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## National Jewish Health Raises Fees for IRB Review

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

Effective July 1, 2012, there will be an increase in the fees charged by the National Jewish Health IRB to review research not eligible for fee waivers. The IRB has not raised fees since 2009 and it is necessary to adjust fees due to cost increases. Our fees remain consistent with, or lower than, fees charged by other local IRBs.

The fee to review initial submissions is increased from \$1750 to \$2000, and the fee for continuing review and study closure is increased from \$1200 to \$1450.

The fees to review study modifications remain unchanged and study modifications can still be submitted in batches. There is only one fee charged per submitted change/modification batch, regardless of the number or type of changes requested in a batch. The fee (\$250 or \$100) is based on the highest level of review required to process all changes. As a reminder, if a batch of billable amendments is submitted at the same time as a billable continuing review, the IRB will assess separate fees for reviewing the batch of amendments and continuing review.

There is no fee to review additions or removals of investigators or study staff.

The fee increase will be applied to research submitted to the IRB on or after July 1, 2012. The IRB will maintain the previous fee schedule (effective April 1, 2009) for studies submitted prior to July 1, 2012.

If you have any questions about the fee structure or eligibility for a fee waiver, please contact the IRB office. The new fee schedule is available on the IRB website at:

<http://www.nationaljewish.org/pdf/IRB%20Fee%20Schedule.pdf>.

## CONTACT US

National Jewish Health  
Institutional Review Board  
1400 Jackson Street  
Room M211  
Denver, CO 80206-2761

Phone: 303.398.1477  
Fax: 303.270.2292

[nationaljewishIRB@njhealth.org](mailto:nationaljewishIRB@njhealth.org)

For more information, contact:  
Wendy Charles  
[charlesw@njhealth.org](mailto:charlesw@njhealth.org)  
303-398-1855

## FDA Issues Final Guidance on Continuing Review

Wendy Charles

In an effort to harmonize U.S. Food and Drug Administration (FDA) guidance documents with those of the Office of Human Research Protections (OHRP), FDA issued its final version of [Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Continuing Review after Clinical Investigation Approval](#).

Most information in the guidance pertains to IRB review considerations, but the following information is also relevant to researchers.

In the section titled “Trial Progress,” FDA encourages scrutiny of enrollment rates. According to the guidance, *“If enrollment in the study as a whole is too low (either because subject enrollment is too low or subject withdrawal is too high), there may not be justification to continue exposing subjects to the risks of the test article because the study itself may no longer be expected to provide sufficient data to answer the scientific question at hand.”*

To address low enrollment, FDA encourages IRBs to evaluate issues affecting enrollment and/or recommend appropriate steps to remedy the situation (e.g., proposals for modification of recruitment practices, adjustment of inclusion criteria, evaluation of reasons for excessive withdrawal, etc.). Therefore, the National Jewish

Health IRB will likely follow-up with researchers who list lower-than-expected enrollment or retention rates.

FDA further clarifies provisions when there is a lapse of IRB approval. Specifically, temporary continuation of already-enrolled subjects may be necessary or appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects (e.g., investigational chemotherapy regimen in an oncology trial), or when withholding those interventions poses increased risk to subjects.

If the investigator determines it is in the best interests of already-enrolled subjects to continue in the research after IRB approval has expired, the investigator should verify that the IRB agrees with continuation as soon as possible. At National Jewish Health, the investigator may petition the full committee or the IRB Chair for a determination, depending on the urgency of the request. The IRB may make a determination for all enrolled subjects as a group or for individual subjects. Investigators may only resume enrollment once continuing review and approval by the IRB has occurred.

To read the entire FDA guidance document, visit: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>.

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## Please remember ...

### Internal Grant Reviews (IGRs):

- 1) To facilitate the IRB’s congruency evaluation, please provide a copy of the grant proposal or progress report for any IGR associated with a specific IRB-approved research study.
- 2) Please remember that the IRB requests 48 hours to process any IGR that lists an IRB-approved study. (This amount of time allows IRB staff to compare the content of the grant proposal or progress report to the IRB-approved protocol.) However, when IRB review is “pending,” any IRB staff member can sign the IGR immediately.

### Curricula Vitæ (CVs):

April 14, 2012 marks the three year anniversary of the IRB’s request for investigators to provide CVs for IRB review. Because CVs expire after three years, please remember that many investigators will soon be required to provide an updated CV.

A study cannot be approved or renewed if a current (within three years) CV is not on file for all investigators.