CONFIDENTIALITY CERTIFICATE

HRSA-18-002B
issued to

Center for International Blood and Marrow Transplantation Research

conducting research known as

"Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries"

This certificate continues the protections of Certificate HRSA-18-002 (expiring on August 1, 2020) for an additional period of time.

In accordance with the provisions of section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), this Certificate is issued in response to the request of Stephen Spellman, MBS, Principal Investigator, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. The Repository continues to receive partial funding from the Health Resources and Services Administration under the Stem Cell Therapeutic Outcome Database contract (HHSH250201700006C) of the C. W. Bill Young Cell Transplantation Program.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the National Opinion Research Center, its data collecting or data processing contractors, or their collaborating service providers, and

2. have in the course of their employment or association access to information which would identify individuals who are the subjects of the research pertaining to the project known as *"Protocol for a Research Sample Repository for Hematopoietic Cell Transplantation, Other Cellular Therapies and Marrow Toxic Injuries"*

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The primary objective of the Repository is to make blood available for research studies related to histocompatibility and hematopoietic cell (HSC) transplantation or other cellular therapy. Blood samples are donated by donors, cord blood units and recipients who have registered, donated or received an allogeneic HSC transplant or other cellular therapy covered under the C. W. Bill Young Transplantation Program or were exposed to a marrow toxic injury.

The following are the types of studies that the National Marrow Donor Program allows the samples to be used without obtaining additional consent from the recipient or donor:

- Studies of histocompatibility including human leukocyte antigen typing, analysis of allele and haplotype frequencies in different populations, evaluation of microsatellites and single nucleotide polymorphisms, examination of minor histocompatibility antigens, or other factors known or found to be involved in donor/recipient histocompatibility.
- Studies of immune regulatory systems including interleukins, interferons, tumor necrosis factors and others as these may influence the outcomes of transplantation or cellular therapy.
- Studies of molecules involved in natural defense systems such as myeloperoxidases, oxidative enzymes, perforins, defensins, adhesion molecules and others.
- Studies of other molecules that may influence the outcomes of transplantation or cellular therapies including coagulation factors and coagulation regulators, platelet and endothelial cell functional and regulatory systems, complement systems, and others.
- Studies of molecular systems known or found to be involved in the proliferation or maintenance of hematopoietic and immune systems including growth factors, cell surface and cytoplasmic receptors, cell cycle regulators, DNA and gene regulatory molecules, DNA telomeres, and others.
- Studies of global genetic diversity through genome-wide association studies or other techniques to evaluate the impact of other genetic factors on transplant or cellular therapy outcomes.
- Studies of the success of transplantation, cellular therapies or supportive care in the management of marrow toxic injuries.
- Use for delinked (anonymous) research.

A Certificate of Confidentiality is needed because the study will generate sensitive information, which, if disclosed, could expose the subjects to adverse economic, psychological, and social consequences. This information may include specific health conditions, household income or other information that could lead to social stigmatization, discrimination, or law enforcement action. The certificate will help the researchers protect the confidentiality of this information from subpoena and other involuntary disclosures.

All records pertaining to the identity of participants in the Repository are kept private and confidential. Personal identifying information will only be released with the express written permission of the participant. Blood samples and all records associated with blood samples are labeled only with a numeric code that contains no personal identifiers. The Center for International Blood and Marrow Transplant Research is compliant with relevant federal regulations regarding privacy and confidentiality, including the Common Rule and the Privacy Rule, and has policies and procedures to maintain compliance with these regulations as they change. In addition, the Center for International Blood and Marrow Transplant Research has held a valid, continuous approval to operate (ATO) since 2008 and currently holds a valid Security Assessment and Authorization package. All of the Center's data systems within the boundary of the existing System Security Program are certified and accredited by HRSA's Office of Information Technology under the ATO.

As provided in section 301(d) of the Public Health Service Act, persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

This Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects subjects from compelled disclosure of identifying characteristics. Researchers are, therefore, not prevented from the voluntary disclosure of such matters as child abuse or a subject's threatened violence to self or others; however, the consent form should indicate clearly a researcher's intention to make any such voluntary disclosure.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on August 1, 2022. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.

Elisa H. Gladstone For Susan Monarez

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