Policy Title: Uses and Disclosures of Protected Health Information for Research Purposes

Policy Summary:
It is the policy of MMC that research shall be conducted at MMC facilities only upon the approval of the MMC Institutional Review Board, which shall provide oversight of all human subject research, and which shall be in accordance with the procedures stated below. Patients and their protected health information (PHI) shall only be used and disclosed according to the laws and regulations applicable.

Policies:
1. **Privacy Requirements:** No research involving uses or disclosures of subject’s PHI may be conducted unless (a) an authorization for use or disclosure of such information is obtained from the subject, (b) a waiver of authorization has been approved by an IRB (c) the health information has been de-identified, (d) the health information is used or disclosed in a limited data set in accordance with a data use agreement, or (e) one of the exceptions listed in 2.a. below applies.

   a. The following circumstances shall be exceptions to the Privacy Rule requirements of this policy:
      i. A subject’s PHI may be disclosed to a person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity, including but not limited to:
         1. Collecting or reporting adverse events, product defects or problems, or biological product deviations; tracking FDA-regulated products; enabling product recalls, repairs, replacement or look-back activities; conducting post marketing surveillance.
         2. Unless the research is subject to waiver of informed consent regulations from FDA, all subjects that fall under the jurisdiction of FDA sign an informed consent document that includes a statement of the possible disclosure to FDA.
      ii. PHI may be used by or disclosed to a researcher as necessary for a review preparatory to research, provided the researcher meets the following three expectations and documents that information in their request to the MMC IRB, who makes the determination.
         1. The use or disclosure is sought solely for such stated purposes;
         2. No PHI will be removed from the MMC’s premises by the researcher in the course of the review;
         3. The PHI for which use or access is sought is necessary for the research purposes.
      iii. PHI may be used by or disclosed to a researcher for research on decedents provided the researcher meets the following three expectations and documents that information in their request to the MMC IRB, who makes the determination.
1. Represents to the MMC that the use or disclosure is sought solely for research on the PHI of decedents;
2. Provides to the MMC, upon request, documentation of the death of the research subject;
3. Represents to the MMC that the PHI is necessary for the research.

iv. PHI may be used by or disclosed to a researcher conducting retrospective research provided that the researcher meets the following expectations and documents that information in their request to the MMC IRB, who makes the determination:
   1. The requirements for written authorization and informed consent, as approved by the MMC IRB, are met; or
   2. MMC’s IRB approves a waiver of authorization and informed consent.

2. **Informed Consent:**
   a. No research at MMC or any MMC-owned facilities that involve human subjects may be conducted unless (1) an informed consent to participate in the research study is obtained from the research subject and approved by the MMC Institutional Review Board (IRB); or (2) MMC’s IRB approves a waiver of informed consent.

3. **Authorization:**
   a. In addition to informed consent under policy statement 2 above, an authorization must be obtained from the research subject unless a waiver of authorization is approved by an IRB, the information is de-identified, the PHI is disclosed in a limited data set pursuant to a data use agreement, or one of the authorization exceptions set forth in policy 2.a above applies.

   a. When requesting an authorization from a subject, MMC shall use an authorization form that contains:
      i. A description of the information to be used or disclosed;
      ii. Identification of the persons or class of persons authorized to make the use or disclosure;
      iii. The identification of the persons or class of persons to whom the information may be disclosed;
      iv. An expiration date or expiration event that relates to the individual or the purpose of the disclosure, which expiration date or event may be “none”, “end of research study” or similar language;
      v. A description of each purpose of the requested use or disclosure;
      vi. A statement of the right to revoke the authorization in writing, procedures to revoke the authorization and exceptions to the right to revoke;
      vii. A statement that information used or disclosed pursuant to an authorization may be subject to redisclosure and may no longer be protected by the federal privacy protections;
      viii. The signature of the subject and date; or if the authorization is signed by a personal representative of the subject, a description of such representative's authority to act for the subject;
      ix. A statement regarding the ability or inability of MMC to condition treatment, payment, enrollment or eligibility for benefits on the
authorization by stating either: (1) MMC may not condition treatment, payment, enrollment or eligibility for benefits on whether the participant signs the authorization when such prohibition applies, or (2) if MMC is permitted to place such conditions, then an explanation of the consequences of the participant’s refusal to sign the authorization.

x. A statement indicating that there may be an exception to requests for disclosures of PHI pertaining to research.

