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IRB Update

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THIS ISSUE

Transitioning Pager Numbers listed in Consent Forms

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

On February 14, 2014, all National Jewish Health active pager contracts with paging vendors will be terminated. Please note that some research consent forms list a pager number as the contact number for the PI and/or other members of the research team.

If a pager number is currently listed in your informed consent form(s), there are three steps for proceeding:

1) If you would like a temporary extension of your pager number, contact Lots Pook (PookL@NJHealth.org) before **February 14, 2014**.

2) You need to inform new and currently-enrolled subjects of the new contact number.
   a. For situations where subjects may provide initial informed consent after your pager is turned off, revise the informed consent form(s) to include the new phone number.

   b. For situations where subjects have already provided informed consent, please reach out to subjects in a manner appropriate to your study and subject population. Consider the desired communication plan and methods simultaneously.

      The communication plan should be based on the following:
      - How long the pager number will remain active
      - Likelihood that a subject will need to contact you about an urgent study-related matter
      - Frequency of study visits
      - Number of subjects in the study
      - Whether other contact numbers are provided in the event of an urgent situation

      There are many methods of communication that may be appropriate for the change in pager number. Here are some examples: (Next page)

CONTACT US

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Transitioning Pager Numbers (continued)

- Send a letter to all subjects via postal mail
- Telephone all subjects now, document the calls, and provide a follow-up letter / sheet at a later date
- Provide an Information Sheet at the next study visit
- Ask subjects to sign a consent addendum with signature obtained at the next study visit or through the mail
- Ask subjects to sign a revised consent form with signature obtained at the next study visit
- If you have an existing email communication relationship with subjects, you may send a secure email. Type "Encrypt" in the subject line of your NJH email to instruct the NJH email server to encrypt the email, directing the subject to the NJH secure email server.

Your communication plan may feature a combination of approaches to reach all subjects before the pager is turned off. As examples:

- If the pager is planned for discontinuation in three months, a researcher may propose to provide an Information Sheet to all subjects whose visits will take place in those three months, and send letters to those subjects not planning to come in for a visit during that time.
- If the pager is planned for discontinuation in one month, a researcher may propose to telephone all enrolled subjects, then give these subjects an Information Sheet at the next regularly scheduled visit. (For higher risk studies, the IRB would ask that the Investigator mail the Information Sheet to provide the documentation in a more timely manner.)

3) Submit to the IRB.

   a. When submitting a document to the IRB to list a new phone number, include your plan for communicating with currently-enrolled subjects. You can provide the plan information directly on the *Change to Protocol or Informed Consent Form* application that will accompany your amended documents. (http://www.nationaljewish.org/getattachment/professionals/research/support/compliance/irb/submissions/irb-amendments/IRB-Change-Protocol-and-Consent.doc.aspx)

   b. Submit your proposed amendment(s) and communication plan(s) to the IRB office **7-10 days before** your pager is turned off.

Please contact the IRB at 303-398-1477 with any questions about this process.

For more information, contact:
Wendy Charles
charlesw@njhealth.org
303-398-1855

Reminder: Consent form templates were revised in November

Wendy Charles

To include the latest provisions from the HIPAA Omnibus Rule, the IRB Office, together with the Privacy Officer and Director of Health Information Management, revised the consent form templates on November 7, 2013 to include more information about subjects' rights under the Omnibus Rule. Please review the November 2013 IRB Newsletter for more information about the changes related to the Omnibus Rule.

We are urging all researchers to use the latest versions of the consent/authorization form templates from the IRB website: http://www.nationaljewish.org/professionals/research/support/compliance/irb/submissions/informed-consent. The IRB will issue stipulations if the new text is not included in newly submitted consent/authorization forms. Researchers have the option of amending existing consent forms.

March Research Managers Meeting

Wendy Charles

In the March Research Managers Meeting, Pearlanne Zelarney and I will present strategies for conducting retrospective research using the National Jewish Health Research Database (NJHRDB) with the fewest regulatory obstacles.

We will answer the following questions:

- What is the NJH RDB and what does it contain?
- What is the Honest Broker program?
- How do I apply to access the RDB or Honest Broker services?
- How do I describe use of the RDB or Honest Broker in my IRB application?
- How can I design my research to increase the likelihood of receiving an "exempt" or "non-human subject" determination from the IRB?

The next Research Manager's Meeting will be held:

March 7, 2014
J105
Noon – 1pm

I've been compiling an email distribution list of research managers and team leads, but I fear I am missing many individuals who serve in a leadership role on their research teams. Please send me an email if you would like to receive future Research Manager meeting notices.

