

# **RESEARCH RESOURCES. . . . .**

## **FACTS:**

**DEPARTMENT OF CLINICAL RESEARCH**

*The OHRP/NIH definition of research is any systematic investigation designed to develop or contribute to generalizable knowledge.*

**IRB**

*All human research studies are reviewed by the*

**FORMS**

*IRB before they begin and at least once annually to evaluate risks to subjects and compliance with*

**INVESTIGATOR'S GUIDE**

*federal regulations and institutional policies.*

**GLOSSARY**

*IRB administrators are available to assist researchers with application submissions.*

# **DEPARTMENT OF CLINICAL RESEARCH**

## **AT A GLANCE**

The MCDH Department of Clinical Research is staffed by a professional team of research scientists, engineers, administrative specialists and research nurses. The expertise of the staff covers a wide range of disciplines including: biostatistics, cardiopulmonary physiology, life sciences, medical biophysics, nursing and research administration.

## **MISSION**

To provide complete research support services to all individuals interested in developing research projects which will lead to improvements in the prevention, diagnosis, and treatment of diseases.

## **SERVICES**

Assistance with research development and project design; completion of research committee requirements (e.g., IRB); research grant preparation and management; biostatistics and data management (e.g., data base development, data analysis); and biomaterials and product testing.

To provide these services, the Department's resources and program capabilities include biomaterials testing laboratory, clinical new pharmaceutical/device human clinical studies (IND/IDE) expertise, computer facilities, desktop publishing/graphics.

## **DCR PERSONNEL**

John Cissik, PhD, RRT, CIM, Executive Director & IRB Coordinator (x6060)  
[john.cissik@hcahealthcare.com](mailto:john.cissik@hcahealthcare.com)

Yvette King, CCRP, Assistant of Executive Director & IRB Recorder (x6060)  
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[morley.herbert@hcahealthcare.com](mailto:morley.herbert@hcahealthcare.com)

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[nancy.nardelli@hcahealthcare.com](mailto:nancy.nardelli@hcahealthcare.com)

# **IRB (Institutional Review Board)**

An Institutional Review Board has been established (45 CFR 46; 21 CFR 56) to review the scientific merit, medical necessity, educational value, and moral, ethical, legal and fiscal aspects of all clinical research at Medical City Dallas Hospital (MCD).

The mission of the IRB is to ensure that research is conducted ethically, in compliance with federal regulations and institutional policies, and that the rights and welfare of human subjects in the research are protected. This mission is accomplished by prospectively reviewing proposed research and the informed consent process to be used to enroll human subjects which includes examination of the risk level/potential benefits to the volunteer subject, adequate informed consent/assent, provision for subject privacy and confidentiality, equity of subject recruitment, and safeguarding of subject rights.

The MCDH North Texas Institutional Review Board is registered with the Office for Human Research Protection (IRB00000852) and its Federal-Wide Assurance number is FWA00000220. Agreements are in place to have the MCDH IRB be the central IRB responsible for research projects at Denton Regional Medical Center, Las Colinas Medical Center, Lewisville Medical Center, Medical Center of Arlington, Medical Center of Plano, Medical Center of McKinney, Medical City Dallas ambulatory Surgery Center and Surgical Center of Plano.

## **NORTH TEXAS IRB CONTACT INFORMATION**

John Cissik, PhD, RRT, CIM  
Executive Director of Clinical Research, IRB Coordinator  
(x6060)

Yvette King, CCRP  
Executive Research Assistant & IRB Recorder  
(x6060)

Allan Naarden, MD  
IRB Chairman  
(x4718)

# FORMS

## NORTH TEXAS INSTITUTIONAL REVIEW BOARD AT MEDICAL CITY RESEARCH PROGRESS REPORT

**Protocol Number and Title:** \_\_\_\_\_

\_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Reporting Period:** \_\_\_\_\_

**1) Subject Experience**

- a) Number of subjects entered this period \_\_\_\_\_ Total number entered \_\_\_\_\_
- b) Number of subjects continuing in treatment or follow-up \_\_\_\_\_
- c) Number of subject withdrawals \_\_\_\_\_
- d) Do you plan to continue enrolling new subjects? YES NO
- e) When do you expect the study to be completed? \_\_\_\_\_

**2) Have any **unanticipated risks** been discovered since the last IRB review? YES NO**  
If yes, please describe (use additional sheets as necessary).

**3) Have there been any **significant new findings** which may relate to the subjects' willingness to continue participation? YES NO** If yes, please describe (use additional sheets as necessary).

**4) Have there been any **adverse events** with any patients in this study? YES NO**  
If yes, were these reported to the IRB? YES NO If not, please explain why not & provide descriptions of the adverse event (use additional sheets as necessary)

**5) Are you having any **problems** with this study? YES NO** If yes, please explain (use additional sheets as necessary).

**6) Have any **changes** been made to the study since it was approved? YES NO**  
If yes, have those changes been approved by the IRB? YES NO If not, please explain in detail the changes and why they were not submitted (use additional sheets as necessary).

