Common Rules Changes

Implementation Date
January 21, 2019

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IRB-01 Chair

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IRB Assistant Director
Continuing Review
Unless the IRB determines otherwise, continuing review of research will no longer be required for minimal risk research:

• Eligible for expedited review
• That ...involves only one or both of the following...:
  A. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  B. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

*ie: Longitudinal Review*

• Key Point – you still must submit revisions and adverse events!!!!
Studies governed by the FDA (IND, IDE, HDE)

• Informed Consent Changes
  – FDA says OK

• No More Continuing Reviews for Expedited Studies
  – FDA say NO; must continue and no greater than 1 year approval
    • This would then be the justification
    • Not many FDA covered studies fall into “Expedited” review
    • However, Full Board protocols that move to “Longitudinal” status must still provide a yearly Continuing Review
No more Continuing Reviews – So What?

• Institutional Oversight?
  – CR’s prompt study staff to report AE’s, revisions, etc.
  – What’s going on with that study.

• Now What?
  – Beef up Post Approval Monitoring?
  – Workload changes within the IRB?
  – What to do with existing studies?
  – Software issues?

• Documentation for requiring a CR?

• Version control of consent forms (no more expiration dates)?
Stamping of Consent Forms

• Currently after each CR, you receive a newly stamped consent form with the “start” and “stop (or expiration)” dates
• We will no longer include an “stop (or expiration) date
  – For any consent form, Full Board or Expedited
• When you submit a consent form revision, you will receive a new consent with a new “start” date only.
• Pro’s
  – If you never edit your consent form, never have to worry about using an “out-of-date” form.
• Con’s
  – Version control is already a problem, this makes it a little harder on study staff
Institutional Oversight? Options

- The IRB may still require a continuing review, but must document reason
- Replaced with something else
- Just let it go!
  - Both OHRP and AAHRPP have stated that they are expecting institutions to have some oversight of local protocols.
No Continuing Review – Expedited Studies
The UF Solution

• Create a “Status Update” in lieu of CR.
  – Default to every 3 years
  – One question regarding status (prompt to report changes, AE’s)
  – If they want to close, make it easy
  – What if they don’t answer?

• Beef up Post Approval Monitoring
Status Report - Response

• PI and key Study Staff notified at 45 days, 30 days, and 7 days
• If we don’t hear back
  – Study is administratively closed after the 3-year anniversary date.
  – Notification goes out to PI and key Study Staff notifying them of the closure
Your study will be CLOSED in 45 days if you do not take action.

Your study was approved via Expedited Review on 1/4/2018. Please let us know if you wish this to remain an ACTIVE research study or if you are no longer conducting this research, by submitting the Status Report activity, located in the study workspace.

If the study is still ACTIVE, please remember to submit:

- Any revisions to the protocol or study staff now or when they occur
- Any Serious Adverse Events or Protocol Compliance violations

Thanks!
What Happened to the Discretionary Policy?

• It’s on it’s way out
  – 3 yr approval of minimal risk studies if not funded

• What happens if the continuing review comes due after January 21, 2019?
  – You will be prompted to submit a continuing review as is the current practice
  – Once submitted, the subsequent approval will follow the “Status Report” process
Demonstration of Status Report within the myIRB Software

Ivana Simic, Ph.D.
Assistant Director, IRBs
Exempt Review Category Changes
Exemption Changes

• Exempt #4
  – Huge change
  – Involves most “chart review” studies
  – HIPAA authorization is now the driving issue
  – What’s left for Expedited #5?
Exempt #4
Chart Reviews, Tissue Collection

• Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
  i. Publically available identifiable private info or identifiable biospecimens
  ii. Biospecimens or data recorded with no identifiers
  iii. Identifiable info retained, but under HIPAA rule
  iv. Governmental research on identifiable private info if collected under a governmental program for non-research purposes.
Exempt #4 – Secondary Research

- re-using identifiable information and identifiable biospecimens that are collected for some other “primary” or “initial” activity.
- The information or biospecimens that are covered by this exemption would generally be found by the investigator in some type of records (in the case of information) or some type of tissue repository (such as a hospital’s department for storing clinical pathology specimens).
Big Change

- Data or specimens no longer have to be “existing” in order to qualify for Exempt #4!
Case Example - 1

- A PI wants to determine any correlation with some genetic marker for hypertension assayed from a blood sample, with age, gender and blood pressure.
  - If samples and data are purchased from a company, or available by registering with some group or public data\tissue bank.
  - This fits Exempt #4 (i)
    - “Publically available identifiable private info or identifiable biospecimens”
What is “Publicly Available”?

