

HOBIT 1572 Preparation

Who should be listed as the PI for each of my Spokes?

- The SIREN-Hub PI should be the PI of record for all spokes whenever possible.
- The PI should be the same on all of your 1572s. Thus, even if the PI is not working at a particular Spoke, s/he should be listed as PI for all 1572s.
- Exceptions will be made for institutions/IRBs that do not allow this.

Who else needs to be on the 1572? Who is considered a sub-investigator?

- All study team members performing critical trial related procedures and/or making important trial-related decisions (such as performing assessments, obtaining informed consent) **MUST** be listed on the 1572 and must provide documentation of additional requirements (CV, medical license, etc.) in WebDCU™. NOTE: Their duties must also be listed on the HOBIT Delegation of Authority log.
- Spoke PI(s) can be listed as sub-investigator(s).

As stated above, whenever possible, the Hub PI (or HOBIT PI) should be the PI of record. If your institution will not allow this, please list your Hub/HOBIT PI as a sub-investigator, if allowed, and inform the SIREN-CCC Site Manager(s).

- All sub-investigators should be listed in Box 6.

Do I need a separate 1572 for each of my Spokes?

- You will need a 1572 for each group of investigators. Thus, if multiple Spokes have the same group of investigators they can be listed on the same 1572. Additionally, if there are multiple IRBs of record among this group of investigators, the respective IRBs can be listed on the same 1572.
- Make sure each Spoke is listed as a study location in Box 3.
- Include the corresponding clinical laboratory facilities in Box 4.
- Make sure each IRB of record is listed in Box 5. Again, multiple IRBs can be listed here.

Do you have a template 1572 I can use?

- The only information you need is for Box 7:
IND # 127194
Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial

What do I do with my 1572 once it's complete?

- Upload the document into WebDCU™. Only one entry needs to be created for all of the people listed on the 1572 (please apply to all team members listed on the 1572). A separate entry will need to be created for each Spoke.
- The CCC Site Managers will then verify the document.
- We do not need a copy of the original 1572; however, please keep a copy on file at your site.
- Please remember to update the HOBIT Delegation of Authority Log each time the 1572 is updated.

I can't upload my 1572 for certain individuals. Why do they not appear in the drop down menu?

- Most likely, that person has not been entered into WebDCU™ for the HOBIT project.

HOBIT 1572 Guidelines (last updated 10/23/14)