HUMAN SUBJECTS RESEARCH

Policies and Procedures

(Includes revisions per the Common Rule effective January 21, 2019)

OFFICE OF ACADEMIC AFFAIRS

ROBERT MORRIS UNIVERSITY

Revised June 2020

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INTRODUCTION

Past abuses in clinical research have led the Federal Government to mandate that researchers safeguard the rights and welfare of the people who are the subjects of their activities. An increasing number of colleges and universities are electing to apply the same protections to human subjects involved in all types of research.

The regulations that govern human subject protection specify the processes required for such protection. Institutions that undertake clinical and/or government-funded research, including government facilities, are required to have an "Institutional Review Board (IRB)" and appropriate procedures and documentation to ensure that human subjects are protected. These organizations conduct at least a brief review of all research performed under their aegis. The research that presents risk to its subjects or which is specifically identified in the regulations is subject to more extensive scrutiny. This document provides guidelines for when review by the Robert Morris University (RMU) IRB must occur. Robert Morris University's Institutional Review Board consists of at least five members of varied disciplines with faculty status. One member is unaffiliated with the University. At least one representative is from each ofRMU's four schools.

Federal law, based on the principles of individuals' rights to privacy and protection of citizens from harm by others, has led to clear rules about the conditions under which we may do research using human subjects. Robert Morris University is committed to these laws based on moral, ethical, and legal grounds. All research that comes under the aegis of the University must meet the procedures established to ensure the privacy and protection of human subjects. These procedures are followed by faculty, staff, and students in any research they conduct regardless of where it is actually conducted. The researchers must also inform all subjects that they are part of a study, what the likely stresses for them will be in the study, must secure their written consent (or parent/guardians'), must preserve their confidentiality with every possible effort, and fully inform the subjects of their right to withdraw from the study at any time for any reason with no penalties.

Any research involving human subjects should be submitted to the IRB for review.

THE INSTITUTIONAL REVIEW BOARD

Purpose The role of the Institutional Review Board (IRB) is to review research that is federally regulated. The IRB is guided by Title 45 Code of Federal Regulations Part 46 and the Ethical Principles and Guidelines for the Protection of Human Subjects of Research provided by The Belmont Report. Except for those categories specifically exempted or waived under 45 CFR 46.10I (b) (1-6) all other research will be reviewed by the IRB.

Composition The IRB will have at least five members (volunteers are nominated by School Deans). The IRB will have members with varying backgrounds representing each of RMU's four schools and the Library to provide an adequate review of the research activities. The IRB will include at least one member who is not affiliated with the University. Terms of committee membership are for three years and are renewable. Typically, a committee member may serve for two consecutive terms. Subsequent terms may be possible should there be a need. The Chair and Co-chairs are to be determined from the committee. All members are required to successfully complete the CITI program modules. Under an expedited review procedure, the review may be completed by the Chairperson or a "sub-committee" which refers to two members of the IRB that are selected by the IRB Specialist. One of these members should be a more experienced member of the full committee.

Meeting Schedule The IRB will meet at least quarterly and may meet more frequently as required. Official meetings will not begin until more than 50% of the members are present.

Responsibilities The responsibilities of the IRB include:

- Each member of the IRB being reasonably knowledgeable about the applicable laws and diligent in reviewing human subject research submitted to the IRB. This is evidenced by the completion of appropriate training in human subject research and IRB policy, procedure, and protocol (i.e., CITI, NIH or equivalent).

- Reviewing and having the authority to approve, require modification, or disapprove research activities under review. Once a completed application (revised per requested modifications, if applicable) is received, a final decision will be provided within IO business days during the regular September to May academic year. Holiday breaks, and the months of June, July, and August may delay the review process.

- Providing notice of its decisions and requirements for modifications and accompanied reasons for modifications and disapproval to the researcher.

- Ensuring that informed consent is obtained and documented in a manner that satisfies federal regulations.

- Evaluating whether the protection for human research subjects is adequate in accordance with the criteria found at 45 CFR 46.111.

- Where appropriate, determining that adequate additional protections are ensured for pregnant women, prisoners, and children as required by subparts B, C, and D of45 CFR 46.

Review of Adverse Event Reports

i. Adverse events that are serious and unexpected will be reported to the IRB Chair/Co-chairs by the researcher via email within 5 business days of the researcher becoming aware of them.
    1. If the Chair/Co-chairs judges that the adverse events are related to the research protocol, then the Chair/Co-chairs will report to the full board at its next meeting, or call an emergency meeting of the board. The board will review the risks and the benefits of the research protocol and consider changes in the protocol, informed consent, and possible termination of research.
    2. If the Chair/Co-chairs judges that an adverse event is unlikely to be related to the research protocol, then the event will be reported to the full board at its next meeting.

u. Adverse events that are neither serious nor unexpected will be reported to the IRB Chair/Co-chairs by the researcher within one month of the researcher becoming aware of them.

Administration

The Associate Provost or designee will serve as the research administrator (RA) responsible for oversight of the human subjects review process. Their responsibilities will include:

- Ensuring communication among administrators, deans, researchers, human subjects, related to the rights and well-being of human subjects.

- Maintaining copies of this procedure, 45 CFR 46, pertinent federal policies, and state laws related to human subjects research.

- Ensuring adequate membership and proposing committee membership.

- For all federally or state regulated research, promptly reporting to the IRB and the Provost and Senior Vice President for Academic Affairs any injuries to human subjects, any unexpected problems, any serious noncompliance, and/or any termination of IRB approval for research.

