

## NHCDR GMP iPSC Line BRAC Application

All applications to obtain the NHCDR GMP iPSC line are submitted to the NHCDR via email at [NINDS@sampled.com](mailto:NINDS@sampled.com). Applicants are required to submit the following in a single file (pdf or word file formats):

- Application Cover Sheet containing the following
  - PI name
  - Contact information
  - Institution or company
  - Project name
  - Submission date
- Biosketch of PI
- Proof of regulatory interaction
- Research Strategy (4 page limit) containing the following elements;
  - An overview of the proposed clinical usage
  - Data showing that the research grade iPSC line (NH50191) has been used as proof of principle
  - Demonstrated understanding of the clinical trial process, including a preliminary plan to move into clinical trials
  - Suitability of the team to accomplish the goals
  - Number of vials requested
- If the application is a request for additional vials
  - Copy of initial research strategy
  - Progress since initial receipt of cell lines
  - Reason for the request for additional vials
- If the application is a re-submission
  - Clearly marked revisions

**Applications for biospecimen access will be received on a rolling submission basis and tentative review and notification dates are below:**

<b>Date Submitted</b>	<b>Targeted Notification Date</b>
October 1 <sup>st</sup> - November 31 <sup>st</sup>	January 1 <sup>st</sup>
December 1 <sup>st</sup> - January 31 <sup>st</sup>	March 1 <sup>st</sup>
February 1 <sup>st</sup> - March 31 <sup>st</sup>	May 1 <sup>st</sup>
April 1 <sup>st</sup> - May 31 <sup>st</sup>	July 1 <sup>st</sup>
June 1 <sup>st</sup> - July 31 <sup>st</sup>	September 1 <sup>st</sup>
August 1 <sup>st</sup> - September 31 <sup>st</sup>	November 1 <sup>st</sup>