Reinvestment in Government-Funded Research
A Great Way to Share

Paul D. Sorlie PhD; Phyliss D. Sholinsky MSPH; Michael S. Lauer MD

On December 8, 1989, Claude Lenfant, then Director of the National Heart, Lung, and Blood Institute (NHLBI) sent a memo to his Division Directors instructing them to inform contractors and grantees about the Institute’s data sharing policy. He wrote, “It is the policy of the NHLBI to make available detailed data from collaborative clinical trials, epidemiological studies, and other large-scale studies … with adequate protection of the confidentiality and privacy of research subjects.” Dr Lenfant wanted assurance that the federal government’s investments in research would achieve maximal potential by enabling researchers who were not direct beneficiaries of those investments to analyze shared data and in turn to share their findings, through publication, with the community. Indeed, one of us (MSL), as an early-career investigator, took advantage of NHLBI’s policy of sharing to publish independent analyses based on data generated by an NHLBI-funded investigation. And the importance of sharing has been recently reaffirmed as a critically important measure of the value of biomedical research.

Since 1989, we have come a long way. At the end of the punched card era, the NHLBI Framingham Heart Study converted massive tabulations of collected variables into 38 monographs that were made freely available for outside researchers, many lacking computing resources. As technology advanced, punched cards moved to reel-to-reel tapes, to big floppy discs, to smaller ones, to CDs, to secure FTP, enabling data transfer with increasing content and efficiency. Data sharing processes eventually moved from ad hoc requests to well defined and documented web-based systems including BioLINCC and dbGaP. Data sharing has also evolved from collaboration of a few studies to massive collaborations that have included more than 50 studies.

Data sharing offered great opportunities for advancing research, but as Dr Lenfant intimated, also presented challenges that went beyond exploiting advances in computing technology. As responsible overseers of federally funded research, we needed to be certain that participants were aware that their data could be shared and that they provided clear consent for sharing. The consent form for Framingham Heart Study participants in 1950 – it was only one page long – looks very different from the one of today. Participant consent now requires permission as to who should or should not receive their data, whether restricted by content or for-profit companies, and whether there are sensitive data that should not be shared with anyone beyond the first-line researchers.

In the current issue of Circulation, the American Heart Association (AHA) describes its broad and comprehensive initiative, the Cardiovascular Genome-Phenome Study (CV-GPS). The AHA recognizes the extensive returns of NHLBI’s decades-long investments in cardiovascular population-based research, which have produced massive quantities of high-quality resources and data to be shared with the research community. The AHA also recognizes a continued need to enable, through funding, innovative phenotyping to expand on what’s already available. Therefore the AHA has initiated a funding process to conduct innovative research that leverages existing studies, including the Framingham Heart Study, the Jackson Heart Study, and other mature population-based cohort studies. They will be funding Pathway Grants of $250,000 per year for 2 years (8 in 2014–2015) and Challenge Grants $500,000 per year for 2 years (1 in 2014–2015). In the CV-GPS funding announcement the AHA states that this innovative research will “point the way toward better-targeted, safer, and more effective treatments, based on a deeper understanding of patient’s characteristics.”

The AHA’s CV-GPS initiative fits the model of capitalizing on existing studies through funding creative investigators armed with new hypotheses, skills, perspectives, and technologies. The initiative builds on a longstanding NIH tradition of funding “ancillary studies,” an important kind of “reinvestment” in NHLBI’s work. We at NHLBI see ancillary study reinvestments as a valid metric of the value of our prior investments. We are particularly pleased when funders outside of NIH, including companies and nonprofit foundations like the AHA, choose to reinvest, as we see this as evidence that our investments are deemed so worthwhile that others wish to help us share them with their grantees. Reinvestment is a kind of sharing: through the CV-GPS the AHA is choosing to dedicate considerable funds to share NHLBI-generated resources and data with outstanding researchers who will now be able to conduct outstanding science. And this kind of reinvestment sharing enabled by professional societies is critically important given the unprecedented fiscal challenges we now face.

(Circulation. 2015;131:00-00.)

© 2014 The Authors. Circulation is published on behalf of the American Heart Association, Inc., by Wolters Kluwer. This is an open access article under the terms of the Creative Commons Attribution Non-Commercial-NoDerivs License, which permits use, distribution, and reproduction in any medium, provided that the Contribution is properly cited, the use is non-commercial, and no modifications or adaptations are made.

Circulation is available at http://circ.ahajournals.org
DOI: 10.1161/CIRCULATIONAHA.114.014204

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association. The views expressed in this essay are those of the authors and do not necessarily reflect the positions of the NHLBI or the United States Government.

From the Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, Bethesda, MD.

Correspondence to Michael S. Lauer, MD, Division of Cardiovascular Sciences of the National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 8128, Bethesda, MD 20892. E-mail lauerm@nhlbi.nih.gov
Just like data sharing, reinvestment sharing presents opportunities and challenges. The CV-GPS projects just awarded by AHA have promise to enhance public health by studying a diversity of interesting problems, from epigenetic determinants of left ventricular structure to correlates of early-onset stroke to integrative genomics of gene-diet interactions related to vascular disease. But the initiative also recognizes that resources and data coming from existing studies live within a framework of informed consent. Just as we at NHLBI are pleased by AHA’s decision to reinvest in and enable sharing of our resources, we are also pleased that the instructions to applicants noted that “investigators will still be required to adhere to the practices established by the parent studies of those databases to protect the quality and confidentiality of the data and samples.”

There is a phrase often used in a military context that is appropriate here, “to serve and protect.” We offer a modified version – “to share and protect.” The NHLBI is dedicated to serving the research community, to providing the best possible access while protecting the almost sacred connection between the original research teams and data coming from existing studies live within a framework of informed consent. Just as we at NHLBI are pleased by AHA’s decision to reinvest in and enable sharing of our resources, we are also pleased that the instructions to applicants noted that “investigators will still be required to adhere to the practices established by the parent studies of those databases to protect the quality and confidentiality of the data and samples.”

Disclosures
None (all authors are full-time employees of the NHLBI)

References


Reinvestment in Government-Funded Research: A Great Way to Share
Paul D. Sorlie, Phyliss Sholinsky and Michael S. Lauer

Circulation. published online November 19, 2014;
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circ.ahajournals.org/content/early/2014/11/19/CIRCULATIONAHA.114.014204.citation
Free via Open Access

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org//subscriptions/