For more information, contact:
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303-398-1855

Research Procedures versus Standard of Care

Warren Capell, MD, COMIRB Director [Reprinted with permission]

The IRB is required to differentiate between procedures that are performed for research purposes and those that are part of a subject's standard care. Ideally, the protocol is written to clearly communicate these differences, but this is not always the case. The Application Form asks the PI to distinguish research procedures from standard care procedures.

Despite this request, it is sometimes difficult for the IRB to sort out whether certain procedures are being performed for research purposes; the distinction, however, is critical for the IRB to judge the risks of the research and ensure research procedures and risks are adequately communicated to subjects.

Here are two characteristics that can help differentiate research from non-research procedures:

Research procedures are dictated by the protocol.

- Protocols describe the procedures needed to maintain a controlled intervention or collect meaningful outcome data. If the protocol (and consent form) is specific as to the type, timing, and/or frequency of a procedure, that procedure should be considered a research procedure. With treatments, if the protocol dictates the treatment choice, dosing, route of administration, frequency, or intensity, that treatment should be considered a research procedure. If it is not necessary to control these aspects of a procedure for the purposes of a study, specifics on how that procedure is performed would not need to be detailed in the protocol.
- Procedures that are not performed for research can be listed or referenced in the protocol, but should be communicated 'as determined by the treatment provider.' If the procedure will happen strictly as part of the subject's care, even if that procedure is important to the study, its specifics can be left up to the patient-provider relationship.

This criterion is the best way to distinguish research from non-research. Again, investigators do not always describe procedures according to these conventions; but understanding this difference can help the IRB communicate with investigators about their research protocols.

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Research procedures are (often) paid for by the research study.

- Providers can typically only bill treatments/procedures that are given strictly for purposes of patient care. These treatments/procedures will usually be FDA-approved and necessary in the normal care and monitoring for patients with the condition being studied. The 'Will I Have to Pay?' section of the consent form can sometimes be used to help decipher which procedures are for research purposes only and which are part of a patient's care.
- Procedures that are performed only for research purposes can be unapproved, investigational treatments. They might also be procedures performed with FDA-approved clinical equipment, but are beyond the monitoring necessary for the care of the patient's condition. Procedures not necessary for caring for patients should generally not be billed to subjects in a research study.

This line of differentiation is also prone to uncertainty, and the IRB is often in a position of needing clarification between this consent form section and the protocol. Some non-FDA-approved investigational devices can be legally billed to the patient or insurance, which muddies this distinction.

Sometimes, research is comparing different forms of FDA-approved treatment options. Even though the treatments/procedures are considered research procedures, they are the typical treatments/ procedures the subject would have received if there had been no study, and clinical billing is appropriate. Good communication from the investigator is often required.

Examples:

1) Following a certain type of shoulder surgery, it is standard of care to obtain follow-up X-rays of the shoulder at 6 months. The research protocol calls for shoulder X-rays outcome measures at 3, 6, and 12 months after the surgery. The protocol should ideally communicate that X-rays will be performed at 3 and 12-months post-operatively for research purposes, and that the results of clinically-obtained X-rays at 6 months will be used in analysis. Subjects can be billed for the 6-month X-rays, but the study should provide the 3 and 12-month X-rays at no cost to the subject or insurance.

2) A new blood pressure medication (AX-10113) is being compared to a control treatment of ACE-inhibitor. The administration of AX-10113 is a research procedure, but the administration of the ACE-inhibitor could be either research or standard care, depending on how the protocol is written:

a. ACE-inhibitor administration is a research procedure: The protocol states that subjects in the control arm will be given lisinopril, starting at 10mg daily and titrated up every 4 weeks until blood pressure control is obtained. In this case, the exact drug, along with the dosing and timing, are specified (dictated) by the protocol and should be considered a research procedure.
b. ACE-inhibitor administration is not a research procedure: The protocol states that subjects in the control arm will be treated with an ACE-inhibitor, as determined by their primary provider. One of the inclusion criteria for this study is that the clinical decision has been made to begin ACE-inhibitor therapy. In this case, any subject who is enrolled will already be receiving a medication from the ACE-inhibitor family, and the specific drug, dose, timing, etc. is all left up to the subject's provider. The protocol does not dictate the use of the control drug, and is therefore not a research procedure.

Summary:

In summary, the research subject must be aware of what is being asked of them for research purposes only, and the risks of those procedures. Without this knowledge, a potential subject cannot accurately weigh the risks and benefits of research.

The IRB must also be able to distinguish between procedures being done for research purposes only and procedures being performed outside of the research, to make those same judgments and to ensure that risks and benefits are adequately communicated to subjects. Considering the detail with which the procedures are dictated by the protocol, and whether subjects will be billed for the procedures, can help the IRB differentiate research from non-research.