APPENDIX B
INFORMED CONSENT GUIDELINES

The Institutional Review Board (IRB) requires that any research involving human subjects be undertaken at Robert Morris University only after the insurance of free and informed consent.

The purpose of the consent form is twofold. First, the consent is to provide clear understanding of the nature of the study for the participant. Second, the consent is to explain the voluntary and elective nature of participation in the study. The consent form must be completed before the subject receives any drug or any device is used.

Three copies of the consent form should be prepared, one to be maintained by the principal investigator, one to be maintained by the subject, and one to be maintained on the subject's record.

Since investigational studies encompass a diverse spectrum of participants and investigators, no single consent "form" can provide adequate information to all parties. Therefore, the following guidelines are provided to prepare informed consent documents:

General Requirements for Consent Form:

a) Place the first page on appropriate department, school, or university letterhead.

b) Specify, in the upper right corner of every page, *"Robert Morris University Institutional Review Board"*, and include a space to indicate the IRB approval date, renewal date and IRB number assigned to the research study. Please see the Sample Consent Form for the format. It is also suggested that a version number of the consent form be included somewhere on the page to ensure that the most up-to-date consent form is used.

c) Specify "*CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY*" at the top, center of the first page (i.e., next to the department, school, or university letterhead).

d) Include a blank for the Participant's Initials at the bottom of each page of the consent form (with the exception of the final, signature page).

e) If applicable, separate changes in second- to first-person style using a row of asterisks.

2) TITLE: The title on the consent form must be identical to the title listed on the research protocol, unless a specific justification (e.g., confidentiality issue, planned deception) for a different title is addressed in the research protocol.

3) INVESTIGATORS:
a) List the PRINCIPAL INVESTIGATOR and all CO-INVESTIGATORS.
b) Include either an address and telephone number for each listed investigator or a common department or school address and telephone number, if applicable.

4) SOURCE(S) OF SUPPORT: List all sources of support for the research study.

5) DESCRIPTION (**Note**: In lieu of incorporating this standard section heading, the standard question format, outlined below, may be used. Regardless of the option selected, all of the information addressed below should be included in this section of the consent form.)

Sample front page:

Robert Morris University
Institutional Review Board
Approval Date:
Renewal Date:
IRB Number:

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: EFFECT OF INJECTATE VOLUME ON MEASUREMENT OF CARDIAC OUTPUT BY THE THERMODILUTION METHOD IN ACUTELY-ILL PATIENTS

PRINCIPAL INVESTIGATOR: Noel R. Fredrickson, Ph.D
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Moon Township, PA 15108
(412)-555-2222

SOURCE OF SUPPORT: NCNR

CONSENT FORM:

Page 1 of 4 Participant's Initials _____

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Consent Form

It is acceptable to use ***standard section headings*** (e.g., DESCRIPTION, RISKS & BENEFITS, ALTERNATE PROCEDURES, COSTS AND PAYMENTS, CONFIDENTIALITY, RIGHT TO WITHDRAW, COMPENSATION FOR INJURY, VOLUNTARY CONSENT), in all capital letters, **or *standard explanatory questions*** (e.g., ***Why is this research being done?***), in bold italics, in the consent form. However, **both formats should not be used.**

Standard Headings for Consent Form Format:

1. Description

A brief and non-technical description of the study should be provided. Included in the description must be the name and purpose of the research, and any experimental drugs/devices or procedures being tested must be outlined. It is imperative that the principal investigator identifies why a particular patient or subject has been asked to participate in the study.

Example: *This study is being undertaken to test the effectiveness and safety of a new experimental drug, (drug name), in the treatment of diabetes which is*

poorly controlled, you are asked to be in this study.

Example: *This study is designed to test the effects of exercise and smoking on blood clotting; because you are a young person who smoke cigarettes you are asked to be in this study.*

The description should also include:
- an explanation of the nature of the investigational drug/device or procedure;
- the expected duration of participation; and
- the type and frequency of tests or diagnostic procedures to be performed on the subject.