**7) Have you submitted/presented any **publications** or **presentations**? YES NO**  
If yes, please provide a list of all publications and/or presentations (use additional sheets as necessary).

\_\_\_\_\_  
Principal Investigator Signature

\_\_\_\_\_  
Date

RETURN TO: Director, Clinical Research, Medical City Dallas Hospital, 7777 Forest Lane, Suite C-740, Dallas, TX 75230 (or FAX to: 972/566-4715)

## (HIPAA Authorization)

### AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

You have a right to privacy. This means all information obtained as a part of this study will only be used as described below. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used without your specific written permission. In addition, if photographs, audiotapes or videotapes are taken during the study, then you must give special written permission for their use. All information about you from this research project will be kept in a locked space.

By signing this Agreement you agree to allow (*put name of investigator here*) and his/her staff (**Researchers**) and the study sponsor, (*put name of sponsor here*) (**Sponsor**), to use and disclose health information that identifies you for the purposes described below. You also agree to permit Medical City Dallas Hospital, its staff, your doctors, and your other health care providers to disclose health information in your medical records to the Researchers and Sponsor for the purposes described below.

The Researchers and the Sponsor may use and share your health information to conduct the research. They may use your health information as described in the informed consent. They may disclose your health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

If information that could be used to identify you has been removed, then the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and Sponsor as permitted by law. Once your health information has been disclosed to another party as indicated above, federal privacy laws may no longer protect it from further disclosure. However, the Researchers and Sponsor agree to protect your health information by using and disclosing it only as permitted by you in this Authorization. These limitations will continue even if you revoke (take back) your Authorization.

You do not have to give this permission and it is all right to refuse to sign this section of the consent form. Your doctor will still treat you even if you do not give your permission for this release of information. Your insurance will still pay your medical bills if you do not give your permission. However, since it is important for the people listed above to have access to your information, if you do not sign this Agreement, you cannot be in the research study.

While the research is in progress, you will not be allowed to see any health information that is created or collected. After the research is finished, you may see the information if you wish. Unless permission is specifically withdrawn, this permission will NOT expire at the end of the research study.

You will be given a copy of this Authorization after you have signed it.

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Signature of Patient

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Date

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Printed Name of Patient

# North Texas Institutional Review Board at Medical City

7777 Forest Lane, C-740

Dallas, TX 75230

972/566-6060 Phone

972/566-4715 Fax

## REQUEST FOR WAIVER OF HIPAA PRIVACY AUTHORIZATION FOR RESEARCH

**IRB PROTOCOL NUMBER:** \_\_\_\_\_

**STUDY TITLE:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

**ADDRESS:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PHONE NUMBER:** \_\_\_\_\_  
\_\_\_\_\_

### WAIVER REQUEST:

1. I am requesting this waiver of authorization for the following purpose (select only one of the following two items):

\_\_\_ The collection of initial screening data to recruit potential research subjects, or to determine study eligibility only.

\_\_\_ Retrospective reviews, research database or repository, or other research study where obtaining a signed authorization is not practical.

## REQUEST FOR HIPAA WAIVER (Cont.)

2. The following protected health information will be created, collected, used and/or disclosed for the purpose of conducting this research (list the specific protected health information here):

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3. I certify that the use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the following elements (select applicable items):

- a. An adequate plan is in place to protect the identifiers from improper use and disclosure. The plan is as follows (select all that apply):

All electronic study will be password protected.

Passwords will be changed on a regular basis.

Access to study data will be restricted to authorized study personnel only.

All paper study records will be kept in locked file cabinets and access limited to authorized study personnel only.

Other \_\_\_\_\_

- b. An adequate plan is in place to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. The plan is as follows: \_\_\_\_\_

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- c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA regulations.



# INVESTIGATOR'S GUIDE

## North Texas Institutional Review Board at Medical City

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7777 Forest Lane, C-740

Dallas, TX 75230

972/566-6060 Phone

972/566-4715 Fax

January 04, 2008

Dear Physicians/Study Coordinators:

Attached please find information which will aid you in submitting a new study to the IRB. The enclosed instructions and model forms should help guide you through each requirement.

Please note the requirement for Protection from Research Risk training, the necessity to disclose information regarding financial compensation by an outside source and health information release requirements.

If you have any questions, please call Yvette King at (972) 566-6060.

Sincerely,

John H. Cissik, PhD  
Executive Dir., Department of Clinical Research  
Coordinator, Institutional Review Board

cyk

Attachment

# Institutional Review Board

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## Institutional Review Board

### Submission Requirements for New Protocol Review

1. **Principal Investigator or approved representative must be present at the meeting to give a brief (5-10 minute) presentation of the protocol and answer questions from the Board.**
2. Submit **22** packets plus the original.
  - A. Each packet must contain:
    1. A Cover Letter from the Principal Investigator\*
    2. A Brief Protocol Summary (2-5 pages)\*
    3. The Study Protocol
    4. An FDA Approval Letter, IDE# or IND# (When applicable)
    5. FDA Form #1572 (When applicable)
    6. A Patient Informed Consent \*, and Assent of a Minor Documents (projects involving minors from ages 7-17)\*

\*These documents must be submitted on letterhead by 4:00 p.m. of the deadline date for submission (NO EXCEPTIONS).