- archives in a public library
- government or other institutional records where public access is provided on request
- a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive.
- if a commercial entity made identifiable biospecimens publicly available to anyone on request or for a fee.
A PI wants to determine any correlation with some genetic marker for hypertension assayed from a blood sample, with age, gender and blood pressure.

If samples and data are obtained from your Pathology Department and your EMR, in order to meet Exempt #4 (ii):

- Either have the Pathology Department link the data to the blood sample, de-identify and send to PI
- PI receives identifiers with blood and data, but only records de-identified data (no link back)
• A PI wants to determine any correlation with some genetic marker for hypertension assayed from a blood sample, with age, gender and blood pressure.
  – Needs to keep PHI
  – Exempt #4 not in play, since (iii) does not reference biospecimens.
  – This could fit under Expedited #5
New Exempt #4

• (iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

• **HIPAA rule doesn’t cover biospecimens**
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
A PI wants to determine any correlation with some genetic marker for hypertension assayed from a blood sample, with age, gender and blood pressure.

- Needs to keep PHI
- All information is in the EMR
- This fits Exempt #4
  - Provided PHI covered by HIPAA rule
  - Consent not the issue, HIPAA Authorization now in play
Case Example - 3

- So if informed consent is no longer in play, but IRB (Privacy Board) has to ensure the HIPAA rule is followed, the IRB must decide to:
  - Require a stand alone signed HIPAA authorization
    OR
  - Waive or alter the HIPAA authorization
Criteria for a waiver or alteration of a HIPAA Authorization

• The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
  • an adequate plan to protect the identifiers...
  • an adequate plan to destroy the identifiers at the earliest opportunity...
  • adequate written assurances that the PHI will not be reused or disclosed to any other person or entity...

• The research could not *practically* be conducted without a waiver or alteration; and

• The research could not *practically* be conducted without access to and use of the PHI.
A PI wants to determine any correlation with some genetic marker for hypertension assayed from a blood sample, with age, gender and blood pressure.

- Needs to keep PHI
- All information is from Medicare data (no tissue)
- This fits Exempt #4 if:
  - The PI is conducting the research on behalf of a federal department or agency
  - Data was all clinically generated
  - Any PHI is covered by HIPAA rule
Exempt #4 - Summary

• Secondary Research (prospective and retrospective) without consent if one of the following:
  1. Publically available identifiable private info or identifiable biospecimens
  2. Biospecimens or data recorded with no identifiers
  3. Identifiable info retained, but under HIPAA rule
  4. Governmental research on identifiable private info if collected under a governmental program for non-research purposes.
<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Have you wished you were dead or wished you could go to sleep and not wake up?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Have you had any actual thoughts of killing yourself?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Have you been thinking about how you might do this?</td>
<td></td>
<td></td>
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<tr>
<td>e.g. &quot;I thought about taking an overdose but I never made a specific plan as to when where or how I would actually do it...and I would never go through with it.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Have you had these thoughts and had some intention of acting on them?</td>
<td></td>
<td></td>
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<tr>
<td>as opposed to &quot;I have the thoughts but I definitely will not do anything about them.&quot;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Have you ever done anything, started to do anything, or prepared to do anything to end your life?</td>
<td></td>
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</tr>
<tr>
<td>Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IF YES, ask: Was this within the past 3 months?</td>
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</tbody>
</table>

Response Protocol to C-SSRS Screening

- Item 1 Behavioral Health Referral
- Item 2 Behavioral Health Referral
- Item 3 Behavioral Health Consult (Psychiatric Nurse/Social Worker) and consider Patient Safety Precautions
- Item 4 Behavioral Health Consultation and Patient Safety Precautions
- Item 5 Behavioral Health Consultation and Patient Safety Precautions
- Item 6 Behavioral Health Consult (Psychiatric Nurse/Social Worker) and consider Patient Safety Precautions
- Item 6 3 months ago or less: Behavioral Health Consultation and Patient Safety Precautions
Demonstration of Chart Review Submission within the myIRB Software

Ivana Simic, Ph.D.
Assistant Director, IRBs
Consent Form Changes
Informed Consent Changes

• Informed Consent
  – Must contain an initial section that provides “...key information that a reasonable person would want to know” to decide if they want to participate.
• New Section in consent template:

5. In general, what do you need to know about this study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

a) In general, what is the purpose of the research, how long will you be involved? **Insert text here**

b) What is involved with your participation, and what are the procedures to be followed in the research? **Insert text here**

c) What are the likely risks or discomforts to you? **Insert text here**

d) What are the likely benefits to you or to others from the research? **Insert text here**

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you? **Insert text here**

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.
Informed Consent Changes

• New statement in consent template section #7:

  “Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative”

• If you are not collecting biospecimens, remove that part!
Informed Consent Changes

• Exceptions to these required changes:
  1. Expedited studies approved prior to January 21, 2019, that are not federally funded.
     a) Don’t have to update to new form at C.R.
  2. If you are using already short consent templates
     a) Banking consent form
     b) Our “Brief” Consent
     c) Waiver of Documentation of Consent form
     d) IRB-02 standard consent form
Miscellaneous Common Rule Changes
1. **Clinical Trial Definition:**
"a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

2. **Human Subject Definition:**
“a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”
3. Removes four categories of activities from the definition of research:

   -- Certain scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship)

4. "Check the box" option for FWA is being eliminated.

   Institutions can, if they desire, continue for purposes of their own internal rules to voluntarily extend the regulations to all research conducted by the institution, but this voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight.
5. Use of a single IRB for multi-site federally funded research – goes into effect in January of 2020

6. Posting of Consent Forms on a national website – not until the website is available.
   – For clinical trials only
   – ClinicalTrials.gov office is assisting in this requirement.
Recent IRB Changes
Recent IRB Changes

• New standard consent form
  – Combined HIPAA into Consent form
  – Template is a page shorter
  – Required for all new submissions
  – No need to revise for existing protocols
### Death & AE Reporting

<table>
<thead>
<tr>
<th>New Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deaths</strong></td>
</tr>
<tr>
<td><em>GMR\MR</em> – All deaths (local or non-local) that are related or the relationship is “more likely than not” (within 5-days).</td>
</tr>
<tr>
<td><strong>AE’s</strong></td>
</tr>
<tr>
<td><em>GMR\MR</em> - Serious &amp; Unexpected and related or the relationship is “more likely than not” (5-days local or not).</td>
</tr>
<tr>
<td><em>GMR</em> – (at Continuing Review only)</td>
</tr>
<tr>
<td>• Only local Serious (but expected) or Unexpected (but not serious - includes an increase in severity or frequency); and</td>
</tr>
<tr>
<td>o Only those that are related or the relationship is “more likely than not”)</td>
</tr>
<tr>
<td>• All previous 5 day reports</td>
</tr>
</tbody>
</table>

* IRB to determine if it is an Unexpected Problem involving Risk to subjects or others (UPR)
* If the IRB receives any death or AE required to be submitted by a study sponsor that is not consistent with these guidelines, the IRB will simply acknowledge receipt.
Ceded Studies / sIRB Studies

• If you want a UF IRB to be the reviewing IRB for a new multicenter study, must meet with the UF IRB “Reliance Team”
• If you are requesting UF to cede the review of a multi-center study to another IRB, submit it, the myIRB smart forms will guide you.
  – It is never a guarantee (local context review)
  – All other reviews are still local (HURRC, OCR, SRMC, COI)
  – Metrics:

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Days to Approve Median</th>
<th>IRB Days Percentage</th>
<th>Study Staff Days Percentage</th>
<th>Reviewer Days Percentage</th>
<th>Meeting Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expedited New</td>
<td>21</td>
<td>5%</td>
<td>70%</td>
<td>19%</td>
<td>0%</td>
</tr>
<tr>
<td>Ceded New</td>
<td>41</td>
<td>4%</td>
<td>89%</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>Full Board New</td>
<td>67</td>
<td>7%</td>
<td>54%</td>
<td>14%</td>
<td>22%</td>
</tr>
</tbody>
</table>
Investigator Guidelines

• Provides a Q & A format for the most common IRB related questions and issues
• Helps offer a consistent response
• Currently 88 - Use them!!!

http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html
IRB Required Researcher Training
Coming Soon - March of 2019

<table>
<thead>
<tr>
<th>Training</th>
<th>Average Time Required to Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Current (min)</td>
</tr>
<tr>
<td>Local IRB Module</td>
<td>20</td>
</tr>
<tr>
<td>NIH\CITI</td>
<td>120</td>
</tr>
<tr>
<td>HIPAA for Researchers</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>150</td>
</tr>
</tbody>
</table>

* If you have a job that requires you to have HIPAA training, you still take that yearly through the Privacy Office!! *
Questions?