NOTE: If the study involves drugs, it must be specified whether or not the drug is FDA-approved, and it must state the dose, rate and frequency of administration.

2. Risks and Benefits

There must be a reasonable description of any attendant discomforts and risks. Should an investigational drug or device be tested, expected side effects of the drug or device should be included in the consent. The likely results should the drug, device, or procedure fail should also be included.

When the risks are identified, any special precautions that are taken to avoid these hazards should be described.

Example: *The possible side effects of radiation therapy to my tumor and chest and neck nodes may be damage to areas of my normal lung, my esophagus, and my spinal cord. I may also have some skin irritation, pain in swallowing, cough, heartburn, and possibly a reduced blood count.*

As part of the evaluation of my therapy, I will permit my doctors, or their designated nurses, to withdraw samples of my blood during the course of the treatment. Possible side effects include minimal discomfort from venipuncture, possible hematoma (black and blue marks), and rare instances of infection or fainting. On the days that blood is drawn, two or three samples will be required, each amounting to less than two teaspoons.

My doctor will closely monitor my condition; and in order for him/her to recognize and treat all of these undesirable side effects early, repeated blood tests, x-rays, and other history and physical examinations will be necessary.

There should also be a description of anticipated, reasonable benefits to the subject, to others, or to scientific knowledge.

3. **Alternative Treatment** (if applicable)

A disclosure of any appropriate alternative procedures or other common treatment regimens that might be advantageous to the subject must be included in the consent. If any common treatment is being withheld, there must be an explanation and description of any risk involved.

4. **Right To Withdraw**

A disclosure that the subject or the subject's legal representative is free to decline participation in the investigation or to withdraw consent to discontinue participation at any time without prejudice to the subject must be included. The voluntary nature of the subject's participation must be clearly explained. It is suggested that the following paragraph be adapted to the individual protocol:

> I understand that I am free to refuse to participate in this study or withdraw at any time.

5. Confidentiality/Right to Privacy

A statement of confidentiality of patient information must be included in the informed consent.

The investigator should indicate how subject anonymity and right to privacy may be affected and how these will be protected. The consent should describe the investigator's plans and include appropriate sections of the following:

> I understand that any information about me obtained from this research, including answers to questionnaires, history, laboratory data, findings on physical examination, biopsy, surgery, or videotapes will be kept confidential. It has been explained to me that my identity will not be revealed in any description or publication of this research. Therefore, I consent to such publication for scientific and scholarly purposes.
>
> Confidentiality statements must be signed by all members of the research staff.

6. **Cost and Payment**

The consent is to include any costs or payments to the subject or reimbursement for related expenses. Subjects must not be induced to participate in the study through excessive offers of money, or other inordinate compensation. If appropriate, include a statement such as the following:

> All laboratory, physician, or hospital costs not related to the research will be charged to me just as though I were not a part of the study.

Some research studies involve equipment or procedures that are not funded and not reimbursed through insurance carriers. If this applies, the investigator is required to state, if possible, which services are the financial responsibility of the patient.

7. **Compensation for Injury or Illness**
A statement describing all rights the subject maintains for treatment or compensation in the event of injury arising from the research must be included in the consent.

Example: *I understand that in the event of a physical injury or illness resulting from the research procedure, no monetary compensation will be made, and I hereby release Robert Morris University and the investigator from any and all liability. Medical treatment, which may be necessary in the event of physical injury or illness, will be provided at the participant's expense. (This statement will be tailored for each individual study.) I can call the investigator to obtain information about treatment if it is needed.*

8. **Agreement to Participate**
A clear statement that the subject agrees to participate in the study with spaces for the subject's signature, investigator's signature and witness' signature and dates should be included in the consent. Finally, a provision should be made for the subject to sign or initial each page if the form exceeds one page in length. The consent should provide an offer to answer any inquiries concerning the investigation by the principal investigator and include the phone number at which the investigator can be most easily reached.

