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Human Subjects Protection Update Children's Hospital, Boston

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www.childrenshospital.org/research/irb

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**Advance Notice of
Proposed Rulemaking:
Request for Comment**

**Guidance on Use of
Personal Cell Phones
For Recruitment and
Communication with
Research Subjects**

Advance Notice of Proposed Rulemaking: Request for Comment - Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators

The U.S. Department of Health and Human Services announced that the federal government is contemplating various ways of enhancing the regulations overseeing research on human subjects. They have provided an advanced notice of proposed rulemaking. This provides the government with an opportunity to receive comment on specific topics before actually proposing regulations. Revisions to the current regulations are now being considered because HHS believes these changes will strengthen protections for research subjects in a number of important ways and eliminate unnecessary burden and delay. There are over 70 questions that HHS would like to receive comments on, however you should feel free to respond to any specific questions or issues of interest. In addition you may provide comments on topics that are not specifically addressed. The deadline for submitting comments is October 26, 2011.

The Hospital has submitted comments from an institutional/administrative perspective. We realize this may not reflect the opinions of others in the clinical research community therefore, we encourage investigators to review these proposed changes and submit comments either individually or through their respective professional organizations. Information on how to submit comments can be found at

<http://www.hhs.gov/ohrp/humansubjects/submitanprmcomment.html>.

A copy of the Children's Hospital response may be found at:

http://childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/ChildrensFinal.pdf

HHS has also posted all comments received on the internet. This may be found at <http://www.hhs.gov/ohrp/humansubjects/readanprmcomment.html>

As a summary, comments are sought on the following:

1. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk. This includes the proposal to eliminate the ability to use discarded specimens without the written consent of the subject. The ability to waive consent as it is currently practiced will no longer be permitted (Please note this has significant implications for the research community at Children's)
2. Using a single Institutional Review Board review for all domestic sites of multi-site studies.
3. Updating the forms and processes used for informed consent.
4. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
5. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to

harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.

6. Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.
7. Providing uniform guidance on federal regulations.

The following chart helps summarize the changes:

<http://www.hhs.gov/ohrp/humansubjects/anprmchangeable.html>

The Advance Notice of Proposed Rulemaking (ANPRM) can be found at <http://www.hhs.gov/ohrp>. Additional information about the changes under consideration can be found at <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>.

NOTE: The ANPRM comment period closes October 26, 2011.

Guidance on Use of Personal Cell Phones For Recruitment and Communication with Research Subjects

The Committee on Clinical Investigation often approves of the use of the telephone to recruit research subjects. In many cases, the committee will require an introductory letter prior to a phone call, however there are limited situations when just an initial call is acceptable. The types and methods of recruitment are approved on a protocol by protocol basis. The Committee requires that any initial phone contact for recruitment purposes be made on a Children's

Hospital telephone (one that will indicate it is Children's Hospital on caller ID). It is important that subjects know (through caller ID) that the call is a legitimate call from Children's Hospital. Once initial contact is made and you have established a relationship with the potential subject, it is acceptable to use other personal phones with the following guidelines.

1. It is highly recommended that when using personal phone you should use the *67 feature when placing the call to prevent your actual cell phone number from being displayed.
2. In situations where you are concerned that recipient phones will block all non-identified calls or you want your number to be displayed, you should advise subjects during initial contact as to how they will be contacted and by whom so they will recognize the calls.
3. Please remember to only use cell phone where appropriate confidentiality can be maintained. Calls should not be made in public locations where others may hear the conversations.

These guidelines assure the appropriate human subject research protections while allowing flexibility as to when and how subjects are recruited. If there are reasons to deviate from these practices, they should be addressed in the protocol and the IRB will review and approve them as appropriate.

(Please note this policy was developed after the hospital and IRB received a significant complaint from a parent who received a call from a research coordinator who was using a personal cell phone and the Caller ID was an out of state number. The parent had not received an initial recruitment letter and questioned whether the call was legitimately from Children's Hospital.)