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Concept Clearance

DEVELOPMENT OF STEM CELL- OR IPS CELL-BASED ASSAYS FOR COMPOUND TOXICITY EVALUATION

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Description of the Goal

- For the Phase I contract, the goal is to develop toxicological related assays in homogenous format that can be used in human stem cell or iPS-derived cells with short time compound treatment.
- For Phase II contracts, the goal is to miniaturize the assays into 384-well and 1536-well plate format.

Description of the Outcome

- **Potential impact?**
  - Assays with various endpoints using iPS-derived cells in a 1536-well plate format will greatly speed up the capacity of screening environmental chemicals.
  - Also, using iPS-derived stem cells will make this screening approach even more relevant and the data more valuable in order to establishing predictive models of how these chemical compounds affect human tissues and pathways.

Description of the Outcome

- **Criteria for evaluating success?**
  - The number of solicitations received with innovative approaches.
  - Technical achievement in growing and utilizing iPS derived stem cells for HTS in miniaturized assay plates.
  - A viable iPS/stem cell assays that meets all the appropriate characterization criteria, i.e. sensitivity, Z' value >0.5
  - Demonstrates significant utility of the assay by characterizing its ability to detect the effects of compounds known to affect the pathway/cellular phenotype.

Description of the Initiative

- **What is the major obstacle/opportunity to address?**
  - Using iPS cells in toxicological screens therefore making them more relevant in-vitro model systems for the future.
- **Relevance to the NCATS' mission?**
  - These assays would be the basis for screening programs such as the Tox21 Program and other qHTS initiatives.
- **Brief summary of ongoing research/activity in this area?**
  - This proposed contract topic is closely related to a previous SBIR contract topic entitled, "Assay Development for High-Throughput Screening of Chemicals of Toxicological Concern" which has successfully produced several new assays to be commercialized by small businesses.