Standard Explanatory Questions Format

1. Why is this research being done?
Describe the purpose of conducting the research.

2. Who is being asked to take part in this research study?
State the reason why the potential subject is being asked to participate in the research study. Also, state the number of subjects to be studied.

3. What procedures will be performed for research purposes?
Include to following statement: "*If you decide to take part in this research study, you will undergo the following procedures".* Include any screening procedures that will be performed.

4. What are the possible risks, side effects, and discomforts of this research study?
Identify all reasonably foreseeable risks (e.g. physical, psychological, legal, or economic) and discomforts that may be associated with the screening procedures, experimental interventions, or monitoring/follow-up procedures performed specifically for the purpose of the research study.

5. What are the possible benefits from taking part in this study?
If applicable, state explicitly that subjects will receive no direct benefit from study participation. If it is possible that subjects may benefit directly from study participation, identify the possible benefits and include the statement, "*However, there is no guarantee that you will receive such a benefit."*

6. Will I be paid if I take part in this research study?

Specify if the subjects will or will not be paid for study participation. If the subjects will be paid address the total payment for completion of all parts of the research study, and address a payment schedule for only partial completion of the research study. Specify any other incentives (e.g. reimbursement for travel, parking expenses, non-monetary rewards, course credit, etc) to subjects associated with their participation in the research study. Address both the overall incentives for total study and completion and how the incentives will be distributed in the event of only partial study completion.

7. Who will know about my participation in this research study?

"*Any information about you obtained from or for this research study will be kept as confidential (private) as possible.* [Specify the procedures (e.g., coding of research data, storage of linkage code information in separate locked files) that will be used to protect the confidentiality of the research subjects. If records will be maintained in such a manner that it may be possible to link directly the research data with the subject' identity, this must be explicitly stated. In this circumstance, additional protections (e.g., password controlled access to the research database) to protect subject confidentiality should be described.] *You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission (release)."*

8. Who will have access to identifiable information related to my participation in this research study?

"In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

Authorized representatives of the Robert Morris University may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies."

9. For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

"The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for [specify the length of time that identifiable research information will be maintained. Note that it is acceptable to specify "indefinitely". Note also that it is a University policy that all research records must be maintained for at least 5 years following study completion.]

10. Is my participation in this research study voluntary?

"Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for

participation in this research study will have no effect on your current or future relationship with the Robert Morris University.

11. May I withdraw, at a future date, my consent for participation in this research study?
"You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above. To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the Robert Morris University.

12. If I agree to take part in this research study, can I be removed from the study without my consent?

Address the following:

a) Specify possible reasons why a subject may be withdrawn from study participation by the investigators.

b) If applicable, indicate what steps will be taken to ensure the subject's safety upon his/her termination from study participation.

c) Specify that any identifiable research information recorded for, or resultingfrom, the subject's participation in this research study prior to the date that s/he was withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

The following sections must also be included in the consent form:

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research during the course of this study and that such future questions will be answered by the researchers listed on the front page of this form.

Any questions which I have about my rights as a research participant will be answered by the Human Subjects Protection Advocate of the IRB Office, Robert Morris University (412-397-6227).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

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For adults (age > 18 years old) determined to be decisionally-impaired and, thus, unable to provide direct consent, incorporate the following standard statements and signature lines:

"

_____

Participant's Name (Print)

The above-named individual is unable to provide direct consent for study participation because

_____

Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____

Representative's Name (Print) Representative's Relationship to Participant

_____ _____*"*

Representative's Signature Date

Incorporate the following statements if the potential subject is capable of exercising some judgment concerning the nature of the research study and whether s/he desires to participate.

"VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research study to the abovenamed participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____ _____*"*

Investigator's Signature Date

For children (age 0-5 years), incorporate the following standard statements and signature lines:

"

_____

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study."

_____ _____

Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____

"Parent's or Guardian's Signature Date

(**Note**: For certain research studies involving children, the signature of both parents is required).