1. One exception, among others, is during a clinical trial, when the individual's right of access can be suspended while the research is in progress if, in consenting to participate in research including treatment, the individual agreed to the temporary denial of access.

2. MMC must inform the individual that the right to access his/her health records in the designated record set will be restored upon conclusion of the clinical trial.

b. The authorization may be in the same document as the Common Rule informed consent to participate in research, and as any optional consent to use or disclose PHI for treatment, payment or health care operations. See Exhibit A for combined template.

c. The authorization is written in plain language.

d. MMC provides the individual with a copy of the signed authorization.

e. A copy of the Informed Consent/Authorization form that meets these standards is attached hereto as Exhibit A.

4. Request for Exemption and Waiver of Authorization: A researcher requesting a waiver of authorization must submit to the IRB a Request for Exemption and Waiver of Authorization Form, attached hereto as Exhibit B. When relying on a waiver or alteration of the (1) informed consent to participate in a research study and/or (2) authorization requirements to use or disclose PHI for research purposes, the IRB shall document the following:

a. An IRB can approve a waiver of informed consent if:

i. The research is to be conducted by or subject to the approval of state or local government officials, and is designed to study:

1. A public benefit or service program;
2. Procedures for obtaining benefits or services under those programs;
3. Changes or alternative to those programs or procedures; and
4. Changes to payment methodology;

ii. Or, for other research purposes including:

1. The research involves no more than minimal risk to the subjects,;
2. The waiver or alteration does not adversely affect the rights and welfare of the subjects;
3. Whenever appropriate, the subjects are provided with additional pertinent information after the conclusion of their participation in the study.

b. Waiver or Alteration of Authorization. MMC’s IRB can approve a waiver or alteration of authorization and complete the following documentation requirements:
i. Identification of the IRB approving the waiver or alteration and the date of the approval;

ii. That the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures;

iii. Specify what PHI was disclosed pursuant to the waiver or alteration, to whom the disclosure was made and the date(s) of such disclosure(s); and

iv. Ensure that the documentation of the alteration or waiver of authorization is signed by the IRB chair or designee.

c. Criteria for Waiver or Alteration of Authorization.

i. MMC’s IRB shall approve the waiver or alteration of the authorization requirement only if it can document that the following criteria for the waiver or alteration have been met:

1. The use or disclosure of PHI involves no more than minimal risk to the individuals or their privacy, based on the following:
   a. An adequate plan to protect identifiers from improper use and disclosure;
   b. An adequate plan to destroy the identifiers at the earliest opportunity (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law);
   c. And an adequate assurances that the PHI will not be reused or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research permitted under this policy.

2. The research could not practicably be conducted without the alteration or waiver;

3. And, the research could not practicably be conducted without access to and use of the PHI.

ii. MMC’s IRB shall approve the waiver or authorization only if, in addition to the documentation required by policy 4.c. above, MMC’s IRB includes in the waiver or alteration approval document, the following:

1. A brief description of the PHI to be used or disclosed;

2. A statement that the alteration or waiver of authorization has been reviewed and approved by the IRB under normal or expedited procedures;

3. And, the signature of the Chair or other member, as designated by the Chair, of the IRB.

5. De-identification: MMC is not required to satisfy the authorization requirement if an IRB determines that the health information is de-identified in accordance with MMC Uses and Disclosures of De-identified Health Information and Limited Data Sets Policy.

6. Limited Data Set: MMC may use PHI to create a limited data set, or disclose PHI to a business associate to create a limited data set, in accordance with MMC Uses and Disclosures of De-identified Health Information and Limited Data Sets Policy.