3. **Each copy must be 3-hole punched.**
4. **Do not staple, paper clip, or clip packets!!!**
5. **Please make copies two (2) sided whenever possible.**
6. **Submit a copy of the training certificate showing you have completed the NIH IRB Computer-Based Training (<http://cme.cancer.gov> or <http://ohsr.od.nih.gov> ) or the MCDH Protection from Research Risks educational program.**
7. **Disclosure of any financial compensation by an outside source relating to the research study in the protocol summary and the informed consent.**

Institutional Review Board

**Model Cover Letter**

Date

Allan Naarden, MD  
Chairman, Institutional Review Board  
Medical City Dallas Hospital  
7777 Forest Lane, C-740  
Dallas, TX 75230

Re: Protocol Title

Dear Dr. Naarden:

I would like to submit the enclosed protocol dated \_\_\_\_\_, Patient Informed Consent dated \_\_\_\_\_, and FDA Form #1572 for consideration by the Institutional Review Board at its meeting of \_\_\_\_\_.

\_\_\_\_\_ will be coordinating this protocol; please forward all correspondence to his/her attention.

This study is sponsored by \_\_\_\_\_.

If I can provide further information please do not hesitate to contact me. Your consideration in this matter is fully appreciated.

Sincerely,

Principle Investigator

Institutional Review Board

**Protocol Summary Outline**

Title:

Sponsor:

IND # or IDE # (if applicable)

Principal Investigator:

Associate or Co-Investigators:

- I. Background (why the study is necessary)
- II. Specific Aims of the Study
- III. Study Design (how the study will be accomplished)
- IV. Inclusion/Exclusion Criteria
- V. Recruitment of Patients
- VI. Potential Risks and Benefits
- VII. Special Precautions
- VIII. Financial Compensation by an Outside Source (e.g., do researchers or their family have a financial interest in the research project such as major stock holdings or funding from the sponsor?)
- IX. Hospital Departments/Services to be assessed by the Research

## Institutional Review Board

### **BASIC ELEMENTS OF INFORMED CONSENT**

(use this checklist to develop the informed consent document)

- A. An informed consent document must contain the following information and a copy must be provided to each patient.
- \_\_\_ 1. A statement that the study involves research. Note whether or not the patient will be informed about the results of the research study.
  - \_\_\_ 2. Identify any sponsor. Explain the relationship (if any) between the study doctor and the sponsor of the research study (e.g., financial compensation to the investigator.)
  - \_\_\_ 3. A lay language (7th-grade level) description of the research purpose.
  - \_\_\_ 4. An understandable (7th-grade level) description of procedures to be used.
  - \_\_\_ 5. The approximate number of patients involved in the study; justification for the exclusion of any particular group of subjects.
  - \_\_\_ 6. The expected time and duration of the Patient's participation.
  - \_\_\_ 7. A description of any reasonably foreseeable risks or discomforts to the patient (or to the embryo or fetus, if the patient is or may become pregnant); any requirement for contraception. In the case of drug use, a full and fair exposition of side effects must be given.
  - \_\_\_ 8. Identification of any experimental procedures.
  - \_\_\_ 9. A statement that there may be risks to participation in the study that are currently unknown.
  - \_\_\_ 10. Any costs to the patient that may result from participation in the research.
  - \_\_\_ 11. A statement of whether the process will require hospitalization.
  - \_\_\_ 12. For research involving more than minimal risk, an explanation as to whether any compensation is involved; and an explanation whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
  - \_\_\_ 13. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be available to the patient.
  - \_\_\_ 14. A description of any benefits to the patient or to others which may reasonably be expected from the research.

## Institutional Review Board

- \_\_\_15. A statement describing the extent, if any, to which confidentiality of records identifying the patient will be maintained. The patient should be made aware that the FDA may inspect records pertaining to their research. Add Health Information Disclosure Statement.
- \_\_\_16. A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the patient is otherwise entitled.
- \_\_\_17. Indication that the patient may discontinue participation at any time without penalty or loss of benefits to which that patient is otherwise entitled; the consequences of the Patient's decision to withdraw from the research (these cannot involve penalties for withdrawing) and procedures for orderly termination of participation by the patient; and a discussion of circumstances under which the Patient's participation may be terminated by the investigator without regard to the Patient's consent.
- \_\_\_18. A statement that significant new findings developed during the course of the research which may relate to the Patient's willingness to continue participation will be provided to the patient.
- \_\_\_19. A statement regarding receipt of a copy of the informed consent document after signatures are complete.
- \_\_\_20. Additional elements of consent for genetic studies (if applicable).
- \_\_\_21. The following statement must be included: **If you have any questions about the research or if you have any research related injuries, you may contact (specify the Name of the Investigator and the Telephone Number). If you have any questions about your rights as a research patient, you may contact John H. Cissik, PhD, IRB Coordinator, North Texas Institutional Review Board at Medical City at (972)566-6060.**

When abbreviations are to be used for brevity, e.g., CBC, EEG, EKG, the first use will be accompanied by the spelled out term in brackets.



