

New NIH Funding Opportunity Announcement

March 27, 2019

NIH recently introduced a new funding opportunity announcement (FOA) designation for prospective basic science studies involving human participants, <u>Basic Experimental Studies with Humans</u> (<u>BESH</u>). FOAs can now have any of the following clinical trial (CT) classifications:

- CT Not Allowed;
- CT Optional;
- Mechanistic CT Only;
- BESH Required; and
- CT Required.

When a Principal Investigator is ready to prepare an application, the PI must select a FOA that accepts the type of research he/she wishes to propose. To aid PIs in selecting the appropriate FOA, UM PIs and departmental personnel should use the <u>NIH Decision Tool</u> to assist in determining if the study is a clinical trial. This tool has been recently updated to incorporate the BESH designation. If the study meets the definition of a clinical trial AND basic research, then a BESH FOA would be appropriate.

For UM purposes, a BESH study is a clinical trial. Therefore, the UM Proposal Contract Routing Form (PCRF-L) should reflect the Purpose Code of Clinical Trial for all BESH proposals.

If you have any questions, please call or email your <u>ORA Contact Person</u>. Thank you.



For additional information, please visit the ORA website at <u>www.ora.miami.edu</u>.

If you have any questions, please email us at ora-si@miami.edu.