VCU Memo

Virginia Commonwealth University

Office of Research Subjects Protection
BioTechnology Research Park
BioTech One, 800 E. Leigh Street, #114
P.O. Box 980568
Richmond, Virginia 23298-0568
(804) 828-3992
(804) 827-1448 (fax)

DATE: March 16, 2011

TO: Inez Tuck, PhD, MBA, MDiv, RN
School of Nursing
Box 980567

FROM: Lisa M. Abrams, PhD
Chairperson, VCU IRB Panel B
Box 980568

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

On March 14, 2011, the following research study was ***approved*** by expedited review according to 45 CFR 46.110 Categories 6 and 7. The approval reflects the revisions received in the Office of Research Subjects Protection on March 14, 2011. This approval includes the following items reviewed by this Panel:

RESEARCH APPLICATION/PROPOSAL: None

PROTOCOL (Research Plan): African American Males Diagnosed with Schizophrenia: A Phenomenological Study, received 3/14/11, version 2, dated 3/9/11
- Inclusion Criteria, received 3/14/11, version 2, dated 3/9/11
- Demographic Survey, received 2/4/11, version 1, dated 1/21/11
- Research Questions, received 2/4/11, version 1, dated 1/21/11

CONSENT/ASSENT (attached):
- Research Subject Information and Consent Form, received 3/14/11, version 2, dated 3/9/11, 4 pages

ADDITIONAL DOCUMENTS (attached):
- Introduction Letter for Clinical Staff, received 3/14/11, version 2, dated 3/9/11
- Flyer: Participants Needed for Research Study, received 3/14/11, version 2, dated 3/9/11

This approval 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 and 828-3992.

Conditions of Approval:

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable):*

1. Conduct the research as described in and required by the Protocol.

2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).

3. Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).

4. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.

5. Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).

6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.

7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in VCU IRB WPP VIII-7):

8. Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.

9. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.

10. All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on http:/www.research.vcu.edu/irb/guidance.htm.

11. The VCU IRBs operate under the regulatory authorities as described within:
    a) U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
    b) U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
    c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).

[010507]

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

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

VCU IRB NO.: HM13492

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.

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

3-14-11 / 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:

Inez Tuck, PhD, MDiv, RN

Professor, Department of Adult Health and Nursing Systems

VCU School of Nursing

1100 East Leigh St.

PO Box 980567

Richmond, VA 23298

Ph: (804) 828-3474

ituck@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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3-14-11/LU/JR

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.*

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3-14-11 /LU /JTE

Introduction letter to the study to the Clinical Staff

Hello Clinical Staff Member,

I am a doctoral candidate at Virginia Commonwealth University, School of Nursing. I am involved in research study to gain a better understanding of the experiences of African American males diagnosed with and treated for schizophrenia. Those selected for the study will be invited to participate in a one-hour interview that focuses on their experience of living with the diagnosis of schizophrenia. The interviews will be audio taped.

The criteria for inclusion in the study are: ability to speak and understand English; having obtained the age of 18 years or older; status as an African American male diagnosed with schizophrenia; having the ability to articulate his story; living independently in the community and able to consent to participate based on outpatient staff's assessment. A critical exclusion criterion will be anyone carrying a diagnosis of primary dementia. At the conclusion of the interview, participants will receive a $20 Wal-Mart gift card to compensate them for their time. I am requesting that you share this information with persons that you believe would qualify for this study and would be interested in participating. You may share with them my contact information or ask them to attend the recruitment sessions offered in the agency. For further information about the study, I can be reached at 804- 828-3347or email andersonlb@vcu.edu.

Thank you for your assistance.

Respectfully,

Lorraine B. Anderson, RN, PhD(c)

School of Nursing

Virginia Commonwealth University

Participants Needed for Research Study

Are you:

☑ **An African-American Male 18 years of age or older?**

☑ **Diagnosed with Schizophrenia?**

If so, you may be eligible to participate in a research study at Virginia Commonwealth University School of Nursing. The purpose of this study is to examine the experiences of African American males diagnosed with and treated for schizophrenia. Participation involves a confidential interview consisting of answering questions at a mutually agreed upon location. Qualified participants will be compensated for their time.

Interview Duration: 1 hour
Compensation: a $20 gift-card upon successful completion of the study

For more information regarding this study, please contact Lorraine Anderson, VCU, School of Nursing at (804)828-3347, or email andersonlb@vcu.edu

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