Definitions:
Research – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research (Department of Health and Human Services). Refer to Glossary for other definitions.

Reference: 45 C.F.R. § 46 et al
Department of Health and Human Services
Title 21, CFR, Parts 50 and 56, FDA Protection of Human Subjects Regulations
MMC Institutional Policy, Uses and Disclosures of De-identified Health Information and Limited Data Sets
MMC Institutional Policy, Accounting of Disclosures of Protected Health Information

Original Date: 5/01
Review Date(s): 10/06

Approval Committee(s) and Dates: Institutional Policy Review Committee 5/24/10
Maine Medical Center Research Institute Privacy Subcommittee 2/26/2010

Policy Sponsor: ___________________________ Date: ______________

Administrative Approval: ___________________________ Date: ____________

Chief Information Officer
EXHIBIT A

Maine Medical Center

Informed Consent and Authorization to Participate in a Research Project TEMPLATE

STUDY TITLE: Please write the entire title here

PROTOCOL NUMBER: Include this line, if applicable

CONSENT VERSION DATE: This is the date the consent was developed or revised

HOSPITAL OR INSTITUTION: Where is the research taking place

INVESTIGATOR: Principal Investigator submitting the application to the IRB

SUBJECT’S NAME (printed):

You are being asked to volunteer for a research study. Research studies include only patients who choose to take part. In order to decide whether you should agree to be part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. Please take your time to make your decision.

You are being asked to take part in this study because you have X (e.g. coronary artery disease which requires bypass surgery, type 2 diabetes, etc).

WHY IS THIS STUDY BEING DONE?
This research is being done because (explain the purpose/hypothesis of this study, in lay terms”).

HOW MANY PEOPLE WILL TAKE PART IN THE CLINICAL TRIAL?
Up to X people will take part in this study in X sites. Maine Medical Center is one of those sites.

WHAT IS INVOLVED IN THE STUDY?
[For randomized trials, include the following language:] You will be “randomized” into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by computer. Neither you nor the researcher will choose what group you will be in. You will have an (equal/one in three/etc) chance of being placed in any one group. The groups are: (explain in one or two sentences what the groups are).
[For nonrandomized and randomized trials, include the following language:] If you take part in this clinical trial, you will have the following tests and procedures:

[List procedures and their frequency under the categories below]. For randomized studies, list the study groups and under each describe categories of procedures. If objectives include a comparison of interventions, list all procedures, even those considered standard.]

- Standard procedures and tests that will be done during the trial which are part of the regular care of a patient with this disease or condition (for example, a complete blood count (CBC) is always drawn the morning after your surgery)
- Standard procedures or tests that will be done during the trial which are being done because of participation in the trial (for example, we will draw a chemistry panel with your routine CBC the day after your surgery.)
- Procedures/tests that are considered experimental and are being tested in this trial

HOW LONG WILL I BE IN THE STUDY?
We think you will be in the study for (months/weeks).
[Where appropriate, state that the study will involve long-term follow-up]

The researcher may decide to take you off this study if (list circumstances, such as in the subject’s medical best interest, funding is stopped, drug supply is insufficient, patient’s condition worsens, new information becomes available, non-compliance with study requirements)

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. [Describe any serious consequences of sudden withdrawal from the study. Also, describe any additional testing or procedures that may need to be done for the safety of the participant because of sudden withdrawal]

WHAT ARE THE RISKS OF THE STUDY?
[For trials that include a medication, intervention, or device] While on the study, you are at risk for these side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and less uncomfortable. Many side effects go away shortly after the (intervention/medication, device) is stopped, but in some cases, side effects can be serious or long lasting or permanent.

[List by regimen the physical and nonphysical risks of participating in the study in categories of “very likely” and “less likely but serious,” “very rare but serious.” Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening]
Risks and side effects related to the (procedure, medication or device) we are studying include: (list risks related to the investigational aspects of the trial. Specifically identify those that may not be reversible)

[For those trials which have reproductive risks because of the medications, intervention, device, or testing] Reproductive risks: Because the (medication, intervention, device, or testing) used in this trial can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse your baby while on this study. Ask about counseling and more information about preventing pregnancy.

