NIH has have received approval from SBA for the topics listed below for budgets greater than $225,000 for Phase I SBIR/STTR awards and greater than $1,500,000 for Phase II SBIR/STTR awards for the PHS 2013-2 SBIR and STTR Omnibus grant solicitations. Applicants are strongly encouraged to contact NIH program officials prior to submitting any award budget in excess of these amounts. Applicants are also required to follow NIH Institute- and Center-specific budget guidance found in PHS 2013-2 SBIR/STTR Program Descriptions and Research Topics for NIH, CDC, FDA and ACF.

1. Biomedical technologies (medical devices, instruments, pharmaceuticals, drugs, therapeutics, vaccines, diagnostics and biologics) requiring Federal regulatory approval (FDA) or clearance to be commercialized.
2. Development of therapeutics (drugs, devices, or biologics) or diagnostics that need clinical testing prior to commercialization.
3. Small and large animal testing of products of tissue engineering and regenerative medicine, drugs, medical devices, therapeutics, and biologics. Studies involving *in vivo* animal experiments. The cost of research animal care can be quite high, with specialized facilities necessary to maintain animals required to perform essential experiments.
4. Development of gene therapy and therapeutic biologics. Production of a sufficient amount of GMP grade DNA, RNA, and proteins for animal and human testing.
5. Clinical trials and other experiments involving human subjects include costs that cover patient recruitment, handling, and monitoring, as well as compliance with human subject project regulations.
6. IND-enabling studies for biologic and small molecule drug development (including toxicology, safety, manufacturing, formulation, etc). Studies that contribute to regulatory filings are typically conducted in accordance with regulations (e.g. GLP) that increase costs and cannot be substituted for cheaper alternatives.
7. Medical device development. Hardware prototyping is costly, as is preparing materials and devices in preparation for testing in humans.
8. Diagnostics development. Assessing the validity of a diagnostic test requires rigorous testing on patient samples, which requires additional funding to procure.
9. Biomarkers and biosignatures of a variety of disorders: reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, biological and behavioral indicators of treatment response, measures of disease progression, to identify dose ranges prior to clinical studies, to define patients to enroll in the clinical study, etc. Due to the rigorous clinical studies required, and regulatory testing needed, the budgets and timelines necessary for successful development need to be enhanced.
10. Drug Discovery/Drug Development: This area of research ranges from the development of novel ligand screening assays (such as computational, high throughput, genetic, molecular/cellular, or whole animal) to novel chemistry approaches, to lead compound identification/optimization preclinical efficacy, IND-enabling studies, and up to FDA Phase I and II clinical trials. Due to the extensive regulatory studies needed to be performed and both preclinical and clinical work, the budgets and timelines necessary for successful development need to be enhanced.
11. Technologies to enhance clinical research: The complexity of conducting and managing clinical research is significant due to the diverse technologies/methodologies currently being used, difficulty in the recruitment of subjects, broad categorical diagnoses of disorders, unique

cultural and developmental aspects of a disorder, etc. These tools/technologies require extensive clinical evaluation, and in some cases regulatory testing, and therefore the budgets and timelines necessary for successful development need to be enhanced.

12. High Throughput Tools for Biomedical Research: Tools for high throughput measures at any level (or combination of levels) of analysis: from genes and molecules through behavior, including cognition and social behavior. The tools typically need to be aimed at rapid acquisition and analysis of data, such as the collection of physiological data from multiple subjects at one time. Due to the technologies that would need to be incorporated into a high throughput system, including such technologies as computer vision, molecular biology, robotics, nanotechnology, microarray fabrication, imaging, etc. the developmental time and budgets need to be enhanced.
13. Tools/Platforms to Improve the Dissemination and Implementation of Evidence-Based Interventions: development of innovative user-friendly tools and platforms to efficiently and effectively disseminate evidence-based treatments/research into services and clinical practice.
14. Novel Tools for Investigating G-protein coupled receptors (GPCRs): technologies and approaches (i.e., novel ways to use new or existing technologies) that will enable researchers to study the structure and/or function of brain localized G-protein coupled receptor proteins (GPCRs) and/or potentially identify novel selective and specific agonists/antagonists to these receptor subtypes. Technologies and approaches aimed at known receptor subtypes or orphan receptors would be of potential interest. Due to the complex, difficult and expensive tools needed to accomplish this work- e.g. robotics for high throughput assays, protein crystallization, ability to purify functional receptors separated from membranes, etc. the budgets and timeline need to be expanded above the current allowances.
15. Advanced instrumentation for cell biology, biophysics and other related investigations (e.g. microscopes, NMR spectrometers, mass spectrometers, light sources, etc.).