include banking where specific aims have been met
• Review studies in pre-submission status
  • Submit or withdraw
Other Things You Need to Know

Study Status

Why is this so important?

- Study Status dictates the level of IRB review (if any) necessary
- Incorrect answers could lead to over-review
- Or worse, under-review and invalidation of collected data
## Which Status?

<table>
<thead>
<tr>
<th>Actions Being Taken</th>
<th>Appropriate Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I’m still enrolling subjects</td>
<td>Remains Ongoing</td>
</tr>
<tr>
<td>2. I’m done enrolling subjects but they’re still completing study visits</td>
<td>Remains Ongoing (Permanently Closed to Enrollment, but Subjects continue to undergo activities)</td>
</tr>
<tr>
<td>3. I’m done enrolling but I’m still reviewing medical records and/or checking for survival</td>
<td>Remains Ongoing (Permanently Closed to Enrollment and Subjects are done with activities)</td>
</tr>
<tr>
<td>4. I’m only analyzing data that I already have</td>
<td>Data Analysis Only</td>
</tr>
</tbody>
</table>

### NOTE OF CAUTION

“Data Analysis Only” does not include continued work with specimens
Certificates of Confidentiality

- October 1, 2017: NIH automatically issues CoC to NIH funded research collecting or using identifiable sensitive information

- Action Items:
  - None with NIH
  - Consent forms must be modified to include CoC language
  - OSIRIS 5.9 must be completed

WePay will be Vincent

- How does this affect your OSIRIS protocol and consent forms?
  - Update at next Modification if Consent Form specifies WePay. Reconsent is not necessary
  - Update at next Modification if OSIRIS specifies WePay
  - No Modification if OSIRIS and/or Consent Form is generic

When modifying: DO NOT SPECIFY VINCENT
Education Requests

• HRPO will provide customized education at your request!

• We can set up a distance learning session in our Learning Center or come to the site of your preference

• Submit a request through www.hrpo.pitt.edu

QUESTIONS?