

Reinvestment in Government-Funded Research A Great Way to Share

Paul D. Sorlie, PhD; Phylliss 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."¹ 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.² And the importance of sharing has been recently reaffirmed as a critically important measure of the value of biomedical research.³

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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.⁴ 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 well-documented web-based systems including BioLINCC⁵ and dbGaP.⁶ Data sharing has also evolved from collaboration of a few studies⁷ to massive collaborations that have included more than 50 studies.⁸

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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 (*Circulation*. 2015;131:17-18. DOI: 10.1161/CIRCULATIONAHA.114.014204.)

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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.⁹ 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).¹⁰ 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,^{11,12} 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."¹¹

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.^{13,14}

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."¹¹

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 data and the best possible access while protecting the almost sacred connection between the original research teams and participants established through their human interactions and bound by their consent. By reinvesting in NHLBI's resources and data, by enabling sharing of these with outstanding scientists, and by assuring that maximal protections remain in place, the AHA is becoming a valued participant in our shared goal of a healthier world.

Disclosures

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

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