## Institutional Review Board

### A Model Informed Consent

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The following procedures or drugs which will be used are experimental, (*list*).

#### Side Effects, Toxicities and Risks

The following risks, side effects or toxicities are possible (*explain in lay terms the risks which may occur to the patient, or to an embryo or fetus if patient becomes pregnant*).

In addition, these procedures (*or the use of drugs*) may involve risks to you which are currently unforeseeable.

#### Extraordinary Costs

The following additional charges will be made because of your participation in the study (*list, if any, otherwise remove this sentence*). (*Address the issue of compensation to the patient in this section.*) You (*will/will not*) be paid for participating in this study.

Your participation in this study will (*require, not require*) hospitalization. Unforeseen consequences of the experiment may require your hospitalization.

No funds for compensation for injuries associated with participation in this study have been set aside. (*Or, if treatment will be provided, explain instead of using the above sentence*). You are free to contact the below listed investigator if you have questions and you may report research related injury to that investigator or to the Institutional Review Board which reviewed this study.

#### Alternatives

The following procedures or courses of treatment are available as alternates to the research procedure. (*List any alternative procedures or treatments. If there are not any, so state in this area.*)

#### Benefits

The following are the direct and indirect benefits which you may derive from participation in this study (*list the benefits*).

Page \_\_\_\_ of \_\_\_\_ Pages

## Institutional Review Board

### A Model Informed Consent

Page 3

#### Confidentiality

Your records will be held confidential by all parties involved in this research study and you will not be identified in any publication. However, the Food and Drug Administration has the right to access your medical/research records and identity, and may have the need to release this information. (***List any other entities who may have access to research-related records***). In addition, personal information may be disclosed if required by state or federal law.

#### Participation

Your being in this study is voluntary. You may refuse to be in the study without penalty to you or without loss of any treatment rights.

You may also leave the study at any time without penalty or loss of benefits.

Under the following circumstances the investigator may need to end your being in this study. (***describe those circumstances***)

#### New Findings

You will be told of anything new learned during this study which could affect your willingness to continue being in the study. Your physician, the sponsor or the Institutional Review Board has the right to terminate the study based on this information.

#### Questions

You have a right to have all questions about the study answered in away that you clearly understand the answer.

**If you have any questions about the research or if you have any research related injuries, you may contact (*specify the Name of the Investigator and the Telephone Number*). If you have any questions about your rights as a research patient, you may contact John H. Cissik, PhD, IRB Coordinator, North Texas Institutional Review Board at Medical City at (972) 566-6060.**

Page \_\_\_\_ of \_\_\_\_Pages



## Institutional Review Board

### **Assent by Minors (7 - 17 years of age) to Voluntarily Participate in a Research Study**

Any new research projects involving a minor as a volunteer patient will require the development and completion of age-specific documentation of assent as well as an informed consent document to be signed by the parent/guardian. Additionally, before any previously approved research projects involving minors as volunteer patients can be re-approved for continuation on an annual basis, an age-specific documentation of assent will need to be prepared in addition to the informed consent document signed by the parent/guardian.

“Assent” means the affirmative agreement of a minor to participate as a volunteer patient in a research project. The mere failure to object should not, in the absence of an actual affirmative agreement, be construed as assent. Following are general assent requirements by age groups (see attached age-specific Model Assent Documents):

Assent by Teens. In addition to the signed informed consent of their parent/guardian, the research project informed consent form should also contain a section for adolescents, thirteen (13) to seventeen (17) years of age, to acknowledge their assent to voluntarily participate in the study.

Assent by Pre-teens. In addition to a signed informed consent by the parent/guardian, a separate, age-appropriate assent form should be provided to children under thirteen (13) and over seven (7) years of age to acknowledge their assent to voluntarily participate in the study.

Waivers to Informed Assent. The IRB will consider waiving the requirement of informed assent upon request of the investigator. A waiver may be granted for those studies in which the investigator can demonstrate that requesting assent is not in the best interest of the minor due to the child’s lack of maturity, psychological state and/or physical state.

If you have any questions about these requirements, or if you need a copy of the entire IRB Policy and Procedures Manual, which more fully details all research requirements at MCDH, please contact either John Cissik or Yvette King, at (972) 566-6060.

## Institutional Review Board

### ASSENT TO PARTICIPATE IN RESEARCH

(Ages 7 – 12 years old)

Study title: *[insert here]*

Doctor in charge of study: Dr. \_\_\_*[full name]*\_\_\_\_\_

We are asking you to be in a research study. You have to decide if this is OK. We want to know if a new way of treating your illness will work. We want you to be in this study because *[specify, e.g., you are sick, you have cancer, your heart pushes your blood too hard, your heart beats differently]*.

If you are in this study: *[edit/add text to complete description from child's point of view if needed]*.

