

IRB Update

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IRB Changes Risk Level Assessments

Richard Weber, MD, FAAAAI, FACA AI; IRB Co-Chair
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On June 14, 2011, the National Jewish Health IRB voted to change the method of assigning risk to studies involving adult participants. Rather than maintain the current classifications; Minimal, Moderate, and High risk levels, the IRB voted to combine the Moderate and High risk levels into a single category of Greater than Minimal risk. This change took effect July 14, 2011 and we hope it will have a positive impact on the review process.

This change allows the IRB to exercise more discretion when assigning oversight and length of continuing review cycles. The IRB will no longer assign renewal cycles based exclusively on the nature of drugs/procedures, but will also consider expected subject accrual, knowledge of actual or expected harm, and investigator experience with similar trials (among other things). In the past, studies involving high risk procedures had consistently received a High risk assessment with a 6 month continuing review cycle. Under the new classification system some of these studies may receive a 12 month renewal cycle or may be asked to submit for continuing review after a specific number of subjects enroll.

This change will affect submissions at initial and continuing review. More details are provided later in this newsletter. Feel free to contact us with questions.

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Possible Change to Risk Level at Continuing Review

Deb Clayton, MA, IRB Regulatory Affairs Monitor

As described in the article above, the IRB will no longer be categorizing studies as Moderate or High risk.

When a study is reviewed for renewal and had previously had an adult risk assessment of Moderate or High risk, the reviewer will make a recommendation to the IRB to change the risk level for the study to either Minimal or Greater than Minimal risk (depending on current risk to subjects). The IRB will consider the recommendation and vote on the change. If the risk level of any study is changed, the new risk level will be documented in the renewal approval letter.

Additionally, the IRB may decide to change the review period at the same time that the risk level is changed. That information will also be conveyed in the renewal approval letter.

These changes give the IRB more flexibility when making determinations, and no longer “pigeon-hole” studies that may have a procedure involved that previously automatically required a 6 month or shorter review period. This doesn’t mean that there will no longer be studies that require short review periods, usually three or six months, and there will still be studies where PIs and physicians performing “riskier” procedures will be required to personally obtain informed consent from subjects.

Since changing the risk level for studies reviewed by the full committee requires full committee review

and approval, the IRB is mandating that these changes for on-going studies only occur at continuing review for any particular study. Documentation of all of the changes will be contained in the text box on page 1 of the approval letter.

There will be no changes when the IRB determines Child Research Assessment categories since these are clearly defined by the regulations, unless the study is going into data analysis and the category in those cases will be changed to 46.404 is another category was initially assigned.

When preparing the continuing review submission, in the section (currently section 28) there is a pull-down menu. The preparer should select the risk level and/or Child research Assessment category for which they have most recent IRB approval.

These changes are in the early stages and we may still find out things that need to be re-tooled. We ask for your patience as we modify the process if we see a trend that might require some “tweaking”. In the long run, this change reduces the regulatory reporting burden for many studies ongoing at National Jewish Health.

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New COMIRB Liaison to NJH IRB

Wendy Charles, MS, CIP, CCRP, Director Research Regulatory Affairs

I’m pleased to announce that Astrid Eder, PhD, is the new COMIRB liaison to the National Jewish Health IRB. Astrid is the COMIRB Senior Regulatory Analyst and is taking over the liaison role from Ita Leitner.

When National Jewish Health serves as the IRB of record, Astrid will assist with the Facilitated (Secondary) Review process conducted by COMIRB. Likewise, she is particularly helpful when COMIRB serves as the IRB of record for research that will have a portion performed at NJH. She can

provide guidance on how to get NJH employees added to the COMIRB protocol and to ensure all documentation is in place before submitting for Facilitated Review to the NJH IRB.

