

INSTRUCTIONS CONCERNING DIAGNOSIS OF DIABETES MELLITUS

THIS SUBJECT IS PARTICIPATING IN A RESEARCH STUDY FOR WHICH THERE ARE SPECIFIC CRITERIA FOR THE DIAGNOSIS OF DIABETES. PLEASE NOTE THAT IN DPT-1 THERE ARE ROUTINE SCHEDULED MEASUREMENTS OF GLUCOSE AND ROUTINE GLUCOSE TOLERANCE TESTS.

Meter readings are not acceptable diagnostic criteria.

THE DIAGNOSIS OF DIABETES REQUIRES:

- [i] casual (any time of day without regard to time since last meal) plasma glucose \geq 200 mg/dL, if accompanied by unequivocal symptoms of polyuria, polydipsia, polyphagia, and/or weight loss,
OR
- [ii] fasting (no caloric intake for at least 8 hours) plasma glucose \geq 126 mg/dL,
OR
- [iii] 2-hour plasma glucose \geq 200 mg/dL during a 75 gram oral glucose tolerance test (OGTT),
OR
- [iv] unequivocal hyperglycemia with acute metabolic decompensation (e.g. ketoacidosis).

The criteria must be met on two occasions (unless criteria [iv] is present).

In DPT-1, unless criteria [iv] is present or the fasting glucose is \geq 250 mg/dl (at the bedside or in the local laboratory on the day of testing), it is preferred that at least one of the two testing occasions involve an oral glucose tolerance test (OGTT). If the first criterion met is [iii], i.e. by the 2-hour OGTT value, the OGTT should be repeated within 60 days.

It is essential that every effort be made to obtain the necessary tests to establish the diagnosis of diabetes.

IF THE CRITERIA FOR DIABETES ARE MET, YOU MUST:

1. **OBTAIN A SERUM SAMPLE TO SEND TO THE CORE LABORATORY**
2. **COMPLETE THE REPORT OF STUDY EVENT FORM**

ALL SUBJECTS HAVING THE DIAGNOSIS OF DIABETES MUST HAVE ALL "END OF STUDY" EVALUATIONS, INCLUDING ICA, IAA, and HbA_{1C}. A MIXED MEAL TOLERANCE TEST SHOULD BE COMPLETED WITHIN 8-16 WEEKS AFTER THE DIAGNOSIS HAS BEEN MADE.