1. We will check your health to make sure you can be in the study. We will take a little blood from your arm with a needle. We will give you a cream to put on your arm, so it will not hurt as much.
2. You will take a pill/medicine xx times a day, every day for xx months.
3. You will come to the doctor's office xx times.
4. You will go to the hospital xx times.
5. Each time you go to the doctor's office/hospital, we will take a little blood the same way as before *[or describe other testing, e.g., Each time you go to the hospital, you will have a needle stuck in your back to take out some fluid./ You will have a test where you lie on a table inside a big machine that takes pictures of your head.]*
6. The study will last about xx [days/weeks/months/years].

If you are in this study, you will help us learn more about how to treat your illness. This might help other kids. Also, you might get better. But, we do not promise this.

Being in this study might make you feel worse. *[Specify in age-appropriate language, e.g., You might get a headache, have a rash, or throw up.]* You might have no bad effects. We do not know. If you do feel worse, we will try to help you as soon as possible.

You do not have to be in this study. If you do not want to be in the study, it is OK. We will treat you the same way as if we never asked.

If you decide to be in the study, you can change your mind later. You can quit any time.

Talk to your parents about the study. They also have to decide if it is OK for you to be in it. Ask all the questions you can think of. You can ask the doctor or your parents. You can ask questions at any time.

We will give you a copy of this form to keep.

## Institutional Review Board

If you want to be in the study, write your name on the line.

\_\_\_\_\_  
Printed Patient Name and Signature

I believe my child understands what will happen in this study and his/her signature shows that he/she agrees to be in the study.

\_\_\_\_\_  
Parent Printed Name and Signature

\_\_\_\_\_  
Date

## ASSENT TO PARTICIPATE IN RESEARCH

(Ages 13 - 17 years old)

Study title: *[insert here]*

Doctor in charge of study: Dr.     *[full name]*    \_\_\_\_\_

We are asking you to be in a research study. You must decide if you agree to be in this study. We are doing this study to *[describe what study is about in 7<sup>th</sup> grade language, e.g., find out if a new medicine works, find out if taking xx drug in a different amount works, find out if a new device helps you hear better]*. We want you to be in this study because *[specify reason for approaching patient, e.g., you have bone cancer, your heart beats differently, you have high blood pressure]*.

If you agree to be in this study, the following will happen to you: *[complete all that apply and add more if needed and specify from child's point of view, e.g.,]*

7. We will do a physical exam to make sure you should be in the study. We will take some blood from your arm with a needle.
8. You will take a pill/medicine xx times a day, every day for xx months.
9. You will visit the doctor's office xx times.
10. You will go to the hospital xx times.
11. Each time you go to the doctor's office/hospital, we will take a little blood. *(or describe other testing, e.g., Each time you go to the hospital, you will have a needle stuck in your spine to take out a fluid sample/ You will have 2 MRIs, in which you lie on a table inside a large tube that takes pictures of the inside of your body.)*
12. The study should last about xx [days/weeks/months/years].

If you are in this study, you will help us learn more about how to treat your disorder. This might help other kids. The treatment we are studying also might help you, but we do not promise this.

The treatment or tests in this study might have side effects. *(Describe in age appropriate language, e.g., You might get a headache, have a rash, or throw up.)* You might have no side effects. We do not know. If you do experience side effects, we will try to make you feel better as soon as possible.

You do not have to be in this study. If you decide to participate, you can change your mind later. You can get out of the study at any time.

If you decide not to be in the study, there is no penalty. We will treat you the same way as if we never asked.

Discuss this study with your parents. They also have to decide whether you can be in it. Ask your parents or the doctor any questions you have about this study. If you have any questions later, you will have a chance to ask then also.

We will give you a copy of this form to keep.

If you agree to participate, sign your name on the line below.

---

Patient Printed Name and Signature

I believe my child understands what will happen in this study and his/her signature shows that he/she agrees to be in the study.

---

Parent Printed Name and Signature

---

Date

Institutional Review Board

**PARENTAL WAIVER OF ASSENT**

(For children 7 – 17 years of age)

I wish to waive obtaining my child’s assent for joining this study because of his/her:

maturity\_\_\_\_\_

psychological state\_\_\_\_\_

physical state\_\_\_\_\_

I believe that the study is appropriate for my child and that his/her best interests are being served by not requiring his/her assent as a pre-requisite for joining this study.

\_\_\_\_\_  
Printed Name and Signature of Parent/Guardian

\_\_\_\_\_  
Date

I concur with the decision to waive assent for this patient for the reason(s) indicated above.

\_\_\_\_\_  
Printed Name and Signature of Principal Investigator

\_\_\_\_\_  
Date

## ADDITIONAL ELEMENTS OF CONSENT:

### GENETIC STUDIES

#### Procedure

Information about you (your child) resulting from the tests on your (your child's) tissue will NOT be provided either to the study doctor or to you. This includes genetic information that may be relevant to your (your child's) prognosis or to treatment for your (your child's) cancer and any incidental findings regarding other disorders, risks of disease, or other characteristics that may be detected by genetic analysis.

