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IRB Update

MARCH 2013

THIS ISSUE

Overview of new HIPAA Omnibus Rule 1
Guidance on Medical Release forms 2
Change in IRB Staffing 2
Please remember… 2

Overview of new HIPAA Omnibus Rule

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs
Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

The U.S. Department of Health and Human Services (HHS) released new regulations effective March 26, 2013 to strengthen the privacy and security protections for health information established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The previous HIPAA Privacy and Security Rules focused on health care providers, health plans and other entities that process health insurance claims. The new omnibus rule greatly enhances a patient's privacy protections, provides individuals new rights to their health information, and strengthens the government's ability to enforce the law.

Of interest to researchers, the final rule reduces burden by streamlining subjects' ability to authorize the use of their health information for research purposes. The rule appears to allow subjects to authorize research on their health information for "future use" as long as the future plans are sufficiently specific. NJH and UCD compliance officials are evaluating options to make the authorization language more flexible.

The changes also strengthen the Health Information Technology for Economic and Clinical Health (HITECH) breach notification requirements by clarifying when breaches of unsecured health information must be reported to HHS. The rule changes from a harm-based assessment to a more objective standard.

For clinical care, individual rights are expanded in important ways. When individuals pay for health care services by cash, they can instruct their provider not to share information about their treatment with their health plan. Patients can also ask for a copy of their electronic medical record in an electronic form. The final omnibus rule sets new limits on how information is used and disclosed for marketing purposes and prohibits the sale of individuals' health information without their permission.

There are many additional requirements in the final rule, and we plan to provide you with frequent updates on how these changes will affect research. To read the final omnibus rule, go to the U.S. Government Printing Office website.

CONTACT US

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Guidance on Medical Release forms

Wendy Charles, Steve Leibold, and Kathy Flesher, Manager, Health Information Management.

When an Investigator plans to supplement medical history for a research study by obtaining medical records from other health care providers, the IRB office will ask researchers to prepare a study-specific *Authorization to Release Protected Health Information* form (HIP-024) template. This will ensure that subjects (or prospective subjects) are provided with a sufficiently complete form to ensure proper communication among institutions.

An instructive guide to preparing a HIP-024 template is provided on page 3 of this newsletter.

For more information, contact:

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Change in IRB Staffing

Wendy Charles

Diana Pruitt, the Regulatory Affairs Review Specialist for two years, recently transitioned to a new role at National Jewish Health. Diana will be working in the Clinical Research Unit part-time as a Regulatory Specialist.

Bruce Van Der Kamp joined the IRB staff after serving as a community member of the IRB for the past three years. Bruce will be assisting with every type of review, but you may have the most interaction with Bruce regarding continuing reviews.

Next time you come to the IRB office, please introduce yourselves and help us welcome Bruce to the National Jewish Health compliance team.

Please remember…

Conflict of Interest Disclosures for all Researchers:

National Jewish Health implemented a new requirement for conflict of interest disclosures. All individuals (principal investigators, co-investigators, research coordinators, technicians and other research staff) listed on a protocol submitted to the IRB or IACUC must complete a study-specific Conflict of Interest and Scientific Misconduct form.

This requirement was implemented for new human or animal protocols submitted or reviewed after January 1, 2013 or for personnel added to a protocol after January 1, 2013.

Research Submissions may be Returned:

The IRB tries, whenever possible, to accommodate submissions in development. However, increasing numbers of submissions have been dropped off at the IRB office for review and approval with major components missing. The IRB cannot review or make determinations for incomplete submissions.

In an effort toward enhanced quality control and to improve document tracking and accuracy of the review process, submissions will now be examined when they are dropped off at the IRB office. If submissions are incomplete, they will be returned to the Investigator or IRB Contact with an explanation of the missing items. Submissions for full committee review will not be scheduled for review until the submission is complete.

Helpful tip:

When a research study involves enrollment of subjects that may need reading glasses, consider purchasing a few pairs of reading glasses you can loan to subjects during research visits.
(Thanks to Jennifer Brandorff for this great tip!)

National Jewish Health

Authorization to Release Protected Health Information

Patient Information

Full Name _____ Medical Record # _____

Address _____

City _____ State _____ Zip _____

Phone # _____ Date of Birth _____

I hereby authorize:

☐ National Jewish Health - Main Campus 1400 Jackson St Denver, CO 80206 PH (303) 398-1580 FAX (303) 398-1211

☐ NJH - Highlands Ranch 8671 S. Quebec St. Ste 120 Highlands Ranch, CO 80130 PH (303) 703-3646 FAX (303) 738-1385

☐ NJH - South Denver 499 E. Hampden Ave. Ste 300 Englewood, CO 80113 PH (303) 788-8500 FAX (303) 788-8505

☑ Other:

Name/Title Organization

Address

City/State/Zip Phone Fax

Release To

Release to:

☐ National Jewish Health - Main Campus 1400 Jackson St Denver, CO 80206 PH (303) 398-1580 FAX (303) 398-1211

☐ NJH - Highlands Ranch 8671 S. Quebec St. Ste 120 Highlands Ranch, CO 80130 PH (303) 703-3646 FAX (303) 738-1385

☐ NJH - South Denver 499 E. Hampden Ave. Ste 300 Englewood, CO 80113 PH (303) 788-8500 FAX (303) 788-8505

☑ Other: National Jewish Health, Attn: (Name of Contact), (Contact's Title)

Name/Title Organization

1400 Jackson Street, (Building and room number of contact)

Address

Denver, CO 80206 (Phone of contact) (Fax of contact)

City/State/Zip Phone Fax

☐ Other:

Name/Title Organization

Address

City/State/Zip Phone Fax

Purpose & PHI Disclosed

☐ Continuation of Care ☐ Insurance ☐ Legal ☐ Personal Use ☑ Other Research Participation

(Mark all appropriate boxes for desired info)

HS#, (name of disease studied)

For Treatment Date(s) _____

☑ Clinic Summary/Consultation ☐ Procedure ☐ Laboratory/Radiology ☐ Pulmonary Test ☐ Cardiology Test

☐ Other (If you want very specific information, mark the box for "Other," and list details here.)

Fees

Pages	1-10	11-40	41+
Patient	$14.00	.50 each	.33 each
Others	$16.50	.75 each	.50 each

According to Colorado State Statute, 6 C.C.R. 1011-1, Chapter 2 Part 5.2.3.4 the following fees may be charged for copies of medical records. Records will be provided to other health care providers at no charge.

Authorization

_____ By **initialing** this area, I authorize the release of my health records that may include information indicating the presence of communicable or venereal diseases, which (If the IRB has approved collection of sensitive information, flag one or both boxes for subjects to put their initials. Otherwise, type "N/A" in the box(es). n as Acquired Immune Defici

_____ By **initialing** this area, I authorize the release of my health records that may include information about behavioral and/or mental health services and/or treatment for alcohol and/or drug abuse.

This request is made voluntarily and the information given is accurate to the best of my knowledge.

I may revoke this authorization at any time in writing, but if I do, it will have no effect on actions taken prior to receiving the revocation.

I understand that information disclosed pursuant to the authorization may be subject to redisclosure by the recipient and is no longer protected by the HIPAA privacy rule.

Without my express revocation, this consent will automatically expire 180 days from the date signed below, unless I request an expiration date less than 180 days.

Signature

My signature is required to validate this Authorization. If I sign this form, my health care, the payment for my health care or my ability to enroll for benefits will not be affected.

Patient or Authorized Representative Signature Date Relationship