

NICHD's Contract Facilities for Contraceptive and Reproductive Health Research Development

C. Leigh Allen; Christopher C. Lindsey; Daniel S. Johnston

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), Bethesda, MD, USA

The priorities of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) include development of novel, safe, and effective non-hormonal contraception for both men and women and the promotion of reproductive health. The NICHD has two state-of-the-art facilities: the Biological Testing Facility (BTF) and Chemical Screening and Optimization Facility (CSOF). To advance contraceptive and reproductive health product development, these facilities have the capabilities and capacity for preclinical and Investigational Device Exemption (IDE)- or Investigational New Drug (IND)-enabling studies. The long-term objective is to enable a preclinical candidate for IND/IDE studies that offers a safe therapeutic option in the field of contraception and/or reproductive health related indications as outlined in the scope of the facilities' PARs. NICHD seeks innovative and validated methods for future clinical development. **The goal of this poster is to provide potential applicants with information on a mechanism to request services from these NICHD-contracted research facilities that would advance their development program with an emphasis on facilitating early-stage development research, bridging studies, pivot studies and entry into clinical studies.** Potential *in vitro* and *in vivo* services available to support that goal include but are not limited to protein generation, X-ray crystallography, high throughput screening, structure activity relationships, hit-to-lead generation, drug metabolism in the CSOF and fertility studies, pharmacology, toxicology, formulation, reproductive tract histopathology, sperm morphology and motility, and other studies in the BTF in pursuit of an IND or IDE application for submission to the US Food and Drug Administration or analogous submissions to other regulatory agencies. The facility has the capability to advance multiple projects simultaneously across the entire product development continuum, is open to foreign institutions, and is not limited to programs with current NICHD support.