#### Voluntary Participation (adult consent for child)

If your child reaches age 18 during this study, his/her consent will be sought to continue participation in this study.

#### Withdrawal

If you (your child) chose to withdraw from the study, your (your child's) tissue samples that are already in the tissue bank will stay there. No additional tissue samples or clinical information about you (your child) will be sent to the tissue bank. If you request it, the link between the data and you (your child) will be removed.

#### Risks

The only risk in this study is the potential loss of privacy with respect to your (your child's) genetic characteristics. We will try to protect your (your child's) privacy by using a code to identify all information that is sent to the tissue bank. We will retain information that links your (your child's) name to the code in the local doctor's office, so that follow-up data can be sent later and linked to earlier data.

In addition, a Certificate of Confidentiality has been obtained from the National Cancer Institute. This certificate prevents information gathered in this study from being disclosed in almost any case, such as a court subpoena or requests for information by an insurer. Information about you (your child) may still be reviewed by officials at the National Cancer Institute or other Federal agencies for legally allowed reviews of federally funded studies.

Institutional Review Board

**AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION**

You have a right to privacy. This means all information obtained as a part of this study will only be used as described below. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used without your specific written permission. In addition, if photographs, audiotapes or videotapes are taken during the study, then you must give special written permission for their use. All information about you from this research project will be kept in a locked space.

By signing this Agreement you agree to allow (*put name of investigator here*) and his/her staff (**Researchers**) and the study sponsor, (*put name of sponsor here*) (**Sponsor**), to use and disclose health information that identifies you for the purposes described below. You also agree to permit Medical City Dallas Hospital, its staff, your doctors, and your other health care providers to disclose health information in your medical records to the Researchers and Sponsor for the purposes described below.

The Researchers and the Sponsor may use and share your health information to conduct the research. They may use your health information as described in the informed consent. They may disclose your health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

If information that could be used to identify you has been removed, then the information that remains is no longer subject to this Authorization and may be used and disclosed by the Researchers and Sponsor as permitted by law. Once your health information has been disclosed to another party as indicated above, federal privacy laws may no longer protect it from further disclosure. However, the Researchers and Sponsor agree to protect your health information by using and disclosing it only as permitted by you in this Authorization. These limitations will continue even if you revoke (take back) your Authorization.

You do not have to give this permission and it is all right to refuse to sign this section of the consent form. Your doctor will still treat you even if you do not give your permission for this release of information. Your insurance will still pay your medical bills if you do not give your permission. However, since it is important for the people listed above to have access to your information, if you do not sign this Agreement, you cannot be in the research study.

While the research is in progress, you will not be allowed to see any health information that is created or collected. After the research is finished, you may see the information if you wish. Unless permission is specifically withdrawn, this permission will NOT expire at the end of the research study.

You will be given a copy of this Authorization after you have signed it.

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Patient

## Institutional Review Board

### **AFTER APPROVAL REQUIREMENTS**

Once your protocol has been approved by the IRB and you begin your study, you will still need to observe the following paperwork requirements:

1. Informed Consent. Written consent must be obtained from all subjects in your study and a copy of the signed consent must be given to the patient. You should keep the original copy of the signed and witnessed consent form in your records of the protocol for a period of three years past completion of the study. Also, you must put a copy of the signed consent form in the subject's medical records and make a note that the consent was obtained prior to entrance of the patient into the study. If this is an inpatient study, be sure the Ward personnel are aware of the study requirements. Changes to the consent form must be reviewed and approved by the IRB before the new informed consent can be used in the study.

2. Adverse Events. You must promptly notify the IRB of all adverse events and protocol deviations that occur to patients you have enrolled in this study. Serious adverse event notifications should be submitted to the IRB within 10 days of occurrence. Also, you must promptly provide the IRB with a copy of any adverse event or safety reports sent to you by the study sponsor.

3. Amendments. You must notify the IRB in writing of any amendments or other changes to the protocol. These changes must be approved by the IRB before you can institute them in the study.

4. Reports. You must provide a periodic interim report to the IRB. The IRB will notify you when your report is due. If you do not provide the requested report, the IRB may administratively close your protocol. Also, when your study is completed or is closed, you must provide a final report to the committee and notify all your sub-investigators.

Institutional Review Board

## North Texas Institutional Review Board at Medical City (IRB)

7777 Forest Lane, C-740, Dallas, TX 75230 Phone 972/566-6060 Fax 972/566-4715

### 2008 Meeting Schedule 12:00 p.m.-1:00 p.m./C-740 Library

<u>Meeting Date</u>	<u>Deadline for Submission</u>
January 16	January 4
February 20	February 8
March 19	March 7
April 16	April 4
May 21	May 9
June 18	June 6
July 16	July 4
August 20	August 8
September 17	September 5
October 15	October 3
November 19	November 7
December 17	December 5

**Meetings will begin at 12:00 p.m. and run through 1:00 p.m.**

All documentation for new study consideration and active protocol updates must be submitted by the deadline, or be placed on the following months agenda.

