



PROTOCOL NUMBER

13472A

1. What type of samples will be used?

Blood samples for DNA testing.

2. From where and how will the samples be obtained?

Samples will be obtained via venipuncture using aseptic technique by the Clinical Research Center nursing staff during the course of the subject's admission for the study.

3. Will the samples be identifiable or potentially identifiable through links or codes?

Yes  No

If yes, please provide a justification why samples cannot be completely encrypted.

For purposes of the study, it is necessary to distinguish between samples from controls vs. patients and to distinguish between samples of patients with various diagnoses.

4. What will be the purpose of taking the sample?

The purpose is to look for genetic markers for various endocrine disorders or puberty.

5. Will the sample be destroyed after this purpose is served?

Yes  No

If no, how will the sample be stored?

The sample will be stored frozen.

Where will the sample be stored?

In the Clinical Research Center.

How long will the sample be stored?

The sample will be kept indefinitely, since the possibility exists that new genetic markers could be found or new ways to find markers may be developed.

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6. Will additional purposes be devised for these samples?

Yes  No

If yes, please explain.

7. Will subjects receive any information back?

Yes  No

If yes, please describe the information that subjects will receive.

8. Who will "own" the sample?

The University of Chicago.

9. Will the University of Chicago investigator remain in control of the sample?

If no, who will have control of the sample?

Yes  No

10. Will the sample be shared with other University of Chicago investigators?

If yes, how will the sample be shared?

Yes  No

11. Will the sample be shared with investigators outside of the U of C?

Yes  No

If yes, how and with whom?

Serum will be stored for assay of inhibin-B in subgroups via a collaborative arrangement with Dr. Carol Foster (University of Michigan). FAS will be assayed by RIA in collaboration with Dr. William F. Crowley, Jr., Massachusetts General Hospital. Blood (5-10 cc x 3) will be collected in EDTA to extract DNA, prepare a lymphoblastoid cell line, and freeze in the CRC Core laboratory for studies of the molecular genetic basis of idiopathic GnD in collaboration with Lawrence Layman, MD.