



NHLBI

Straight talk with... Daniel Levy

The Framingham Heart Study (FHS) has long been a beacon of biomedical research, yielding landmark findings on everything from the links between elevated blood pressure and stroke to the genetic risk factors underlying cardiac arrhythmias. Now, the fabled 65-year-long study of cardiovascular disease is the beacon of a more modern trend in science: tight budgets. Thanks to the automatic cuts in US government spending known as sequestration, the approximately \$9-million-per-year contract the FHS receives from the US National Heart, Lung, and Blood Institute (NHLBI) was reduced by \$4 million on 1 August. The renewal of the contract, scheduled for 2015, is expected to run for only two or three years, instead of the usual seven as it has been in the past. And next month, the most visible effects of the cuts will take hold, when 19 layoffs (out of a total of 90 total staff members) go into effect.

Overseeing the budget-related turbulence is Daniel Levy, a medical officer at the NHLBI who joined the FHS nearly 30 years ago and has served as the study's director since 1994. **Elie Dolgin** met with Levy in Framingham, on the outskirts of Boston, to discuss how he's taking the new funding realities to heart.

Can you offer an example of a project immediately affected by the 40% budget reduction?

There are a number of research projects that we have that will be impacted by the budget cut. One of them is a program that I've spent many years of my life working on. It's called the SABRe CVD Initiative—that stands for the Systems Approach to Biomarker Research in Cardiovascular Disease. And one of the subcomponents of that research program is to identify new biomarkers of disease risk. That program in particular, because it was funded by the core contract, is affected considerably, by 40% reduction in the current year's funding. We will be scaling back the scientific scope of that project, and, unfortunately, also the timeline of the initiative will be delayed.

How so?

The original scope was to measure 180 promising protein biomarkers in 7,500 Framingham study participants. The actual number of biomarkers we end up measuring will be some number lower than 180. I'm not sure how many fewer, but quite a few less than we had originally hoped for. This is a project that we were very optimistic would identify new protein biomarkers of cardiovascular disease and for major risk factors of heart disease, and scaling back our project reduces the impact it may have in the future.

In-person physical exams have been called the lifeblood of the FHS, but they're obviously expensive. Will those continue under the shrunken core budget?

We expect to explore every avenue possible to continue those exams, and that might include investigator-initiated research grants [such as extramural RO1s or intramural NIH grants] that allow the exams to continue even if the level of funding related to sequestration does reduce the support for the core contract for those exams.

Will you also implement cheaper alternatives?

If doing the best possible research involves using other methods—be it online questionnaires or apps that you can use on a smartphone—that will be the sort of thing we investigate and consider. Our goal is to reinvent ourselves in ways that allow us to remain highly relevant, highly productive and at the cutting edge of science.

When the study first began, there was a dream of following a large group of relatively healthy people to gain insight into the root causes of cardiovascular disease. That was back in 1948, and it was envisioned as a 20-year project. So, Framingham has had to reinvent itself a number of times, and we will do it again.

Tell me about the 19 people who are being let go.

We all are quite concerned and feel quite a bit for the people whose jobs here have been lost as a result of the budget cuts that have occurred. The overwhelming majority of those 19 people were involved in the [clinical] exams. Our senior investigators have not changed, we have an active and vibrant fellowship program, we have many statisticians and analysts and we certainly have retained the vital nucleus for being able to look into the future.

Are there lessons that can be learned from past funding cuts to other epidemiological studies?

The Atherosclerosis Risk and Communities Study [started in 1987 in four US communities], for example, faced a challenge a number of years back and there was a hiatus between exam cycles. They looked at that hiatus and identified scientific opportunities, and through initially investigator-initiated grants they were able to fund the nucleus of another exam cycle. That nucleus of funding was then supplemented by other NIH funding mechanisms, and exams once again returned to ARIC and are ongoing right now. So that's a lesson for us: that one can endure a period of challenge and emerge from it strong and continuing to do great science.

Do you expect FHS to enroll a fourth generation of participants?

It would be presumptuous of me to say that I'm confident we'll be recruiting a fourth generation of study participants, but we were successful at recruiting a third generation, and that third generation allowed us to strengthen our program in genetic research, to identify family patterns of disease, to identify genetic indicators of disease, and to look at proteomics and metabolomics and transcriptomic patterns associated with disease and its major risk factors. So, I'm hopeful that we'll someday be able to recruit a fourth generation so we can continue and build upon this important work.