

NIH expands early-stage human testing of infectious disease treatment candidates

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The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has awarded contracts to three organizations to support early-stage human clinical trials of investigational infectious disease treatments. The new awards for the [Phase I Clinical Trial Units for Therapeutics](#) increases the number of funded organizations under the program from two to three, expanding capacity for conducting early safety testing of novel investigational drugs.

Each of the three awardee institutions has the potential to receive NIAID funding estimated to be up to \$90 million per contract over a 10-year period. The contracts will support up to 12 clinical trials per year across the three sites.

"A significant challenge in drug development is moving promising agents for treating [infectious diseases](#) into initial testing in humans to evaluate their safety," said NIAID Director Anthony S. Fauci, M.D. "These new contracts expand our ability to identify and accelerate the development of promising therapeutics to combat existing and potential microbial threats to public health."

Established in 2008, the Phase I Clinical Trial Units for Therapeutics assess the safety of investigational drug candidates for use against a broad range of emerging and re-emerging infectious diseases caused by viruses other than HIV as well as bacterial, parasitic and fungal pathogens. To date, these units have conducted vital Phase I human

clinical trials of new influenza antivirals as well as investigational therapeutics to treat diseases such as methicillin-resistant *Staphylococcus aureus* (MRSA) and multi-drug resistant tuberculosis. A previous award under this program helped fund early [clinical trials](#) of an antiviral drug called a fusion protein, which is designed to guard against multiple flu strains, including the deadly H5N1 strain of avian influenza. The drug has advanced to Phase II trials.

The awards are designed to be responsive to [public health](#) needs, and specific trials will be developed over the course of the contract period. The current round of contracts was awarded to the following organizations:

- DynPort Vaccine Company in Frederick, Maryland
- Clinical Research Management in Hinckley, Ohio
- Duke University (new awardee) in Durham, North Carolina

Provided by NIH/National Institute of Allergy and Infectious Diseases

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