Mail all Correspondence to:  
John H. Cissik, PhD  
Executive Dir., Department of Clinical Research  
Coordinator, Institutional Review Board  
Medical City Dallas Hospital  
7777 Forest Lane, C-740  
Dallas, TX 75230

For assistance contact Yvette King at (972) 566-6060  
12/07

## Institutional Review Board

### **North Texas Institutional Review Board at Medical City (IRB) 2008 Committee Members**

\*Allan Naarden, MD, Chairman, (Neurology, Ste. C-740, Ph 972/566-4718) (10/85)

Todd Baker, ThM, PhD, (Clergy, Ste. A-140, Ph 972/566-7584) (5/97)

Rebecca Brakke, BA, (Non-Inst. Member, 7027 Eudora, Dallas, TX 75230, Ph 214/363-0921) (4/96)

\*Brian Cohen, MD, (Reproductive Endocrinology, C-625, Ph 972/566-6686) (01/05)

Leah Domstead, Esq, (Attorney, 13355 Noel Rd., Ste 650, Dallas, TX 75240, Ph 972/789-2833) (8/99)

\*Deborah Echtenkamp, RN, (Pedi Hem/Onc, D-6<sup>th</sup> Floor, Ph 972/566-7367) (10/03)

\*Theresa Eichenwald, MD, (Internist, Ste. C300-H, Ph 972/566-6000) (01/05)

Ken Glass, MD, (Non-Inst. Member, 3521 Cornell Ave., Dallas, TX 75205, Ph 214/522-3953) (1/06)

Betty Hayes, (Non-Inst. Member, 7437 Malabar, Dallas, TX 75230, Ph 214/363-5741) (9/05)

\*Cynthia Latney, RN, (Director of Adult Critical Care, Ste. D-308, Ph 972/566-6842) (11/06)

\*Carl Lenarsky, MD, (Pediatric Hematology/Oncology, Ste. D-400, Ph 972/566-4449) (1/98)

\*Mitchell Magee, MD, (Cardiothoracic Surgery, Ste. A-323, Ph 972/566-4866) (1/07)

\*June Marshall, RN, (Magnet Project Director, ER-Admin Ofc Bldg. A 1<sup>st</sup> Floor, Ph 972/566-7172)(03/07)

\*Barry Mirtsching, MD, (Hematology/Oncology, Ste. B-342, Ph 972/566-5588) (1/07)

\*Julie Pao, MD (OB/Gyn, 12200 Park Central Dr., Suite 403, Dallas, TX 75251 Ph 972/774-9990)(1/08)

\*Nicki Roderman, RN, (Clinical Nurse Specialist @ MCPlano – Critical Care Unit, 3901 W. 15<sup>th</sup> Street, Plano, TX 75075, Ph 972/335 –5835)(05/07)

\*Michael Savin, MD, (Hematology/Oncology, Suite D-400, Ph 972/566-7790) (9/98)

\*Stephane Thurman, RN, (Staff Development Coordinator - Education @ MCPlano, 3901 W. 15<sup>th</sup> Street, Plano, TX, Ph 972/529-3735)(05/07)

#### **\*Alternates For Scientific Members**

John H. Cissik, PhD (Respiratory Physiologist, Ste. C-740, Ph 972/566-6060) (7/94)

Armand Derausseau, Pharm D., (Pharmacy Director, Ste. A-177, Ph 972/566-8251) (9/01)

#### **IRB Coordinator**

John H. Cissik, PhD, (Exec. Dir., Clinical Res., Ste. C-740, Ph. 972/566-6060) (7/94)

#### **Recorder**

Yvette King (Research Coordinator, Clinical Research, Ste. C-740, Ph. 972/566-6060) (2/99)

# IRB Glossary

## *Administratively Closed*

Administrative decision of the IRB based on PI non-responsiveness to IRB requests. This can occur prior to initial IRB approval or any time following IRB approval.

## *Adverse Event (AE)*

Any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated with the research or the use of a medical investigational test article. An AE does not necessarily have to have a causal relationship with the research, or any risk associated with the research or the research intervention, or the assessment.

## *Approval*

The IRB has reviewed the protocol/informed consents and feels the investigator has undertaken every effort to minimize risk to the subjects, the research plan makes adequate provision for monitoring the safety of the patients, were satisfied with the investigator's provision for subject privacy and confidentiality, found recruitment of potential subjects to be equitable, feel that proper informed consent/assent would be obtained from each subject as appropriate prior to their enrollment in the study and finally that the investigator's methods safeguarded the rights of vulnerable subjects.

## *Assent*

Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. Mere failure to object to the research may not be construed as assent.

## *Assurance*

A formal written, binding commitment that is submitted to a federal agency in which an entity promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

- **Federal-Wide Assurance (FWA)** An agreement between a federally funded entity and OHRP that stipulates methods by which the entity will protect research participants.

## *Audit*

A system to assess protocol compliance with and adherence to the Federal regulations and guidelines. Periodically, IRB records for the selected protocols may be reviewed to capture the initial IRB approval date, dates of renewal, occurrences of adverse events and, if applicable, lapses of IRB approval.

