

For those who I have not met yet, my name is Matt Wladkowski and I am the Regulatory Affairs Coordinator in the Translational Research Department. One of my goals is to create an IND/IDE registry for the institution.

I hope this will be a useful resource in which Investigators can access basic regulatory information about their projects at anytime, such as approval dates. To assist you in staying in FDA compliance, I will send out reminders when your annual reviews are due to FDA, once your study has been added to the registry.

The registry also has a second purpose, ensuring that the Institution has knowledge of every FDA regulated study that is being conducted here at Children's Hospital, in case of an FDA audit. This information can also be useful to Children's for marketing purposes, fundraising, and grants.

Follow these steps to add your study to the registry:

- 1) Click on the following link to access the registry form:  
[http://chbelibrary.tch.harvard.edu/sites/researchstudy/Lists/ind\\_ide\\_registry/NewForm.aspx?Source=http%3A%2F%2Fchbelibrary%2E%2Ftch%2E%2Fharvard%2E%2Fedu%2Fsites%2Fresearchstudy%2FLists%2Find%5Fide%5Fregistry%2FAllItems%2Easpx](http://chbelibrary.tch.harvard.edu/sites/researchstudy/Lists/ind_ide_registry/NewForm.aspx?Source=http%3A%2F%2Fchbelibrary%2E%2Ftch%2E%2Fharvard%2E%2Fedu%2Fsites%2Fresearchstudy%2FLists%2Find%5Fide%5Fregistry%2FAllItems%2Easpx)
- 2) You will be asked to input your Children's ID
- 3) Fill out the form and then hit "save and close" on the top tool bar.
- 4) At this point your study has been added to the registry

Please add any of your current FDA regulated studies to the registry by August 7<sup>th</sup>.

The entire registry can be viewed here:

<http://chbelibrary.tch.harvard.edu/sites/researchstudy/default.aspx>

Just click the link "IND/IDE Registry" on the left hand tool bar.

I have granted access to the Investigators listed on a spreadsheet Research Administration had previously created; I hope that this registry will be more useful, comprehensive and accessible. If you have a staff member that handles these matters for you, please e-mail his/her name to me and I will grant them access to the registry.

If you have any questions about the registry or about your current/potential project, I will be glad to assist you in these matters.

For more regulatory information please visit the regulatory resources website:

[http://www.childrenshospital.org/cfapps/research/data\\_admin/Site2640/mainpageS2640P13.html](http://www.childrenshospital.org/cfapps/research/data_admin/Site2640/mainpageS2640P13.html)

Thank You

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