For children (age 6-13 years old), incorporate the following standard statements and signature lines:

"

_____

Participant's (Child's) Name (Print)

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Parent's or Guardian's Name (Print) Relationship to Participant (Child)

_____ _____
Parent's or Guardian's Signature Date
(**Note**: For certain research studies involving children, the signature of both parents is required)

VERIFICATION OF EXPLANATION
I certify that I have carefully explained the purpose and nature of this research study to the abovenamed child in age appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.
_____ _____ _____"
Investigator's Signature Date

For children (age 14-17 years old), incorporate the following standard statements and signature lines:
"
_____
Participant's (Child's) Name (Print)

_____ _____
Participant's (Child's) Signature Date
I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Parent's or Guardian's Name (Print) Relationship to Participant (Child)
_____ _____"
Parent's or Guardian's Signature Date
(**Note**: For certain research studies involving children, the signature of both parents is required)

For an individual who agrees to participate in the research study but is unable to sign his or her name, the individual should make his/her "mark" on the Participant Signature line. The signature of a witness to this "signature/mark" of the study participant should be included on the respective informed consent document.

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CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

****

Waivers and Exceptions of Informed Consent Requirements
Waiver of Informed Consent for Minimal Risk Research Studies
The IRB can approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or may waive the requirement to obtain informed consent from some or all of the research subjects provided that each of the following criteria are met:
1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration; and
4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

To be considered for such a waiver, the principal investigator must, in the recruitment section of the corresponding IRB research protocol, request a waiver of the requirement to obtain informed consent for some or all of the research subjects and must address each of the above criteria including a justification of its applicability to the proposed research and/or the subject population for whom the waiver of consent is being requested.

Waiver of the Requirement to Obtain a Signed Informed Consent Document
The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the research procedures if either:
1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or

(**Note**: If a waiver is granted based on this criterion, each subject must be asked whether s/he wants documentation linking her/him with the research, and the subject's wishes will govern.)

2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

To be considered for such a waiver, the principal investigator must, in the recruitment section of the corresponding IRB research protocol, request a waiver of the requirement to obtain a signed informed consent document for some or all of the research procedures and must address whichever of the above criteria is applicable to the research procedures for which the waiver is being requested to include an appropriate justification for its applicability.

Note that if the IRB grants a waiver of the requirement to obtain a signed consent form for some or all of the research procedures, this does not eliminate the requirement to obtain the informed consent of the subject for participation in the respective research procedures. Thus, accompanying this waiver request should be a script of the information that will be provided to potential subjects in obtaining their verbal consent for participation in the respective research procedures. This verbal consent process should include all of the basic and additional, applicable elements of informed consent addressed above. The waiver request should also address (i.e., within the recruitment section of the corresponding IRB research protocol, the mechanism that will used by the investigators to document that the verbal consent of subjects has, in fact, been obtained.

APPENDIX C

EXAMPLE COVER LETTER FOR INFORMED CONSENT

Dear (your subjects)

I am (tell the subject who you are)

The purpose of this study (tell them the purpose of your study – one or two paragraphs – if you are asking them to complete a questionnaire, ask them to complete it)

Your voluntary response to this request constitutes your informed consent to your participation in this activity. You are not required to participate. If you decide not to participate, your decision will not affect your current or future relations with _____.

(explain the time it takes to complete the activity i.e., "the questionnaire will take approximately 15 minutes to complete" and provide directions for the return of the instrument – you may wish to offer to share the results of the study with the subject "upon their request")

(If needed, provide a paragraph providing information to the subject about what to do if they find any of the activity unsettling i.e., "if you find any of the activity unsettling or distressing you do not need to complete the activity" and/or "please talk to /or please call _____" – you may also want to provide additional information to the subject i.e., addresses of organizations that can provide additional information, etc.)

This activity has been approved by the Robert Morris University Institutional Review Board. This Committee administers the University policy covering the protection of human subjects. The Committee may be contacted through the Chairperson.

Thank you for your valuable contribution to this research.

Sincerely,

Your name

For more information contact Chairperson – Robert Morris University's Institutional Review Board.