

H.R. 2820, The Stem Cell Therapeutic and Research Reauthorization Act of 2015

Duke University Medical Center's Statement of Support

September 4, 2015

Dear Congressman Smith and Congresswoman Matsui:

On behalf of the Robertson Clinical and Translational Cell Therapy (CT2) program at Duke University Medical Center, I write in strong support for House passage of H.R. 2820, the Stem Cell Therapeutic and Research Reauthorization Act of 2015. This important bill would reauthorize both the National Cord Blood Inventory (NCBI) Program and the C.W. Bill Young Cell Transplantation Program (the Program) from FY 2016 through FY 2020.

The CT2 program was created in 2010 and aims to provide the administrative and laboratory-based infrastructure to conduct early clinical trials of cellular therapy products in both adult and pediatric populations. Specifically, its components include:

- Cell Therapy Clinical Trials in traditional areas such as blood cancers and leukodystrophies, but also in new areas such as sickle cell anemia, brain injuries, cerebral palsy, stroke, and autism.
- Basic Research Labs to further understand the mechanistic pathways of cord blood and to develop donor-based, off-the-shelf cell products.
- A Good Manufacturing Practice (GMP) Facility – an ISO class 7 cell processing facility for advanced cell and tissue-based therapeutic products to be used in Phase I and II clinical studies.
- Quality Systems Unit – a team of six quality experts that ensure compliance with federal regulations and with requirements from accreditation agencies.
- The Carolinas Cord Blood Bank, the second largest biorepository for human cord blood in the United States.

The field of cord blood transplantation and research offers hope for a growing number of pediatric and adult diseases and conditions. Specifically, cord blood transplantation treats and often cures patients with certain life-threatening blood cancers and other hereditary diseases. In addition, recent studies indicate that cord blood transplantation may be an effective therapy for other serious conditions, such as autism, traumatic brain injury, stroke and cerebral palsy.



DEPARTMENT OF PEDIATRICS
DIVISION OF PEDIATRIC BLOOD & MARROW TRANSPLANTATION
PEDIATRIC STEM CELL LABORATORY
CAROLINAS CORD BLOOD BANK

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On behalf of our patients, we thank you for your leadership on H.R. 2820 and for all you do in service to our nation.

Sincerely,



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Chief Scientific Officer and Medical Director, Robertson Clinical and Translational Cell Therapy Program
Director, Pediatric Blood and Marrow Transplant Program
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