

SAN JOSE STATE UNIVERSITY

**HUMAN SUBJECTS-INSTITUTIONAL REVIEW BOARD
PROTOCOL NARRATIVE**

I. APPLICATION

II. PROJECT TITLE

Developmental Impact of Growing up with a Sibling with Critical Congenital Heart Disease (CCHD)

III. INVESTIGATORS AND STAFFING

NAME OF INDIVIDUAL	QUALIFICATIONS	RESPONSIBILITIES
Joanna Fanos, Ph.D.	Faculty, Psychology Dept.	Will oversee project as P.I.
Chris Landon, M.D.	Physician, Ventura County Medical Center (VCMC)	Will recruit participants from VCMC

IV. INVOLVEMENT OF OTHER INSTITUTIONS

- a. Ventura County Medical Center will provide 3-5 adult siblings of individuals with CCHD. See attached IRB approval letter from David Chase, M.D.
- b. I do not have any affiliation with VCMC nor any personal financial interest.
- c. I have no potential conflict of interest, nor does Dr. Christopher Landon.

V. ABSTRACT

It is estimated that approximately 2 of every 1,000 live births will have critical congenital heart disease (CCHD). Recently, Newborn Screening (NBS) programs for CCHD have begun throughout the U.S.; in addition, prenatal screening programs are increasingly utilized. As programs are developed throughout the U.S., it is necessary to include an awareness of the impact of a diagnosis on the family, particularly the healthy siblings, known to be at risk for psychosocial distress in other childhood chronic conditions. The research objectives of this subcontract are to: a). Identify major areas of long-lasting concern for siblings who grew up with a brother or sister with CCHD; b). Assist in the development of recommendations for CCHD NBS screening and prenatal screening that will improve psychosocial outcomes for siblings. Our hypothesis is that growing up with a sibling with CCHD is a potentially distressing experience. Dr. Fanos will interview over the phone for approximately 45 minutes 3-5 adult siblings drawn from Ventura County Medical Center, using a semi-structured interview guide. This project is a sub-contract from a larger grant to the University of New Hampshire (HRSA # H46MC24093). Lessons learned will improve the implementation of NBS programs for CCHD. These interviews will provide pilot data for the development of a larger grant on siblings of children with CCHD.

VI. HUMAN SUBJECTS INVOLVEMENT

A. SUBJECT POPULATION

The sample will consist of 3-5 adult siblings of patients in the Ventura County Medical Center. They will be from the ages of 18 and older and of varying ethnicities.

B. RECRUITMENT PLAN

The medical provider will contact adults with CCHD followed in the Ventura County Health Care system and ask if they have an adult sibling who might be interested in participating in this study (see Appendix A). If so, they will be asked to contact the sibling and invite participation in the study. In about 2 weeks, the medical provider will phone the patient and ask if their sibling is interested in learning more about the study, and this conversation will be documented (see Appendix B). If positive, within two weeks, Dr. Fanos will follow up with a phone call to the sibling. The sibling will be asked if this is a convenient time to talk; if not, a phone appointment will be made. At that time Verbal Consent will be obtained (see Appendix C). The sibling will then be interviewed using a semi-structured Interview Guide (see Appendix D). The entire interview will last from 30-60 minutes. At the end of the interview, Dr. Fanos will ask if participants would like the Verbal Consent Form mailed to them. This project will recruit 3-5 siblings of an individual with CCHD at VCMC.

Inclusion criteria:

All adult siblings, male or female, and of varying ethnicities, 18 years and older, will be eligible for this study.

Exclusion criteria:

Individuals will not be eligible if they are: 1) less than 18 years of age; 2) pregnant women; 3) have a serious medical condition that might influence outcome measure assessment; and 4) have difficulty understanding English.

C. RESEARCH METHODS AND DESIGN / PROCEDURES

Participants will be interviewed individually over the phone for 30-60 minutes. The interviews will begin with open-ended questions and move to more specific probes if material is not forthcoming. Dr. Fanos will conduct all interviews; these will be audiotaped and transcribed verbatim. Using the method of content analysis described by Weiss⁷ the qualitative interview material will be coded into predominant themes. These data will identify areas in the implementation of newborn screening for CCHD that need improvement as well as ways in which to do so. Dr. Fanos has conducted funded research (including that of NIH) for 25 years on the impact of various serious if not lethal medical disorders on the family, particularly the siblings.

