To: Human Subjects Research Investigators and Staff  
From: R. Peter Iafrate, Pharm.D.  
Chairman, Health Center IRB-01  
Re: Changes in Addendum A

Addendum “A” serves two purposes: to list those regulatory requirements the Principal Investigator is agreeing to, and to list all those individuals “engaged” in the research. Recently these two events have lead to a need for the IRB to revise Addendum A.

1. The OHRP has changed their definition of “engaged investigator” to include anyone obtaining informed consent. In the past, we have not required these folks to be on Addendum A, with this revision, anyone obtaining informed consent must be listed.

2. With the launching of EPIC, those who are being given access to EPIC is being tightly controlled. As it relates to research, Shands needs a way to insure that the IRB has approved study staff that “need” to have EPIC access and thus access to PHI, and what type of access they need. Going through this process, the IRB has discovered that certain individuals are accessing PHI that should not be.

The revised Addendum A (a truncated version is shown below) includes an additional column which requires that the functions be included for each individual engaged in the research. At the bottom of the form, there are 6 options, lettered A-G, you simply place all the appropriate letters in the column provided, for each individual.

<table>
<thead>
<tr>
<th>Study Role</th>
<th>Study Functions (indicate all that apply from list below)</th>
<th>Affiliation</th>
<th>First Name</th>
<th>Last Name</th>
<th>Degree</th>
<th>UF ID#</th>
<th>COI*</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator</td>
<td>A, B, C, D, E</td>
<td>UF</td>
<td>Peter</td>
<td>Iafrate</td>
<td>PHARMD</td>
<td>12345</td>
<td>N</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IRB Related Study Functions:  
A. Interacts or intervenes directly with study subjects for research related purposes  
B. Performs study related activities but does not interact directly with the study subjects  
C. Obtains informed consent  
D. Accesses or obtains, for research purposes, any Protected Health Information (PHI) from a paper or Electronic Medical Record (EMR)  
E. Enters research related orders into EPIC for subsequent study physician or provider's electronic signature approval  
F. Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations  
G. All of the above
So, who should be included on Addendum A?? The answer is anyone involved in your study that is performing any of the items A through F.

Bottom line, as of December 1st, 2011, the revised Addendum A must be used when researchers submit any of the following to IRB-01:

1. Submitting a new protocol.
2. Submitting a continuing review. In this case you do not need to obtain the signatures of any staff listed on the previously approved Addendum A. If you wish to add any new study staff you need to also submit a revision and obtain signatures for anyone who is added to Addendum A.
3. Submitting a revision that adds anyone to Addendum A between December 1st and your next continuing review. In this case, update the new Addendum A with all current study staff, submit a strike-out/underline copy with the changes you are requesting, and the signatures of only the study staff you are adding.