

## Why Renew Now?

The Special Diabetes Program (SDP) is due to expire on September 30, 2014. It is fair to ask why it is so important to renew the program a year in advance of its sunset date. Historically, Congress has always renewed SDP a year prior to its expiration to avoid disruption to the program's long-term clinical trials and studies and to ensure that federal funds invested to date are most effectively used.

**Without the certainty that comes from a multi-year funding extension, the National Institutes of Health (NIH) must stop funding promising new research that will take several years to complete; and it will have to start shutting down or scaling back key ongoing SDP projects. Uncertainty surrounding future SDP funding is already having a visible negative impact on research. That impact will grow every day SDP funding is not renewed. Listed below are some examples of the negative consequences.**

- The SDP established a major clinical trials network—Type 1 Diabetes (T1D) TrialNet—that is screening 20,000 relatives of T1D annually and testing strategies for disease prevention and early treatment. TrialNet has already stopped initiating new trials in newly diagnosed patients because of the uncertainty of funding beyond FY 2014. Applications for new drug development projects have stopped being accepted because of the uncertainty of future SDP funding even though new therapeutic agents are ready for testing.

- SDP created The Environmental Determinants of Diabetes in the Young (TEDDY), a long-term study to provide a coordinated, multidisciplinary approach to understanding the infectious agents, dietary factors, or other environmental conditions that trigger T1D in genetically susceptible individuals. TEDDY requires coordinated efforts of research teams capable of identifying at-risk newborns and collecting clinical data and biosamples over many years. It is difficult to maintain this sort of massive, effort, with over 8,000 at-risk children enrolled at birth and followed until age 15, when funding is uncertain.

- The Beta Cell Biology Consortium (BCBC), created by the SDP, is a highly successful research consortium studying how insulin-producing beta cells develop and function, and whether it is possible to coax new beta cell formation in the pancreas. Renewing SDP now would avoid disruption to the research momentum built up over the last several years.

**Renewing now is not just about avoiding disruption. It is also about giving NIH the green light to capitalize on incredibly promising opportunities presenting themselves right now. A multi-year extension of the SDP this year means that:**

- NIH would be able to launch approved trial concepts and new prevention trials of agents that effectively treated newly diagnosed patients, and continue to consider new clinical trials for disease prevention and early treatment through TrialNet.
- A clinical trial testing the ability of oral insulin to prevent T1D would proceed.
- Another trial testing whether certain agents can slow the progression of T1D in newly-diagnosed patients would proceed.
- New prevention trials testing other promising agents that may prevent T1D would be launched.
- The BCBC would be renewed, ensuring that scientists can push further towards discovering ways to replace or regenerate insulin-producing cells as a way to cure T1D.

- The career development of pediatricians specializing in T1D program would continue.
- SDP research supporting development of the artificial pancreas would continue, bringing this revolutionary treatment device to patients closer to reality.
- The groundbreaking research into the genetic causes of T1D—and perhaps other autoimmune diseases—would continue. To date, SDP has identified nearly 50 genes associated with T1D, and now the challenge is to understand how these genes may influence disease development. Further research is ongoing to pinpoint the exact genes to understand their function in T1D.

## Summary

This is just a sampling of the scores of promising lines of research that await funding. We have come a long way on the path to a cure for T1D, thanks in large part to the Special Diabetes Program. But there is still a great deal of ground to cover. While JDRF and other private funders are doing all they can to advance T1D research, they cannot fill the gap if the SDP is not renewed. Early renewal is consistent with past practice, will avoid disruption, and send an important signal that this area of research remains a national priority, ensuring that the fruits of prior SDP investments will be harvested rather than being delayed for years. NIH itself put it well in its 2011 report to Congress on SDP.

“The potential payoff from the investment in these large-scale long-term studies is only beginning to be realized. These efforts have set the stage for future research progress that is expected to be fully realized in the years to come. This important line of research could not be undertaken at all, or at least not at an unprecedented scale, without the financial aid and organizational resources of the Special Diabetes Program.”