Wright State University IRB

Humanitarian Use Device (HUD) InfoED Submission Guidance

New HUD Submissions After October 1, 2018

Create a New HUD application by following these instructions:

- 1. Click the **Human Subjects** button in left-hand menu
- 2. Click the **Create New**
- 3. The form wizard with pop up in a new window. Select **HUD Initial** from the list and then click **CONTINUE.**
- 4. Then follow normal screens to create your application packet.

Complete the HUD Initial Submission form making sure to answer <u>all</u> questions and attach <u>all</u> supporting documentation.

When you are ready to submit, click the SUBMIT icon on top right-hand side of the table to forward it into the route. If you do not do this, the submission will not be in the route and the IRB Office will not be informed that it is ready for review.

Continuing HUD Approvals Previously Transferred to InfoED

Last year continuing HUD approvals were transferred into InfoED via the Initial Review/Continuing Review Form process. To better facilitate the HUD submission/review process for investigators and ensure compliance with related regulatory requirements, separate HUD Initial and Continuing Review forms were developed in 2018.

Therefore, to enter in required information at the time of your next continuing review (as of September 1, 2018) **you are required to complete and submit both the WSU IRB HUD Initial Submission and WSU IRB HUD Continuing Review forms** via the following instructions:

- Find and open your approved submission in the system.
- In the top-right corner select **HUD Initial**, then click **ADD NEW** button.
- Click the Add Institutional Forms/Supporting Documents link at the bottom of the Components Table. In the pop-up box click the checkbox next to WSU IRB HUD Continuing Review. Then click the ADD button to add the form to your Components table. The form will then appear in your table.
- Complete both forms making sure to answer <u>all</u> questions and attach <u>all</u> supporting documentation.
- When you are ready to submit, click the **SUBMIT** icon on top right-hand side of the table to forward it into the route. If you do not do this, the submission will not be in the route and the IRB Office will not be informed that it is ready for review.

Note: You do not need to complete the regular IRB Continuing Review Form in addition to the new HUD forms. Also, at the time of subsequent continuing reviews, you only need to complete the HUD Continuing Review Form. Additional HUD policy and guidance can be found at: <u>http://www.wright.edu/research/compliance/institutional-review-board-polices-procedures-and-guidelines</u>