



Crescent City Institutional Review Board  
2820 Canal Street . New Orleans, LA 70119  
(504) 822-4067 . fax (504) 822-4068 . email: irb@ccirb.com

March 17, 2011

William Smith, M.D.  
New Orleans Center for Clinical Research  
2820 Canal Street  
New Orleans, LA 70119

1928 Alcoa Highway  
Knoxville, TN 37920

RE: New Orleans Center for Clinical Research  
Your application dated 3/17/2011  
Site Guidelines Approval Letter

Dear Dr. Smith:

I have reviewed your request for approval of the site guidelines for New Orleans Center for Clinical Research - Knoxville. This type of request is eligible for expedited review under FDA regulations.

This is to confirm that your site guidelines were approved.

You are granted permission to use your site guidelines described in your application effective immediately.

Contact Debbie Pusateri (504-822-4067; fax 504-822-4068; email: dpusateri@ccirb.com) if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink that reads "Brandon M. Wool".

Brandon M. Wool, MD  
IRB Chairman

CCIRB

MAR 17 2011

APPROVED  
MODIFIED

## New Orleans Center for Clinical Research – Knoxville

### Site Guidelines

We want to thank you for being a participant in this study, and welcome you to our facility. Your role, while here, is to help us in conducting a research study. It is very important that you take your responsibility seriously and understand the standards discussed below.

As you may have noticed, the facility is continuously locked to maintain limited access. After admission to the facility, you will not leave the unit unless accompanied by a staff member. During certain times, you may be instructed to remain in your room or another specified location. At certain times, the door of your room may be required to remain open. It is important that you follow the staff instructions. Please do not enter the processing lab or staff areas unless you are specifically directed to by a staff member.

As we inspect your personal possessions, the staff will quarantine (lock up) any medications (prescribed or over the counter), food items, tobacco products, and lighters/matches. No weapons or illegal substances are allowed in our facility. If any of these are found in your possessions, you will be asked to leave and return to the facility after disposing of the weapon/illegal substances.

NOCCR is not responsible for lost or stolen personal property; therefore if you have brought any items that are particularly valuable, we recommend that you make arrangements for these to be returned to your home.

Smoking is never permitted in the building. Anyone found to be smoking anywhere in the building will be fined up to \$250 and/or may be immediately dismissed from the study. If you are participating in a study that allows smoking, the staff may take you to an outside designated smoking area for a smoking break. This smoking break will be provided only at times when a staff member is available to accompany you.

Shoes or slippers must be worn at all times. Bare feet or stocking/sock feet are not permitted. This is for your safety.

Throughout the study, the staff will be asking you about any changes in the way you feel, including nighttime status checks. Generally, the volunteers are asked to retire for the evening by 11:00PM. You will be permitted to use the restroom, get water or read quietly after this time.

Visitors (including family members) are usually allowed during 10 AM to 5PM and from 7PM to 9PM. Children are not permitted to stay in the facility without another adult to attend to him/her. Our space for visitors is limited and we ask that visits should usually be limited to an hour. Visitors are permitted only in the common areas, and are subject to the same rules and restrictions as the volunteers. Visitors should be aware that their bags are subject to search both when they arrive and leave the research unit.

While you are in the study facility, you may not eat or drink anything unless approved by the staff. Visitors may not bring food into the facility unless authorized by the staff. Studies may specify what you can eat and drink, and meals may be served at specific times with time limits within which to eat. Some studies may require that you eat all of your food whether or not it is something that you like; we are usually unable to make substitutions.

Following the study schedule is extremely important and it is your responsibility to be where you are supposed to be at the proper time. You will be informed of your schedule. Take time to review this and please ask the staff if you have questions. If the study in which you are participating has outpatient visits, plan on being at least 15 minutes early and if transportation problems arise, please inform the staff as early as you become aware of the problem as they may be able to provide assistance to prevent you from being late for your visit. In the event that you arrive late, you will be warned that subsequent late visits will result in a fine of \$75.00 for each occurrence. The fines will be deducted from your study stipend.

Abusive language and destructive behavior will not be tolerated.

State and federal law mandates that confidentiality of our volunteers be maintained, therefore, no photography (still or video) will be permitted in the research site without specific written informed consent.

**Occasionally, a volunteer does not take his/her responsibility seriously.** A system for imposing financial penalties for certain infractions has been adopted. Some of the violations have fixed fines while others have ranges. In the case where a range is given, the penalty will depend on the severity of the violation and will be based on the discretion of the unit supervisors. You may be fined up to the total amount of your volunteer compensation set forth in the consent form, additionally; you may be dropped from the study. During the study, **if you test positive for drugs of abuse, you will forfeit all compensation to which you would otherwise have been entitled.**

<u>Violation</u>	<u>Fine Amount</u>
Tardiness (After 1 <sup>st</sup> occurrence warning)	\$75.00 each late visit
Stealing	\$100, plus restitution
Property destruction	\$50 - \$100, plus replacement/repair costs
Fighting (physical attack)	\$50 - \$250
Smoking in Facility	\$250 and possible dismissal from study
Disruptive behavior	\$50 - \$100
Failure to follow staff instruction	\$50 - \$100
Non-compliance of any facility rule	\$50 - \$100

**Note:** Deceptive attempts to avoid swallowing study medication will result in \$250 - \$500 fine and volunteer will not be asked to participate in future NOCCR studies.

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At the conclusion of the study, there is a possibility that you may be asked to return to have a laboratory test repeated because of an unusual result. These tests are considered part of the study and need to be repeated to ensure your safety. Failure to return for this visit may have an impact on our willingness to have you participate in future studies, and more importantly, could have an impact on your health.

During the study, we need to be able to contact you. Please make sure that the telephone numbers and emergency contact information are current.

Before signing this form, please ask all questions you wish about any information that is unclear to you.

**Consent:** I have reviewed this form and am satisfied with the answers to the questions I have asked. I understand what is expected of me during this study and agree to cooperatively participate. I voluntarily consent to abide by the rules and instructions and know that I may have my compensation reduced as outlined above.

\_\_\_\_\_  
Signature of Volunteer

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

\_\_\_\_\_  
Printed name of Volunteer

\_\_\_\_\_  
Signature of Witness

Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

\_\_\_\_\_  
Printed Name of Witness