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## Reminder about Increase to Review Fees

For studies submitted to the National Jewish Health IRB after July 1, 2012, there is an increase in the fees to review research not eligible for fee waivers. 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.

For more detail about the review fees, refer the [April 2012 Newsletter](#).

## Recruiting New National Jewish Health Patients

**Ron Berge, Executive Vice President, Chief Operating Officer, and Chief Compliance Officer**  
**Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer**

Some researchers have recently asked if it's acceptable to send a letter to future patients or enclose it with the new patient packet suggesting to them that they might qualify for a research study in which they are enrolling patients. An argument could be made that the scheduled patient is now being treated by the NJH physician and thus the physician/researcher has the legal authority under HIPAA to contact the patient. But has a treatment relationship begun before the patient arrives on campus? We believe not. More importantly, we believe it sends a bad message to the individual who has made an appointment. It puts NJH in a position of putting our goals above our patients' goals and that simply isn't true. Yes, research is one of our primary missions but we worry that a new patient could get the impression that if they don't enroll in a study they may not get the best care possible. We will not put ourselves or our patients in that position. Subject recruitment should begin after patients have begun their treatment here.

Finding enough qualified individuals to participate in your research study is often not easy. Subject recruitment can include one or all of the following methods: contact your own patients, ask your colleagues for permission to contact their patients, post flyers, run media ads, etc.

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# IRB Provides New Templates for Informed Consent forms

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

The IRB Office recently created some templates to help researchers obtain informed consent.

1. [Standard statements for risks and procedures](#)

This document provides suggested language that can be inserted into informed consent documents to describe common procedures or risks. The document features a Table of Contents on the first three pages to help researchers locate desired topics more quickly. The Table of Contents also features internal hyperlinks to assist with document navigation. To jump to a desired topic listed in the Table of Contents, hit the CTRL key and click on the topic description.

2. [Scripts to obtain verbal informed consent](#)

When determining study eligibility by phone, there is often need to collect identifiable information about subjects. Likewise, researchers often need to instruct subjects to complete a questionnaire or to withhold food or certain medications before subjects provide written informed consent and authorization. These activities are considered regulated research activities and require verbal informed consent (under a Waiver of

Documentation of Informed consent and a Partial Waiver of HIPAA Authorization). For the IRB to approve a verbal informed consent process, we need to know what researchers plan to say to obtain informed consent.

We are providing two sample telephone scripts researchers can use to describe the planned telephone interaction.

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Please let the IRB Office know if you find any errors with these documents or have any questions.

As a reminder, the wording in consent templates should only be considered as a starting point to writing consent descriptions. Any wording should be customized to the unique circumstances of each study.

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## Honest Broker Process: Size and Origin of the Subject Population Matters

Pearlanne Zelarney, MS, Research Data Curator  
Ted Wade, PhD, Principal Investigator, Honest Broker System

A main concern of the Honest Broker process is protecting patient confidentiality and also providing samples and data in a non-human subject research manner. If the researcher is requesting data from a population that they initially gathered (in a research protocol) or if the population is small and easily identifiable by the researcher, we can no longer protect patient confidentiality. This means that an Honest Broker cannot recode a researcher's own data or sample repository for use in a new non-human subjects research study. If a researcher works exclusively on the same subject population and had previously received a limited dataset or specimens for that population, or the dataset/specimens are from a patient population

that is very small and/or has a rare disease diagnosis, there is a greater risk of unintentional re-identification by the requesting researcher. In those cases, the Honest Broker will need to completely de-identify the sample or data.

To access Honest Broker services, visit the [Research Database web page](#) and click on the *Honest Broker Services* tab.

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