THE UNIVERSITY OF CHICAGO

AMENDMENT SUBMISSION FORM
INSTITUTIONAL REVIEW BOARD
OFFICE OF RESEARCH SERVICES
Room S144 MC 1108
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Phone: 773-702-6505 / Fax 773-834-0659
http://ors.bsd.uchicago.edu/HS

Protocol Number 13472A

For Office Use Only
Amendment #

Any change to an approved research protocol, including the research plan, consent process and form, co-investigators, other research personnel, and/or methods of subject recruitment, requires the submission of an Amendment. Please clarify the change(s) to be made and the rationale for the change. The revised protocol, consent form, advertisements, and/or Investigator Brochure with the changes clearly identified, using a highlighter, must be submitted. A cover letter or additional information may also be attached. If revisions are not summarized and if the revised portions of the pertinent documents are not highlighted, the amendment package will be returned to the submitting investigator.

Amendments to protocols may not be initiated until IRB approval has been obtained.

PRINCIPAL INVESTIGATOR

Last Name: Rosenfield

First Name: Robert

PROTOCOL TITLE

Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty

The following changes are proposed for this protocol:

☐ **Principal Investigator change**

Please list the name of the new Principal Investigator

Last Name

First Name

BSD ID# -

☐ **Co-Investigator change**
If you are adding or removing a coinvestigator or coinvestigators, please complete and submit supplemental form A

☐ **Other research personnel change**
If you are adding or removing a member of the investigative staff (other than a coinvestigator), please complete and submit supplemental form B

☐ **Primary contact change**

Last Name

First Name

BSD ID# -

9470171021

Reset

☐ **Title change**

New Protocol Title

☐ **Drug**

If a drug is being added to the protocol please submit the Supplemental Form D .

☐ **Device**

If a device is being added to the protocol please submit the Supplemental Form F.

☐ **Study population**

Age Range (check all that apply)

- ☐ 0-7 yrs.
- ☐ 8-17 yrs.
- ☐ 18-58 yrs.
- ☐ 59+ yrs.

Type of Subjects

- ☐ inpatients
- ☐ outpatients
- ☐ healthy volunteers
- ☐ UC employees
- ☐ UC Students

Special populations to be included in the research (check all that apply):

- ☐ minors under age 18 - Supplemental form C must be included
- ☐ pregnant women
- ☐ fetus/fetal tissue
- ☐ prisoners
- ☐ economically disadvantaged
- ☐ decisionally impaired
- ☐ mentally retarded
- ☐ illiterate
- ☐ Non-English speaking

☐ **Number of Subjects**

Please indicate the number of additional subjects to be recruited into the study.
In addition, please indicate the new total number of subjects.

To be added ☐☐☐☐ Total number of subjects ☐☐☐☐☐

If an increase in the number of subjects is requested, please provide a justification for the increase.

1. Is a **revised protocol** necessary as a result of this amendment? ☐ Yes ☒ No*

   If yes, please attach the revised protocol and clarify the following

   Version # _____ Version Date _____

2. Is a revised **consent form** necessary as a result of this amendment? ☒ Yes ☐ No*

   If yes, please attach the revised consent form and clarify the following

   Version # _____ Version Date 1/7/05

   Version # _____ Version Date _____

3. Is a revised **advertisement** necessary as a result of this amendment? ☐ Yes ☒ No

   If yes, please attach the revised advertisement.

4. Is a revised **Investigator Brochure** necessary as a result of this amendment? ☐ Yes ☒ No

   If yes, please attach the revised Investigator Brochure and clarify the following:

   Version # _____ Version Date _____

5. Is a change in drug dosage (increase or decrease) being proposed? ☐ Yes ☒ No

   If yes, a revised protocol must be sent to the Dept. of Pharmaceutical Services, Section of Investigational Drugs (MC 0010) once the dose changes are approved by the IRB.

6. Please describe the specific changes to the previously approved protocol and provide sufficient rationale for each change to allow the committee to make a decision. Use additional pages as necessary. *If a revised protocol and/or revised consent form is not needed, please explain why revisions to the document(s) are not necessary.

The Child Patient and Volunteer Consent Forms dated 1-7-05, the Child Volunteer Assent Form dated 11-23-04, and the Child Patient Assent Form dated 11-23-04 have been revised to include changes as requested by Dr. Sheridan. Specifically, 1) the number of study subjects is added to the Volunteer consent form, 2) the absence of side effects of leuprolide use in children is now specified in both consent forms, and 3) since pregnancy testing is not indicated (all study subjects are in early puberty, not sexually mature), no changes are indicated in this regard.

7. **Risk-Benefit Assessment**

Are the risks to subjects affected (increased or decreased) by the amendment? ☐ Yes ☒ No

If **yes,** describe how the amendment will affect the risk-benefit ratio for the subjects.

8. **Reaffirmation of Informed Consent/Assent**

Is it necessary to inform subjects who have already consented to participate in the research of the amendment? ☐ Yes ☒ No

If **yes**, should they be given and asked to resign the full revised informed consent form OR should an addendum to the informed consent document be prepared for discussion with the subjects? **Select One.**

☐ Full Revised Informed Consent Document ☐ Addendum

9. **Notification of Subjects Who Have Completed Participation**

Is it necessary to notify subjects who have completed their participation in the research? ☐ Yes ☒ No

If **yes**, describe how this will be done AND submit the documents (if applicable) that will be used.

10. Is **expedited review** being requested? ☐ Yes ☒ No

As per the federal regulations, minor administrative changes can be reviewed through an expedited process. The IRB has agreed that the following types of simple administrative changes and minor adjustments which do not affect the risk/benefit ratio **may** be considered for expedited review (please check all that apply):

☐ Adding or removing an institution

☐ Changes in the PI

☐ Changes in Participants

☐ Adding a standardized (validated) questionnaire

☐ Modification of a previously approved advertisement including mode, verbiage, etc.

☐ Submission of or modification to investigational brochures;

☐ Modifications to the consent form to include the following:
1) Adding or removing information from the consent form so that it is consistent with an already approved IRB statement (i.e. cost section, phone number changes);
2) revising the consent form to reflect what was already approved in the protocol;
3) defining a phrase(s) more clearly in lay language; or
4) incorporating in the consent form updated IRB-mandated language.

☐ Minor editorial changes to the protocol and/or consent form which do not alter the meaning or procedures (i.e., spelling changes, revising a statement)

☐ Removal of a questionnaire from protocol and its reference on consent form.

☐ Software Upgrades

In addition, if the original protocol was reviewed through an expedited review procedure, the amendment MAY be eligible for expedited review.

☐ **Please check here if the original protocol was given expedited approval.**

SIGNATURE

(This form must bear the original signature of the principal investigator)

Principal Investigator	**Date**
Department Chair Signature (Only if not externally funded)	**Date**

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