Franciscan Children's

RESEARCH APPLICATION
FOR IRB REVIEW

Project Title:

_____

Principal Investigator(s) (name, FC department, and contact information):

_____

Co-investigator(s) (name and FC department):

_____
_____
_____
_____

Department Director of PI (Name and Signature Required):

_____

Departmental Director of Co-Investigator(s) (Name and Signature(s) Required):

_____
_____
_____

Date of Submission:

This form is to be used when submitting a research application to the Institutional Review Board at FC. *Incomplete applications will not be reviewed*. Please complete the outline below to describe your proposed project. Please address each section using additional space as needed.

Applications should be submitted to the IRB, lhughes@franciscanchildrens.org

1. Project Summary (please include the purpose of the project; study hypotheses; a brief description of the subjects, study design, and methods; anticipated results; and plans for disseminating the findings)

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2. Study Benefits (State benefits to the research subject, the medical/scientific community, and to the general public's health and welfare).

3. Study Risks (List the possibilities for harm to the subjects as a result of their participation in the research, including discomforts, hazards, or inconveniences and indicate what measures will be taken to prevent or to minimize these risks).

4. Confidentiality (State what steps will be taken to maintain confidentiality of data anonymity/privacy of subjects).

5. Contact with Subjects

a. Does this research involve any non-affiliated person (someone who is not an employee or staff member of FC) who will recruit, treat, observe, provide information to subjects, or otherwise participate in this research? ( )no ( )yes (If "yes", please complete Appendix A)

b. Who will supervise their conduct as it pertains to the research subjects?

c. Describe their involvement with the subjects/research study.

d. Address the following issues with respect to the professional qualifications of each non-affiliated person involved in the research study. (May attach CV) *CITI training certificate must accompany application*

1. Degrees achieved (identify type and institutions)
2. Licenses held (all states)
3. Hospital/health care organization affiliations

6. Study Subjects

a. Will the study involve children as research subjects? ( ) yes ( ) no

b. Will subject be legally competent to consent or refuse to participate?
( ) yes ( ) no (If "no" who will consent?): _____

c. Will all subjects be English speaking?

( )yes ( ) no (If no, what provisions have been made for non-English speaking participants?

d. Will subjects be hospitalized for this project? ( ) yes ( ) no

1. If hospitalized for medical reasons, will participation in this study increase the length of stay? ( ) yes ( ) no
2. If outpatients, will extra visits be required for this study over and above those required for the subject's clinical care? ( ) yes ( ) no
3. If the answer to (1) and (2) above is **yes**, state the anticipated source of payment for hospitalization, visits, and tests required solely for purposes of this study:

e. Will subjects incur charges, specifically as a consequence of participation?
( )yes (if "yes", state specifically what they will be charged for) ( )no

f. Will there be payment to subjects?
( )yes (state terms of payment, including amount, who will receive it, what form it will take, formula for pro-rating, if any, and when it will be paid) ( )no

g. Outline methods for recruitment including identifying and contacting potential subjects. Also, state follow- up contact procedures, if any, to be used. (Please attach samples of any letters, advertisements, etc.)

h. Outline the process by which the subject's consent will be sought. (State the length of time between the conclusion of the consent process and the beginning of the subject's participation, and who will conduct the consent discussion.)

i. State specific criteria for subject eligibility for this study (e.g. "normal kidney function" is not an acceptable inclusion criterion but instead should be listed as, "Creatinine X times the upper limit of hospital normal").

j. State specific criteria for subject exclusion for this study.

7. Study Components

a. Controlled Substances in Schedule II ( ) yes ( ) no

b. Investigational Drug(s) ( ) yes ( ) no
(if **yes,** indicate IND# and submit copy of investigator's brochure)
IND#_____

c. FDA Approved Drug Used in Accordance with FDA Labeling ( ) yes (x) no

d. Use of an Approved Drug ( ) yes ( ) no

e. Review of Medical Records or other existing data (x) yes ( ) no

f. Audio Recordings ( ) yes ( ) no

g. Visual Recordings and/or photographs ( ) yes ( ) no

h. Telephone Interviews and/or Personal Interviews (please attach copy) ( ) yes ( ) no

i.. Questionnaires and/or Psychological or Similar Tests (please attach copy) ( ) yes (x) no

j. On-line/Internet-based Questionnaires or Survey (s) ( ) yes ( ) no

k. Handling of Blood and/or Bodily Fluids (please provide documentation that all study staff have been instructed in the relevant OSHA regulations). N/A

8. Research Support
a. ( ) Outside funding-specify: _____

b**.** ( ) Internal (FHC) funding-specify: _____

c. ( ) None
(If you checked a or b please complete Appendix B)

9. Information about Possible Conflicts of Interest
Do any of the researchers have a conflict of interest (financial, investigator / provider, or other) related to the proposed research?

( ) yes ( ) no

If yes, each researcher having a conflict of interest must be identified and the conflict described in the above application and any conflict must also be described in the consent form for the participants.

I, the undersigned, accept the responsibility for assuring that this study will be conducted in accordance with all applicable federal and state laws and regulations and the policies of Franciscan Children's Hospital, with regard to the protection of human subjects participating in this study.

I agree to request and obtain approval from the Institutional Review Board prior to making any changes in this study as described in the application. I also agree to promptly notify the IRB of any emergent problems that may arise in the course of the study, including untoward results or unanticipated side effects.

Signature of Principal Investigator(s): _____

Franciscan Children's Hospital

IRB Application

APPENDIX A - Review by Other Institutions/Institutional Reliance

Project Title: _____
_____

Principal Investigator(s): _____ _____

I. Has this proposal been reviewed by an Institutional Review Board/Human Subjects Committee at another institution?

( ) no ( ) yes ( ) N/A-FC ( ) to be submitted

Submission Date:

Pending Approval:

Approval Date:

Deferral Date:

A. Name of institution:

B. If known, application ID # at other institution:

C. Principal Investigator for other submission:

D. Is a Reliance agreement being sought? _____Yes _____No
If yes, please provide detail(s) of request.

Franciscan Children's Hospital
IRB Application

APPENDIX B - Project Funding

Project Title: _____
_____

Principal Investigator(s): _____ _____

I. Funds for expected support for the proposed research

Have been awarded	( ) no	( ) yes
Have been applied for	( ) no	( ) yes
Will be applied for	( ) no	( ) yes

II. Funds will be administered through the business office at:

( ) FC

( ) Other-please specify: _____

II. Grant/Contact Number:

A. Period of support (start-end dates):
B. Amount of support for each year: