



UNIVERSITY OF CALIFORNIA, SAN DIEGO  
HUMAN RESEARCH PROTECTIONS PROGRAM

**FACT SHEET**

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**Type 2 Diabetes Research Guidelines**

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A common requirement for treatment studies of insulin-resistant (Type 2) diabetes is an observational period to determine the baseline level of hyperglycemia prior to institution of treatment. Because there are both short term and long term risks associated with untreated hyperglycemia, Institutional Review Boards (IRBs) are required to carefully evaluate the risks and benefits of participation in studies that include a period of observation without treatment.

In 2003 a working group of endocrinologists from the UCSD's Department of Medicine's Division of Endocrinology/Metabolism convened to develop safety guidelines for the conduct of Type 2 diabetes clinical studies. These guidelines are intended to address both eligibility of potential participants for enrollment in clinical studies, and ongoing monitoring of blood sugar during such studies. The working group made the observation that recommended standards of care for diabetes are seldom achieved in the real world, and that the majority of Type 2 diabetic patients always experience some degree of hyperglycemia. In addition, they believed that it was important not to restrict eligibility for participation in studies only to those individuals with minimally elevated blood sugars, as this would potentially give biased scientific results and would preempt the study of more severe forms of the disease.

The working group arrived at the following consensus guidelines that will be used by UCSD's IRBs until additional evidence becomes available that would modify the assessment of risks and benefits in persons with Type 2 diabetes.

**Protocol Eligibility**

Studies of Type 2 diabetes may be approved by the IRB if the following conditions are met:

1. The study duration will not exceed six months
2. Baseline fasting plasma glucose levels of potential participants are 225 mg/dl or below.
3. For study participants who have fasting plasma glucose levels between 200 and 225, study procedures include blood glucose monitoring at intervals not longer than one week

**Protocol Monitoring**

During the conduct of a study enrolling Type 2 diabetic patients, if for any reason an individual subject's fasting glucose level exceeds *250 mg/dl on two occasions at least one week apart*, then the study must include either:

1. a mechanism for instituting more effective glycemic control within the study, or;
2. this finding must be used as a criteria for termination of participation in the study, and a mechanism must be described in the study for instituting effective glycemic control as a part of the termination procedures.

These specific conditions are in addition to the overall assessment of risks and benefits made by the IRB, and are not the sole criteria used by the IRB in its assessments of the safety and ethics of conducting studies. They are provided as guidelines to UCSD researchers to improve the consistency of diabetic care in research settings.