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Revision of Informed Consent Documents Associated with FDA-Regulated Clinical Trials

Sherri Gabbert, PhD, Clinical Research Quality Assurance Analyst
Deb Clayton, MA, IRB Regulatory Affairs Monitor

As you may be aware, Public Law 110-85 (also known as the FDA Amendments Act of 2007) requires posting of all FDA-regulated clinical trials on www.ClinicalTrials.gov. This law also amended the Public Health Service Act to mandate ClinicalTrials.gov registration and results reporting of “applicable clinical trials” funded in whole or in part by a grant from *any agency* of the Department of Health and Human Services.

On January 4, 2011, the FDA amended the informed consent language regulations to include a specific statement noting that information will be included in the ClinicalTrials.gov database and made available to the public. [Federal Register, vol. 76, no. 2, January 4, 2011, p256; 21 CFR 56 (c).] Therefore, the National Jewish Health IRB requires that informed consent forms for all FDA-regulated protocols include the following newly mandated language. (The language need not be verbatim.)

“A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. law. This web site will not include information that can identify you. At most the web site will include a summary of the results. You can search this web site at any time.”

Procedure for implementing the new rule:

This requirement applies to all FDA-regulated studies reviewed or approved on or after March 7, 2011. The FDA will enforce compliance effective March 7, 2012.

IRB Record Search:

The NJH IRB has examined all FDA-regulated studies reviewed or approved after March 7, 2011. We have notified affected investigators of this requirement and will assist with compliance.

Initial Submission:

Informed Consent documents (for the Main Study) accompanying new applications submitted for

review will be screened for the presence of the new element. Consent forms that do not contain the new language will be returned to the IRB Contact for revision and resubmission. (Note: if there is a sub-study that does not require enrollment in the Main Study the sub-study informed consent must also contain this language. If the subject must enroll in the Main Study in order to participate in the sub-study, the requirement is waived for the sub-study consent forms.)

Continuing Review:

The IRB will verify inclusion of the new required language for these FDA-regulated studies at continuing review.

Voluntary revisions at any time:

The PI may voluntarily, or at the request of the sponsor, submit consent revisions to include this language—even if not required to do so. Submissions to revise the consent form must include the requisite Change to Protocol/Consent form, tracked-changes consent version, and clean version for stamping. The IRB requires that the consent version date be updated as well.

Per FDA guidance, re-consenting of current trial participants will not be required.

The IRB has included the new language in the informed consent templates posted on the IRB website.

If PIs feel that the requirement does not apply to them, they should consult with IRB staff.

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Changes to Submission Forms

Wendy Charles

The IRB normally rolls out submission form revisions each July to stay current with changes to regulations or to clarify confusion. The 2011 changes were delayed one month to accommodate the IRB's change in risk levels. The IRB attempted to make as few form changes as possible. The following is a list and description of changes.

New Protocol Application:

- Removed requirement for High Risk Addendum
- Added explanation that a Grant Proposal is required only if NJH is the grant recipient
- Added line for billing email address
- Added notification of HealthONE's electronic submission system
- Added regulatory jurisdiction options for Department of Defense and "None Known"
- Added reminder to consider subjects who speak only Spanish when justifying exclusion criteria
- Fixed OHRP links
- Modified adult risk level to reflect only two risk choices: "Minimal" and "Greater than Minimal"
- Added a reminder that a Waiver of Informed Consent may be needed if children's data or specimens remain identifiable after age 18

Completion Report and Advertisement

Submissions: Added line for billing email address.

CR Report form, Change Protocol and Consent form, and Change/Update form: Added the option for "Greater than Minimal" to the risk drop-down menu. Also added a line for billing email address.

NJH Biobank form: Added instructions for how to submit updates to approved/acknowledged forms.

NJH Clinical Trials Listing: Modified submission instructions and added Brooke Fritz as a contact in the web team.

We sincerely tried to identify all areas that may be impacted by the new processes described earlier, but we may not have identified all necessary changes. Please let us know if any form is confusing or incomplete.

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