## *Benefit*

A valued or desired outcome; an advantage.

***Beneficence***

An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

***Case Report Form (CRF)***

A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

***Children***

Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted. A formal assent is required before children participate in research.

***Clinical Trial***

A controlled study involving human subjects, designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

***Cognitively Impaired***

Having either a psychiatric disorder ( *e.g.*, psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder ( *e.g.*, mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

***Competence***

Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

***Compliance***

Adherence to all the trial-related requirements, good clinical practice (GCP) requirements, and the applicable regulatory and institutional requirements.

***Confidentiality***

Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

***Continuing Review***

Periodic review of a research study by an IRB to evaluate whether risks to participants are reasonable in relation to potential benefits and to verify that the study continues to meet regulatory and institutional requirements. Continuing review shall be conducted at intervals appropriate to the degree of risk but not less than once per year.

***Data and Safety Monitoring Board***

A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

***Deviation***

Any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control & the has not been approved by the IRB.

***Drug***

Any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

***Entity***

An organization, institution or being that has its own existence for legal or tax purposes and possess OHRP-approved Assurances.

***Exempt Research***

Research determined by the Institutional Review Board (IRB) to involve human subjects only in activities involving minimal risk (i.e. surveys, data collection, retrospective chart review).

***Expedited Review***

Review of proposed research by the IRB chair or a designated voting member rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research (i.e. Exempt Studies).

***Experimental***

Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness.

***FDA***

Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

***Full Board Review***

Review of proposed research at a convened meeting at which a majority of the voting membership of the IRB is present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

***Grant***

Financial support provided for research study designed and proposed by the Principal Investigator(s).

The granting agency exercises no direct control over the conduct of approved research supported by a grant.

***Guardian***

An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

***HIPAA***

Health Insurance Portability and Accountability Act of 1996. Mandates the maintenance of privacy for a subjects personal information.

***Human Subjects***

Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains; (1) data through intervention or interaction with the individual; or (2) identifiable private information.

***Incapacity***

Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. See also

***Incompetence***

Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.

***Informed Consent***

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the entity or agents thereof from liability for negligence.

***Institutional Review Board (IRB)***

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

***Investigational Device Exemptions (IDE)***

Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations.

***Investigational New Drug or Device***

A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

***Investigational Product***

A device or pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

***Investigator's Brochure***

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

***IRB Records***

IRB records include but are not limited to: all minutes of IRB meetings, a copy of all proposals reviewed including all amendments, investigator brochures, and any supplemental information including recruitment and informational materials, consent forms, information submitted for continuing review, all correspondence, and IRB membership with a resume for each member.

***Justice***

An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

***Legally Authorized Representative***

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

***Medical Device***

A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

***Minimal Risk***

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests. In research involving prisoners, minimal risk is also defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

***Monitoring***

The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

***Non-Affiliated Member***

Member of an Institutional Review Board who has no ties to the parent entity, its staff, or faculty. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher, homemaker).

***Office for Human Research Protections (OHRP)***

The office within the U.S. Department of Health and Human Services, responsible for implementing DHHS regulations governing research involving human subjects.

***Permission***

Parent(s) or guardian's written agreement to the participation of their child or ward in research.

***Principal Investigator (PI)***

The scientist or scholar with ultimate responsibility for the design and conduct of a research project.

***Protocol***

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

***Quorum***

A quorum is defined as a majority of the voting members appointed to the IRB membership. In the case of the IRB, a quorum must include at least one member whose primary concerns are in non-scientific areas. At meetings of the IRB, a quorum must be established and maintained for the deliberation and vote on all matters requiring a vote.

***Request for Additional Information***

The IRB has reviewed the study and has requested changes or clarifications.

***Research***

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

***Retrospective Studies***

Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

***Risk***

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk".

***Serious Adverse Event (SAE)***

A SAE is defined as death; a life threatening experience; hospitalization (for a person not already hospitalized); prolongation of hospitalization (for a patient already hospitalized); persistent or significant disability or incapacity; congenital anomaly and/or birth defects; or an event that jeopardizes the subject and may require medical or surgical treatment to prevent one of the preceding outcomes.

***Sponsor***

A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator) and the employees are considered to be investigators.

***Study***

All components of a research project.

***Study Closure***

Study approved by the IRB can be closed by the investigator, the sponsor, the IRB,

***Suspension/Termination***

IRB approval is suspended/terminated and all research activity halted as the result of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with or the requirements or determinations of the IRB.

***Survey***

Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

***Tabled***

The IRB has reviewed the study and determined that extensive changes are necessary. The study will be re-reviewed once changes have been made.

***Unexpected Adverse Event***

An UAE is any adverse event and/or reaction, the specificity or severity of which is not consistent with the informed consent, current investigator brochure or product labeling. Further, it is not consistent with the risk information described in the general investigational plan or proposal.

***Violation***

A deviation from the IRB approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data.

***Voluntary***

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate(or to continue to participate) in a research activity.