VCU Memo

Virginia Commonwealth University

Office of Research Subjects Protection
BioTechnology Research Park
800 East Leigh Street, Suite 114
P.O. Box 980568
Richmond, Virginia 23298-0568
(804) 827-0868
Fax: (804) 827-1448

DATE: July 28, 2011

TO: Debra E. Lyon, PhD, RN, FNP-BC, FNAP
Family and Community Health Nursing
Box 980567

FROM: Elizabeth Ripley, MD, MS
Vice Chairperson, VCU IRB Panel B
Box 980568

RE: **VCU IRB #: HM13492**
Title: African American Males Diagnosed with Schizophrenia: A Phenomenological Study

On July 22, 2011, the changes to your research study were ***approved*** in accordance with 110 (b) (2). This approval includes the following items reviewed by this Panel:

PROTOCOL (Research Plan): African American Males Diagnosed with Schizophrenia: A Phenomenological Study, received 6/30/11, version 3, dated 6/29/11

CONSENT/ASSENT (attached):

- Research Subject Information and Consent Form, received 6/30/11, version 3, dated 6/29/11, 4 pages

Please Note: At this time of review, the VCU IRB acknowledges the change in Principal Investigator from Inez Tuck, PhD, MBA, MDiv, RN, to Debra Lyon, PhD, RN, FNP-BC, FNAP.

As a reminder, the approval for this study expires on February 29, 2012. Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

The Primary Reviewer assigned to your research study is Lou Usry, RN. If you have any questions, please contact Ms. Usry at lusry@mcvh-vcu.edu and 828-9229; or you may contact Jennifer Rice, IRB Coordinator, VCU Office of Research Subjects Protection, at jlrice@vcu.edu or 828-3992.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: African American Males Diagnosed with Schizophrenia: A Phenomenological Study

VCU IRB NO.: HM 13492

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is to find out what life is like for an African American man diagnosed with schizophrenia.

You are being asked to participate in this study because you are an African American male, who is diagnosed with schizophrenia.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to attend one interview session in a private room in the clinic where you receive your medical care. The session will last approximately one hour. In the session, you will be asked to talk about what it is like to be an African American male diagnosed with schizophrenia. The meetings will be tape recorded so we are sure to get everyone's ideas, but no names will be recorded on the tape.

RISKS AND DISCOMFORTS

Sometimes talking about these subjects causes people to become upset. Several questions will ask about things that have happened to you that may have been unpleasant. You do not have to talk about any subjects you do not want to talk about, and you may leave the session at any time. If you become upset, the study staff will give you names of counselors to contact so you can get help in dealing with these issues.

BENEFITS TO YOU AND OTHERS

You may not get any direct benefit from this study, but, the information we learn from people in this study may help us design better programs for African American males diagnosed with schizophrenia.

COSTS

There are no costs for participating in this study other than the time you will spend in the interview session.

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7-22-11/LU/JR

PAYMENT FOR PARTICIPATION

You will receive a $20.00 Wal-Mart gift card for completion of your interview.

ALTERNATIVES

The alternative is to not participate in this study.

CONFIDENTIALITY

Potentially identifiable information about you will consist of interview notes and recordings. Data are being collected only for research purposes. Your data will be identified by ID numbers and ages, not names, and stored separately from medical records in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted within 7 years of completion of the study. Access to all data will be limited to study personnel. A data and safety monitoring plan is established.

We will not tell anyone the answers you give us; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. Personal information about you might be shared with or copied by authorized officials of the Department of Health and Human Services (if applicable).

What we find from this study may be presented at meetings or published in papers, but your name will not ever be used in these presentations or papers.

The interview session will be audio taped, but no names will be recorded. At the beginning of the session, all participants will be asked to use initials only so that no names are recorded. The tapes and the notes will be stored in a locked cabinet. After the information from the tapes is typed up, the tapes will be destroyed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study.

Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- the study staff thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

APPROVED

7-22-11 / LU / JR

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

Debra E. Lyon ,PhD, RN, FNP-BC, FNAP Associate Professor and Chair, Department of Family and Community Nursing

VCU School of Nursing

1100 East Leigh St.

PO Box 980567

Richmond, VA 23298

Ph: (804) 828-5635

delyon@vcu.edu

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research

Virginia Commonwealth University

800 East Leigh Street, Suite 113

P.O. Box 980568

Richmond, VA 23298

Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at *http://www.research.vcu.edu/irb/volunteers.htm.*

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CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study. I will receive a copy of the consent form once I have agreed to participate.

_____

Participant name printed Participant signature Date

_____

Name of Person Conducting Informed Consent

Discussion / Witness [3]

(Printed)

_____ _____

Signature of Person Conducting Informed Consent Date

Discussion / Witness

_____ _____

Principal Investigator Signature (if different from above) Date [4]

[3] *[A witness to the signature of a research participant is required by VA Code. If the witness is to be someone other than the person conducting the informed consent discussion, include a line for the witness to print his/her name and lines for signature and date.]*

[4] *[The purpose of this signature is to ensure that the principal investigator is aware of who has been enrolled in studies. The principal investigator's signature date need not correspond to that of subject or witness, but should be provided after both the subject and witness have signed.*

APPROVED

7-22-11/ Lu /JR