For more information about risks and side effects, ask the researcher or contact X.

ARE THERE BENEFITS TO TAKING PART IN THE CLINICAL TRIAL?
[For those trials that have no direct benefit to the subject] There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from this research.

[For those trials that may have a direct benefit to the subject] You may benefit from the treatment/procedure provided to you by this research. (Include a sentence or two describing the benefits)

[For those trials that include approved methods of treatment] The possible benefits of taking part in the research study are the same as receiving (medication, intervention, device, testing) without being in the research study.

WHAT OTHER OPTIONS ARE THERE?
Instead of being in this study, you have these options: [List alternatives including commonly-used therapy]

[For those trials that include approved methods of treatment] You may get (medication, intervention, device, testing) even if you do not take part in the study.

Please talk to your regular doctor about these and other options.

WHAT ABOUT CONFIDENTIALITY?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. [Include an explanation of where records are kept, if data is coded, etc.]

WHAT ARE THE COSTS?
You or your insurance company will not be charged for any tests or services specifically required by this research study unless the tests or services are clinically indicated or part of your standard treatment. You will still be responsible for the cost of your usual ongoing medical care, including procedures, non-study medications, and tests that your
study doctor or regular doctor requires during this study as part of your usual medical care.

*(If subjects are to be compensated for their participation please insert the terms of compensation here. If payment will be greater than $600.00, you must insert the following language).*

If your study payment is greater than $600.00 a year Maine Medical Center will send you a W-9 form to complete and return. You will then be sent a 1099 form for your taxes as you must report this as taxable income. Maine Medical Center will not take taxes out of any compensation you receive as part of this research study. If you have any questions, the research staff can assist you.

**WHAT IF I AM INJURED DUE TO MY PARTICIPATION IN THIS STUDY?**

In the case of injury or illness resulting from this clinical trial, emergency medical treatment is available, but will be provided at the usual charge. Maine Medical Center will not compensate you or your insurance company in the event of any injury.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is your choice. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.

We will tell you about new information that may affect your willingness to stay in this study.

**PERMISSION TO USE OR RELEASE IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH PURPOSES**

**WHY AM I BEING ASKED TO RELEASE THIS INFORMATION?**

As part of this clinical trial, you are being asked to allow investigator to [release or collect] health information about yourself. This information will be collected, entered onto a database with the health information from others taking part in this clinical trial, and studied in order to briefly repeat the purpose of the study from the previous page. Investigator may also need to obtain copies of any medical records you have with other health care providers.

**WHAT AM I BEING ASKED TO RELEASE?**

For this clinical trial, the following information will be collected: [Identify / describe the information in a specific and meaningful fashion for example:]

- Your date of birth,
- Your past medical history
- Your weight, blood pressure, temperature and the results of your physical examination from each visit
- All medication you are currently taking and will take during the study
- Etc.]
[For trials without a sponsor or where the investigator is keeping all of the data, include the following 2 sections]

WHO WILL SEE THIS INFORMATION?
Personnel or members of the Maine Medical Center Institutional Review Board, personnel from the Office of Human Research Protections or any regulatory agency may see parts of your medical records related to this clinical trial and, therefore, will see your name and other personally identifiable information about you. The information collected is the property of investigator, and you will not be able to get it back. In the event of any publication regarding this study, your identity will not be disclosed.

WILL THE INFORMATION COLLECTED AS PART OF THIS STUDY BE DESTROYED WHEN IT IS NO LONGER NEEDED?
It is difficult for investigator to know how long your information will be kept at least until the end of the clinical trial, but most likely it will be kept on a database at investigator’s office for an indefinite length of time. We do not know when your information will no longer be used, and there is not expiration date after which it will be discarded.

