

ASH recommends cross-disciplinary engagement to advance regenerative medicine

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The American Society of Hematology (ASH) has developed specific recommendations to the scientific community and federal agencies to help propel collaborative research in regenerative medicine in order to make real strides in improving patient care. These recommendations were released today in *Blood*, ASH's premier scientific journal, in the article titled "Enhancing Research in Regenerative Medicine."

Regenerative medicine is a multidisciplinary approach to treating diseases and disorders by enabling the body to repair, replace, restore, and regenerate damaged or [diseased cells](#), tissues, and organs. The field is becoming increasingly attractive as therapeutic research targets, including the broadening use of stem cells, for a variety of health conditions yield promising results. However, the lack of coordination of research efforts, disjointed funding mechanisms, and absence of harmonization of regulatory requirements of [regenerative medicine](#) research threaten to significantly delay the application of research in this field to new therapies.

"Hematologists have been at the forefront of the regenerative medicine field for decades and are poised to provide great insight and leadership in steering the field in the right direction," said David A. Williams, MD, of the Children's Hospital and Dana-Farber Cancer Institute in Boston and Harvard Medical School, and co-author of the workshop report detailing ASH's recommendations. "In addition, as the leading society of hematologists, ASH has been working to leverage the expertise of its members and foster collaboration among like-minded groups and federal

agencies in this area. ASH plays a unique and potentially pivotal role in advancing the field."

ASH's key recommendations to address the challenges in the field include important considerations for the National Institutes of Health (NIH) and the general scientific community. Specifically, ASH recommends that:

- NIH make regenerative medicine research a priority by recognizing the field across the interests of multiple NIH Institutes. The Office of the Director at NIH would be the ideal leader of efforts to establish a regenerative medicine program or center at NIH.
- The U.S. Food and Drug Administration and NIH re-examine the current clinical trials methodologies and determine if these designs are useful in the utilization of cell-based therapies. This joint effort should be directed toward building a consensus for the design of clinical trials across multiple disease disciplines that will optimize the opportunity for data collection and dissemination.
- The scientific community at large should work to improve communication between basic and clinical scientists in regenerative medicine. Hematologists and ASH can provide crucial leadership in helping to facilitate an improved dialogue among key players in this growing field.

"Recent advances in stem and iPS [induced pluripotent stem] cell research have propelled the field of regenerative medicine forward with such speed that the regulation of these therapies has lagged behind," said Armand Keating, MD, Vice President of ASH and co-author of the

paper. "As with all new technologies, there is a risk of the 'hype' overshadowing the need for hope. The scientific, regulatory, and advocacy communities must collaborate in order to provide accurate, timely, and unbiased information to the public."

These recommendations are based on the dialogue of a working group of experts from the fields of hematopoietic stem cell biology, embryonic [stem cells](#), transplantation biology, and gene therapy convened late in 2009.

Provided by American Society of Hematology

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