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## **2. OBJECTIVES**

### **2.1 Research Questions**

Research questions of the troglitazone cohort include assessing differences over time within the troglitazone cohort and between the troglitazone cohort and the concurrent control group consisting of approximately 600 DPP participants randomized to double-placebo on or before May 27, 1998 with regard to the following:

- Time to confirmed diagnostic levels of diabetes, by ADA criteria (FPG  $\geq$  126 mg/dL [7.8 mmol/L] or 2-hour plasma glucose  $\geq$  200 mg/dL [11.1 mmol/L] after a 75 gram oral glucose tolerance test).
- Development of fasting hyperglycemia (FPG  $\geq$  140 mg/dL [7.8 mmol/L]).
- Reversal of IGT to a state of normal glucose tolerance.
- Change in hyperglycemia as measured by glycohemoglobin and fasting and 2 hr. plasma glucose.
- Change in insulin secretion and sensitivity.
- Change in body weight.
- Occurrence and magnitude of risk factors for cardiovascular disease.
- Occurrence of cardiovascular morbidity and mortality.
- Occurrence and magnitude of major adverse events.

The troglitazone cohort will be offered lifestyle group sessions four times per year. Weight change within the troglitazone cohort will be determined. The troglitazone cohort and the approximately 600 DPP participants randomized to the DPP intensive lifestyle intervention on or before May 27, 1998, will be compared on weight change.

### **2.2 Subgroup Research Questions**

Other research questions of the troglitazone cohort include assessing subgroups of troglitazone-treated participants with regard to the following:

- Consistency of the effects across the ethnic, age, and other selected subgroups.
- Baseline demographic, clinical, biochemical, and psychosocial parameters that predict outcome.