PRINCIPAL INVESTIGATOR REQUEST FOR
WAIVER OF HIPAA PRIVACY AUTHORIZATION FOR RESEARCH

Please provide contact information for a representative who can answer any questions that the IRB might have concerning this submission:

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<th>Name:</th>
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<td>2nd Contact: name + e-mail or phone number</td>
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This box is for IRB use ONLY.

Form Instructions:
- Enter the information in the appropriate fields on this page.
- You will need to provide specific information after question 2. Please delete the text "<Type your response here>" and enter your answer. Instructions on how to answer the question are in a box following this line. Delete the instruction box after answering the question.
- All submissions must be typed.
- If you are submitting this form as part of a regular submission, you must submit 4 copies (the signed original plus three photocopies) along with the rest of your paperwork.
- If you are submitting this form by itself, please submit just two copies (the signed original plus one photocopy) of this entire form.
- This form is available on the IRB-01 website at: http://irb.ufl.edu/irb01/hipaaforms.htm
- This form is available on the IRB-03 website at: http://www.hscj.ufl.edu/irb/forms.asp

Date: May 31, 2012
Principal Investigator: ___________
IRB Project #: ___________
(if known): ___________
Project Title: ___________

The Principal Investigator must: (1) initial all of the blanks at questions 3, 4, 5, and

HIPAA Waiver Request for IRB Project #: ___________
IRB version 04/19/2011 05/30/2012
PI version 5/31/2012 1:49:42 PM 6/24/2012 8:54:11 AM 23/2012 1:38:00 PM
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1. **This is** a request to waive patient authorization **to enroll** subjects in the study?

   - [ ] No. Go to Question 2.
   - [ ] Yes. Go to Question 3.

   for: (check all that apply)

   - [ ] identifying and recruiting subjects.  
   - [ ] enrolling subjects.

2. **Is this a request to waive patient authorization to identify and/or contact potential subjects for the study?**

   - [ ] No. Do not proceed or submit this form.

   - [ ] Yes. Will you disclose identifiable information to anyone **outside** your covered entity (e.g. release initials, names, birthdates, etc of people who do not meet eligibility criteria to the study sponsor)?

   - [ ] No. Do not proceed or submit this form.

   - [ ] Yes. Go to Question 3.

2.3. **The following protected health information will be created, you collected, create, used or disclosed as a result of (a) the need to identify subjects or (b) the subject's participation in this research under this waiver (see hidden text for suggested language):**

   <TYPE ANSWER HERE: Principal Investigator must describe PHI >

34. **I certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least the following three elements (a, b, and c):**

   a. An adequate plan is in place to protect the identifiers from improper use and disclosure. The plan is described as follows. Indicate how identifiers will be protected (check all that apply):
Data is recorded on paper. Describe how paper records will be protected:

Data stored on an institutional desktop computer. Describe protections:

Data stored on an institutional server that is encrypted, password protected, and backed up.

Temporarily collect data via a portable device:
- Institutional laptop that is encrypted and password protected.
- Data transmitted via the internet to a server. Data also stored on the portable device. Describe:
- Data transmitted immediately via the internet to a server. Data never stored on the portable device. Describe:
- Other - describe, including protective measures such as encryption, password protection, etc:

Other. Describe, including protective measures such as encryption, password protection, etc:

<TYPE ANSWER HERE: Principal Investigator must describe plan>

b. Approval of a HIPAA waiver requires that an adequate plan be in place to de-identify (destroy the identifiers) at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. Indicate which methods you will use to de-identify the data that you have collected/used under this waiver (check all that apply):

- Hardcopy of identifiers/key code shredded.
- Electronic copies de-identified and are now anonymous.
- Redacting identifiers as you record information.
- Research conducted at the VA, therefore all research records including identifiers must be retained in accordance with the VHA Record Control Schedule or a minimum of 6 years, whichever is longer.
- Other:
The plan is described as follows:

<Type ANSWER HERE: Principal Investigator must describe plan. For requests involving the VA, include the following language: “All research records including identifiers must be retained in accordance with the VHA Record Control Schedule or a minimum of 6 years, whichever is longer.”>

c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by HIPAA regulations;

45. _____I certify that the research could not practically be conducted without access to and use of the protected health information, this requested waiver. Explain why it is impractical to conduct the research without the waiver of authorization (check all that apply):

☐ It would be inappropriate to contact people who do not qualify for the study
☐ No direct subject contact to obtain authorization
☐ Unreliable/inaccurate contact information for subjects
☐ Subjects may be deceased. Submit a HIPAA Certification of Research on Decedents’ Only PHI available at:
    http://irb.ufl.edu/docs/HIPAA/decedent.docx.
☐ Other:
    <Type ANSWER HERE>

5. _____I certify that this research could not practically be conducted without access to and use of the protected health information.

66. _____I certify that I will only access PHI under this waiver until the end of the study.

Signature of Principal Investigator                  Date
For IRB-01 Office Use Only

This waiver was approved under: Full review ___ Expedited review ___

_________________________________________  Approval Date
Signature of IRB Board Member

_________________________________________
Expiration Date
Can we add a comment here that says only information collected throughout the study using the waiver to enroll…or if authorization is being obtained the information should not be listed.
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