**Epilepsy Therapy Screening Program (ETSP)**

Preclinical testing program to identify new therapies to address the unmet medical needs in epilepsy
- Established in 1975 and known for 40 years as the Anticonvulsant program; tested over 30K compounds; contributed to 11 marketed antiseizure drugs
- New ETSP name reflects focus on drug resistant epilepsy and expansion into areas of disease prevention and modification
- Open to small molecules, biologics, natural products and devices
- No cost to participant, participant IP protected, and confidentiality maintained

Contact: Brian Klein, brian.klein@nih.gov

**Preclinical Screening Platform for Pain (PSPP)**

Provides a platform to identify and profile non-addictive, non-opioid therapeutics for pain

**NIH HEAL INITIATIVE**

Contact: Smriti Iyengar, smriti.iyengar@nih.gov

**Initial Translational Efforts (IGNITE)**

Grant funding to build on innovative basic science findings and initiate preclinical drug discovery and development
- Neurotherapeutic Agent Characterization and In vivo efficacy studies (PAR-21-122)
- Development and Validation of Model Systems and/or Pharmacodynamic Markers to Facilitate Neurotherapeutic Discovery (PAR-21-123)
- Assay Development and Neurotherapeutic Agent identification (PAR-21-124)

R61/R33 up to 3 years. Up to 750k for the entire project

Contact: Rebecca Roof, Rebecca.roof@nih.gov

**NINDS Division of Translational Research (DTR)**

**Mission:** To accelerate basic research findings toward patient use for neurological disorders and stroke by providing funding, expertise, and resources to the research community.

**DTR** offers a variety of programs that support the design, implementation, and management of research activities critical to translational challenges in the treatment of neurological disease. 
https://www.ninds.nih.gov/current-research/research-funded-ninds/translational-research

**Join our Listserv:**

**Biomarker Initiatives: Neurological Disorders and Pain**

- Discovery of Biomarkers, Biomarker Signatures to Facilitate Clinical Trials for Pain Therapeutics (HEAL): RFA-NS-22-050
- Development of Biomarkers for Neurological/Neuromuscular Disease: PAR-22-089
- Analytical Validation of a Candidate Biomarker for Neurological Disease: PAR-21-056 (U01), PAR-21-057 (U44)
- Clinical Validation of a Candidate Biomarker for Neurological Disease: PAR-21-058 (U01), PAR-21-059 (U44)

Contact: Carol Taylor-Burds (NINDS), carol.taylor-burds@nih.gov, Ram Arudchandran (HEAL), Ramchandran.arudchandran@nih.gov

**BPN – Small Molecules**

Cooperative agreement and SBIR Fast-Track award programs support Small Molecules drug discovery & development
- Customized infrastructure, expertise, contract access, and grant funding (combined up to $12M/project)
- Grant and contract support: medicinal chemistry, compound database, PK, toxicology, drug manufacturing and formulation, phase I clinical trials
- PAR-20-122 (UG3/UH3) up to 5 years
- PAR-20-111 (SBIR) up to 5 years

Contact: Charles Cywin, charles.cywin@nih.gov
BPN – Biologics

Cooperative agreement and SBIR Fast-Track award programs support Biologics drug discovery & development

- Includes optimization and early development activities, IND-enabling studies, assembly of IND application
- Grant and contract support as needed for example pharmacokinetic studies, toxicology (GLP and non-GLP), safety testing plus access to experts in therapeutics development through a consulting service
  - PAR-21-163 (UG3/UH3) up to 5 years
  - PAR-21-233 (U44 SBIR) up to 5 years

Contact: Chris Boshoff, chris.boshoff@nih.gov

Ultra-Rare Gene-based Therapies (URGenT)

Funding/resources to advance gene-based therapies from late-stage pre-clinical development into first-in-human clinical testing

PAR-20-030 (U01, Clinical Trial Optional)

- Accelerates development of a clinical candidate with biological rationale and proof of concepts towards an IND filing & clinical trial initiation with access to CRO/GMO, SMEs and with a budget associated with the award
- Provides investigators with mechanism to access CRO/GMO, SMEs for nonclinical therapeutic

PAR-22-028

Contact: Chris Boshoff, chris.boshoff@nih.gov

Pain Therapeutics Development Program (PTDP)

Goal: Accelerate development of novel, non-opioid, non-addictive analgesics

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Development</th>
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<tbody>
<tr>
<td>Phased (UG3/UH3) research grant</td>
<td></td>
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<tr>
<td>Therapeutics can be biologics or small molecules</td>
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<tr>
<td>Grant features access to biopharma-experienced consultants and NIH-sponsored Contract Research Organizations</td>
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<tr>
<td>End goals include IND submission, Phase I Clinical Trial and formation of partnerships to progress candidate therapeutic through clinical testing</td>
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<tr>
<td>Eligible institutions include academic institutions &amp; small businesses</td>
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Contact: Mary Ann Pellymounter, mary.pellymounter@nih.gov

Therapeutic and Diagnostic Devices & BRAIN

Cooperative agreements including SBIR Fast-Track for development validation, verification, and early clinical studies.

Scope of this program supports projects that are either:

- Very close to the “final system” with similar manufacturing process as the device to be marketed or studied in a larger clinical trial following the completion, OR
- Require early feasibility clinical data to inform the final device design or manufacturing processes

TND: RFA-NS-21-021 (UG3/UH3), RFA-NS021-022 (SBIR)

Contact: Nick Langhals, nick.langhals@nih.gov

Small Business Program

NIH small business programs (SBIR/STTR) are congressionally mandated funds to encourage research/development leading to commercialization

- More than $70M in annual set-aside funds for small business
- Includes therapeutics, neurotech, diagnostics and research tools
- Awardes have access to assistance programs and investor show case opportunities
- Omnibus PAR-22-176 (SBIR), PA-22-178 (STTR), and other specific announcements
- Contact us to learn more!

Contact: Emily Caporello, Emily.caporello@nih.gov

Office of the Neural Exposome and Toxicology (ONETOX)

Provides resources to advance knowledge of internal and external exposures that affect nervous system health, leads research related to chemical threats

Contact: David Jett jettd@ninds.nih.gov

Neural Exposome
- Databases of neurotoxins and gene-environment interactions
- Grant funding for research into how exogenous, endogenous, and behavioral factors impact brain health

Countermeasures Against Chemical Threats (CounterACT)
- Grant funding for basic and preclinical translational research on chemical threats to national security
  - RFA-23-027 (R01) Early-stage and New Investigators are encouraged
  - RFA-22-239 (UG3/UH3), RFA-23-025 (R21) translational research

Chemical Safety
- Resources for drug safety in translational research and management of biohazards and dual use research concerns (DUROC)