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## Contacting Patients for Prospective Research Participation

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

National Jewish Health recently re-evaluated its position as to whether research coordinators or recruiters can directly contact clinical patients of Investigators for research purposes.

After reviewing the current practice at University of Colorado Hospital, National Jewish Health decided to adopt their policy and permit direct patient contact by research coordinators under certain conditions.

Whether the coordinator or recruiter sends a letter or places a telephone call, they must communicate to potential subjects that:

- 1) They work with the patient's doctor and name that doctor stating, for example, "I am Abby Road and I work for Dr. Penny Lane at National Jewish Health."
- 2) Then state that they are contacting potential subjects with the permission of the doctor, name the doctor, such as "Dr. Penny Lane".
- 3) They will notify the subject's doctor if they decide to join the study.

Additional requirements:

- 1) Research Coordinators or recruiters may only contact patients who are patients of investigators listed on the study.
- 2) Research coordinators or recruiters may not contact patients on campus directly without the patient's permission. When patients are on campus, the doctor may ask patients if they are interested in discussing a research study with the research coordinator. After the patient agrees to this request, the research coordinator may then see the patient to discuss the research study.
- 3) Limit the number of attempted contacts to three. Beyond 3 attempts, patients tend to feel harassed.
- 4) As usual, the recruitment method must be approved by the IRB.

## CONTACT US

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## Recruitment Strategy - Making Changes Post-Initial Approval

Deb Clayton, MA, IRB Regulatory Affairs Monitor

It has been my experience as an IRB Reviewer at NJH for several years that the subject recruitment strategy for any study can change during the life of that study. Most frequently, the study staff decides to try an additional strategy than what was included in the initially approved proposal. I encourage Principal Investigators and their staffs to think strategically when developing the recruitment strategy in the New Protocol Application, considering all of the things that could be implemented to maximize enrollment. Sometimes it isn't possible to consider everything when developing a recruiting plan. It is possible to amend that initial plan by submitting a few items to the NJH IRB for review, approval and/or acknowledgement.

If the PI decides to use the study as a recruitment database after the study commences, he or she can amend the New Protocol Application to add that provision. Also the PI would have to create a separate HIPAA authorization (HIP-004) for the study describing what subject information will be retained for the database. The database authorization is separate from the HIP-004 for the

research project. If the PI wishes to contact subjects enrolled in the study for possible participation in future studies that should also be described in the New Protocol Application and HIP-001 allowing future contact should be also be submitted.

As a reminder, if web advertising or flyers weren't approved as part of the initial strategy, it is not enough to submit an ad, add language or a flyer to the IRB for review and approval. The recruiting section of the New Protocol Application must be amended to include any new type of recruiting strategy before subjects are recruited.

As with all things, if you have any questions, please feel free to give us a call. We are glad to help!

For more information, contact:

Deb Clayton  
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## Obtaining Services from HCA-HealthONE Facilities

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

As a friendly reminder, be aware that for any human subject research study that may require the services from any of the HCA-HealthONE facilities, a Facility Services Agreement will be required. The type of services involved may include one or all of the following:

- Inpatient / outpatient services
- Pharmacy
- Lab Services
- Radiology
- Nursing Services

Facility Ethics and Compliance Officer:

The primary contact for making these arrangements is through the Ethics and Compliance Officer (ECO) assigned to each facility. ECOs are available to assist researchers in making arrangements for research-related services and drafting contractual agreements. It is strongly

recommended to contact the appropriate ECO prior to obtaining final IRB approval in order to avoid delays in starting the project.

ECO Phone Numbers:

The Medical Center of Aurora: 303-695-2834  
North Suburban Medical Center: 303-450-4510  
Presbyterian/St. Luke's Medical Center:  
303-839-6772  
Rose Medical Center: 303-320-2646  
Sky Ridge Medical Center: 720-225-1362  
Spalding Rehabilitation Hospital: 303-363-5605  
Swedish Medical Center: 303-788-5270

For more information, view the HCA-HealthONE Facility Services Agreement website:  
<http://healthonecares.com/research/submitted-obtaining-services-from-hca-healthone-facilities.htm>

# Requirements for Identifying Prospective Subjects

Wendy Charles  
Steve Leibold

Now that coordinators and recruiters may telephone patients of investigators, they may believe they can now identify prospective subjects from medical records. Be aware that accessing medical records to determine a subject's eligibility for research participation is considered a regulated activity under both the Common Rule and Privacy Rule. Both the Office for Human Research Protections (OHRP) and the Office for Civil Rights (OCR) provide guidance on this topic. Here are some basics:

## Common Rule:

<http://answers.hhs.gov/ohrp/questions/7257>

Although the HHS regulations do not specifically reference medical record searches, such an activity must be reviewed and approved by an IRB when the activity involves human subjects research and the research does not meet the criteria for exemption.

In general, informed consent of the subjects, or parental permission for children involved in research, must be sought and documented.

In order to permit investigators to obtain and record identifiable private information for the purposes of identifying potential subjects, the NJH IRB can waive the requirement of informed consent for such activities. In assessing the level of risk to determine whether a waiver of informed consent or parental permission is permissible for the identification of potential subjects, the IRB need only consider the risk of investigators accessing the subjects' identifiable private information, not the risks of the research in to.

## Privacy Rule:

<http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp>

If the covered entity obtains documentation that an IRB has partially waived the Authorization requirement to disclose PHI to a researcher for

recruitment purposes, the covered entity could disclose to the researcher that PHI necessary for the researcher to identify and contact the individual.

## Guidance:

Here is some general guidance to ensure correct compliance through the IRB, Privacy Board, and other departments:

- 1) The process for screening records for prospective subject eligibility must be described in the New Protocol Application.
- 2) The investigator must request a Waiver of Informed Consent.
- 3) The investigator must request a Waiver of HIPAA Authorization.
- 4) For access to paper records or the EMR, the Health Information department will request the approved Waiver forms (or the IRB approval letter) before allowing access to paper medical records. The Privacy Officer or the EMR manager may perform an audit of access to EMR and may request verification of proper authorization.
- 5) For access to the National Jewish Health Research Database for recruitment, the investigator must complete the Supplemental Access to NJH Repositories form.
- 6) Only members of the direct patient care team may access their patients' PHI in the EMR, paper medical records or the NJH RDB unless a patient authorization has been obtained.
- 7) The investigator may not record or receive information for determining prospective subjects' eligibility for a particular study until that study receives IRB approval and waivers are granted.

For more information, contact:

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## IRB Education Schedule

Deb Clayton

On Tuesday, February 8, 2011 from 10:00 - 11:00 am, Deb Clayton will give a presentation for new researchers, fellows, study staff and anyone who thinks they might need a refresher on Human Subjects Research and How to Work with the NJH IRB. More information will be available as the session is closer. This is a must-see for folks who are new to human subjects research at NJH!

02/08/2011	New Researcher Orientation	Deb Clayton	10:00 - 11:00 am
03/01/2011	Investigators' Responsibilities in Research: Two Physician-Researcher Perspectives Richard Weber, MD & Phillip Corsello, MD		10:00 - 11:30 am (90 min)
04/05/2011	Conflicts of Interest in Research and how they are Managed		10:30 - 11:30 am
05/03/2011	Informed Consent: Policy, Process and Documentation (includes: exculpatory language and subject compensation)	Deb Clayton	10:00 - 11:30 pm (90 min)
06/07/2011	Unanticipated Problems	Wendy Charles	10:30 - 11:30 am

All sessions are in Heitler Hall.

For more information, contact:

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