This study is a direct result of the prior study on parental response to NBS for CCHD (June 1, 2013-May 31, 2014). Funding is a subcontract to Dr. Fanos from HRSA grant to UNH # H46MC24093 (Dr. Monica McClain, PI) from June 1, 2014 to May 31, 2015.

¹Weiss RS. *Learning from strangers: The art and method of qualitative interview studies*. NY: Free Press, 1995.

D. MATERIALS AND DEVICES

- 1) Demographic information will be gathered (see attached).
- 2) A semi-structured interview guide will be administered one time only over the phone (see attached)
- 3) Dr. Fanos will record information during the phone discussion by using a digital recorder. No participants will be photographed. The information will be used to provide examples of areas of major concerns. If any direct quotes are used in presentations or publications, all that will be stated would be “as one young man said...” or the like.

E. CONFIDENTIALITY

All research material will be stored in a locked cabinet in Dr. Fanos’ office. All study information will immediately be assigned a numerical code. There will be one master list of participants to which only Dr. Fanos will have access. Only study personnel will have access to the files. No voice recording will be played publicly but only for the purpose of transcription. Once the digital recording has been transcribed, the file will be deleted on both Dr. Fanos’ computer as well as on the computer of the transcriptionist. Once data analysis has been completed, the master list of participants will be destroyed. The transcription of the interviews will be retained for approximately a year, but any identifying information (e.g., name of a family member) will be deleted.

F. COMPENSATION

None.

G. POTENTIAL BENEFITS

There may be no direct benefit to the sibling of participating in the research. However, they may benefit from knowing that they have contributed to information that could be of help to other siblings of children diagnosed with CCHD.

H. POTENTIAL RISKS

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- 1) One risk is that some of the discussions may make the participant feel uncomfortable or upset.
 - 2) Another risk is to confidentiality.
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I. RISK REDUCTION

1) One risk is that some of the discussions may make the participant feel uncomfortable or upset. They will be reminded that they are free to decline to answer any questions they do not wish to answer, and they may stop the interview at any time. If undue distress is noted by Dr. Fanos, Dr. Landon (co-investigator) will refer the participant to Ventura County Behavioral Health.

2) Another risk is to confidentiality. Dr. Fanos will store all demographic information in a locked file in her office. All data will be kept confidential according to standard practice. No individual identities will be used in any reports or publications from the study. There will be one master list of participants to which only Dr. Fanos will have access.

VII. INFORMED CONSENT**A. CONSENT PROCESS**

The medical provider will contact adults with CCHD followed in the Ventura County Health Care system and ask if they have an adult sibling who might be interested in participating in this study (see Appendix A). If so, they will be asked to contact the sibling and invite participation in the study. In about 2 weeks, the medical provider will phone the patient and ask if their sibling is interested in learning more about the study, and this conversation will be documented (see Appendix B). If positive, within two weeks, Dr. Fanos will follow up with a phone call to the sibling. The sibling will be asked if this is a convenient time to talk; if not, a phone appointment will be made. At that time Verbal Consent will be obtained (see Appendix C). The sibling will then be interviewed using a semi-structured Interview Guide (see Appendix D). The entire interview will last from 30-60 minutes. At the end of the interview, Dr. Fanos will ask if participants would like the Verbal Consent Form mailed to them. This project will recruit 3-5 siblings of an individual with CCHD at VCMC.

B. ASSENT PROCESS AND OTHER SPECIAL CONSENT PROVISIONS

N/A

C. WAIVER OF WRITTEN CONSENT

Since the participants will live in the Ventura, California area, phone interviews will be conducted. Therefore, a waiver of written consent is requested (see attached Verbal Consent Form).

D. DEBRIEFING

N/A

E. CONSENT FORMS

See attached.

VIII. OTHER

N/A