OR

[For trials with a sponsor, or where the data is collected and sent to someone other than the investigator, include the following 2 sections]

WHO WILL SEE THIS INFORMATION?
The sponsor or data collection center, and the Food and Drug Administration (FDA) will receive copies of the study records, but you will not be personally identified in these records. Employees of sponsor or data collection center, the FDA, Maine Medical Center Institutional Review Board or any regulatory agency may see parts of your medical records related to this study and, therefore, will see your name and other personally identifiable information about you. As part of this research study you are being asked to authorize release of your medical records as required by the contract agreement between the sponsor and Maine Medical Center. The information collected and sent to sponsor or data collection center is the property of sponsor or data collection center, and you will not be able to get it back. In the event of any publication regarding this study, your identity will not be disclosed. Your clinical trial information, which does not personally identify you, and is sent to sponsor or data collection center might be further disclosed. If disclosed by sponsor or data collection center, the information is no longer covered by the federal privacy regulations.

(If information is to be released to financial services for payment you must add the following language to the ICF)
Personal information about me, including my name, address and social security number, will be released to Financial Services for the purpose of payment.

WILL THE INFORMATION COLLECTED AS PART OF THIS STUDY BE DESTROYED WHEN IT IS NO LONGER NEEDED?

It is difficult for sponsor/data collection center or investigator to know how long your information will be kept. Your information will be kept at least until the data are sent to FDA/data collection center/sponsor, but most likely it will be kept on the database at sponsor/data collection center for an indefinite length of time. We do not know when your information will no longer be used, and there is not expiration date after which it will be discarded.

CAN I STOP MY INFORMATION FROM BEING USED?

If you leave the study, and do not wish to have any more of your personal data collected, you must notify investigator in writing. You may also call investigator at telephone number and your request to stop collecting information will be honored, but you must also notify investigator in writing. To notify investigator in writing, send your request to: investigator, address, attn: contact name. Any data that has already been collected will continue to be seen and used as described previously.

WHAT IF I DO NOT AUTHORIZE YOU TO COLLECT AND RELEASE MY HEALTH INFORMATION?

If you agree to be in this clinical trial, you are authorizing the release of your health information as part of the trial. If you do not want to release your health information, you may not take part in this clinical trial (do not sign this form if you do not want to take part in this clinical trial, or you do not want to release your health information).

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury contact Investigator at telephone number or Co,Sub-Investigator at telephone number.

For questions about your rights as a research participant, contact the Maine Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights) at (207) 885-8195.

[Attach the appropriate set of signature lines]
Informed Consent and Authorization to Use or Release Identifiable Health Information for Research Purposes

(Signature Lines for an Adult’s Informed Consent and Authorization Document)
I have read, or have had read to me, the above information before signing this authorization form. I agree to participate in this clinical trial. I do authorize the use or disclose of my personal health information for the purpose of this research. I have been offered ample opportunity to ask questions and have received answers that fully satisfy those questions.

________________________________________   _________________
Signature of Patient or Authorized Representative   Date        24 hr time

_____________________________________________
Printed Name of Patient or Authorized Representative

______________________________________________________  _________________
Signature of the Person Obtaining Consent/Authorization  Date          24 hr time

________________________________________   _________________
Signature of Witness        Date           24 hr time

________________________________________   _________________
Signature of  Interpreter, when applicable    Date           24 hr time

A copy of this authorization form must be given to each subject entering the study.
Informed Consent and Authorization to Use or Release Identifiable Health Information for Research Purposes

(Signature Lines for a Child’s Assent) I understand the purpose of the procedure(s) and the risks/benefits involved in its performance.

________________________________________________________________________

Signature of Patient       Date           24 hr time

Printed Name of Patient

If the patient refuses to sign, or the parent/guardian/s request that the child not sign, indicate reason on the line above.

I have fully explained to (subject's name) the nature and purpose of the above-described procedure and the risks/benefits involved in its performance. I have answered and will answer all questions to the best of my ability. I will inform the subject of any changes in the procedure or the risks and benefits if any should occur during or after the course of the study.

________________________________________________________________________

Signature of Person Obtaining Consent and Authorization  Date           24 hr time

Parent/Guardian giving permission for the child:

________________________________________________________________________

Signature of Patient or Authorized Representative  Date           24 hr time

Printed Name of Patient or Authorized Representative

________________________________________________________________________

Signature of Patient or Authorized Representative  Date           24 hr time

Printed Name of Patient or Authorized Representative

________________________________________________________________________

Signature of Witness  Date           24 hr time

Signature of Interpreter, when applicable  Date           24 hr time
Exhibit B

Submission Form for Request for Waiver of Authorization

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<thead>
<tr>
<th>Request for Waiver of Authorization</th>
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<tbody>
<tr>
<td>Principal Investigator:</td>
</tr>
<tr>
<td>Project or Protocol Title:</td>
</tr>
<tr>
<td>Contact person</td>
</tr>
<tr>
<td>Address:</td>
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### SPONSOR / FUNDING INFORMATION

Will this project/protocol be supported by an external funding agency?  

- [ ] No  
- [x] Yes

**List Sub-investigator/Co-investigators**  
None [ ]

**Faculty Sponsor (if applicable)**

**LOCATION OF RESEARCH:**

Where will the study take place?  

Include all locations for study related activities here or on separate sheet.

- [ ] No  
- [x] Yes

Will the PI be conducting and/or supervising study related activity at any sites not under the jurisdiction of this IRB? If yes, please provide name and address for each location AND documentation of approval to conduct research at these sites. Note. Additional IRB approval may be required from these sites if an individual at this site, not an employee/student of this institution/organization, is performing research under this application.
Exhibit B

Request for Waiver of Authorization

Answer all of the following questions. Attach additional pages if needed

1. ☐ Explain why the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals who PHI will be collected:

2. ☐ Explain why the research could not practicably be conducted without the alteration or waiver of Authorization:

3. ☐ Explain why the research could not practicably be conducted without access to and use of the protected health information;

4. ☐ Describe the possible benefits of the research to A) the general population and B) the group of individuals whose PHI you propose to use or disclose

5. ☐ Describe the possible privacy risks to individuals whose protected health information is to be used or disclosed:

6. ☐ Describe the plan to protect the identifiers from improper use and disclosure:

7. ☐ Describe the plan to destroy the identifiers. (If there is no intent to destroy identifiers, discuss the health or research justification for retaining the identifiers, or such retention is otherwise required by law)

8. ☐ Describe your security steps to protected health information so it will not be reused or disclosed to any other person or entity, (except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by regulation).
Exhibit B
Request for Waiver of Authorization

RATIONALE for Waiver of claimed

The information must include a brief specific description of the procedure(s) involving the human subjects in sufficient detail to demonstrate to the IRB / Privacy Board reviewer that the research protocol meets the requirements for each category for Waiver of Authorization in this human subjects research protocol. The text should be approximately 300 words or less on a separate sheets in sufficient detail to allow reviewer to judge exemption criteria.

THE SYNOPSIS OF THE PROJECT OR PROTOCOL, INCLUDE:

1. The objective of the research project and background of study.
2. The rational for the use of the selected subject population & plans for recruitment & consent.
3. The procedures that will be performed to generate research data & risks to subjects' privacy, if any. Include a copy of your data recording tool.
5 Include copy of questionnaires, surveys or brief outline of questions to be asked.
6 Attach a copy or copies of your Data Use Agreements or explain why such agreements are not required

INVESTIGATOR’S ASSURANCE

I certify that the information provided in this request for Waiver of Authorization is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research protocol. I agree to comply with all requirements of the IRB and Institutional policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the research protocol,
- Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least 6 years following termination of the project,
- Necessary review by the IRB will be sought if changes made in the research protocol may result in the research no longer meeting the criteria for exemption.

I have read and understand the Policy concerning Waiver of Authorization

Principal Investigator

Date