- Maintaining federal research records.

TYPES OF REVIEWS

The investigator is responsible for carefully reviewing the criteria for exempt, expedited, and full-review studies as defined in the Code of Federal Regulations Title 45 Part 46.101. However, the IRB ultimately determines the category of approval. All research involving human subjects must be reviewed by the IRB, even if the investigator believes the study qualifies for exemption. If PI plans to publish research, the proposal must go before the IRB Committee, regardless of type of review application.

According to 46.104 of the Code, Exempt, Limited, Expedited, and Full Review are defined as following:

I. Exempt Review

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes: most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the

subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.l l l(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of"health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.l l l(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.l 16(a)(l) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.l 1l(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

In addition to the federal exempt regulations:

The RMU Polling Institute conducts opinion polls that are traditionally considered exempt research.

The Oral History Center conducts interview projects that are exempt. (Language taken from Valerie Raleigh Yow, Recording Oral History: A Guide for the Humanities and Social Sciences, Second Edition (Walnut Creek: AltaMira, 2005).

In 2003, the U.S. Office for Human Research Protection (OHRP), part of the Department of Health and Human Services (DHHS), working in

conjunction with the American Historical Association and the Oral History Association, has determined that oral history interviewing projects in general do not involve the type of research defined by HHS regulations and are therefore excluded from Institutional Review Board oversight.

It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to "generalizable knowledge" that they are not subject to the requirements of the DHHS regulations at 45 CFR part 46 and, therefore, can be excluded from IRB review. Although the DHHS regulations do not define "generalizable knowledge," it is reasonable to assume that the term does not simply mean knowledge that lends itself to generalizations, which characterizes every form of scholarly inquiry and human communication. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their often unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the way any individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of interviews offer up not similar "generalizable" information but a variety of particular perspectives on the topic.)

Exempt Research Involving Children*

Although under federal regulations exemptions <u>are</u> permitted where children are participants in research, research involving children must be reviewed by the IRB *except* as noted below:

1. Chart/Medical Record Review
    a) A chart/medical record review may be conducted if permission was granted at the time of admission for chart reviews for such purposes, and
    b) No identifying information is to be collected from the chart/medical record (i.e., name, address, phone number…)
2. Observational Studies

a) Observational studies may be considered exempt as long as videotaping or audiotaping is not involved, and no identifying information is recorded.

3. Educational Research conducted in educational settings, involving normal educational practices, such as:
   a) regular and special education instructional strategies.
   b) the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
   c) no identifying information is to be recorded or disclosed outside of research.

   https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#transition-orovision . Under exemptions

* Note: "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction on which the research will be conducted. In Pennsylvania the following stipulations apply:

1. If the minor is between the ages of 13 and 17, the parent or guardian must give informed consent and the child must give informed assent.
2. If the minor is below the age of 13, the informed consent of the parent or guardian must be obtained and the child must be given an explanation of the research. This may entitle the use of a consent form especially prepared to facilitate the understanding by a minor of such age.

II. Limited IRB Review

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria in §46.111. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB)

There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7, and 8.

- Exemption 2 is for research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited IRB review is required only if the third provision of the exemption is being used - that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this provision of Exemption 2, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

- Exemption 3 is for research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited IRB review is required only if the third provision of the exemption is being used- that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this provision of Exemption 3, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

- Exemption 7 is for the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which broad consent is required. This exemption requires limited IRB review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained.

- Exemption 8 is for secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

[Refer to sections 45 CFR 46.104(d)(2)(iii), 46.104(d)(3)(i)(C), 46.104(d)(7), and 46.104(d)(8)(iii) of the revised Common Rule .]

III. Expedited Review (completed by a sub-committee of the IRB)

Expedited review approval may be given if the study involves no more than minimal risk and falls within one of the expedited categories as described in the Code, which is subject to review and change:

1. Clinical studies of drugs and medical devices only when the drugs or devices have been approved for marketing and are used as prescribed.

2. Collection of blood samples by finger stick or venipuncture from non-pregnant healthy adults in amounts less than 550 ml in an eight-week period and no more than twice per week.

3. Prospective collection of biological specimens by non-invasive means (e.g. hair and nail clippings, extracted teeth, excreta and external secretions, uncannulated saliva, placenta removed at delivery, amniotic fluid obtained at rupture of membrane prior to or during delivery, dental plaque and calculus, mucosa! and skin cells collected by swab and sputum collected after saline mist nebulization.)

4. Collection of data through non-invasive procedures routinely employed in clinical settings, excluding x-rays or microwaves (e.g. physical sensors that do not shock or invade the subject's privacy, weighing or testing sensory acuity, magnetic resonance imaging, EEG, EKG, moderate exercise or strength testing with healthy non-pregnant subjects.)

5. Research involving data, documents, records or specimens collected for non-research purposes, such as medical records.

6. Collection of data from audio or visual recordings.

7. Research on individual or group characteristics when considering the subject's own behavior (including perception, cognition, motivation, identity, language, communication, socio-cultural beliefs, practices or behavior) or research employing survey, interview, oral history, focus group or program evaluation measures for purposes of research.

The requirements of expedited research have been updated to include:

- No continuing review of expedited research is required unless the IRB has a reason to require it and can justify that reason.
- No continuing review for projects conducting data analysis only.

IV. Full Board Review

A full board review is conducted when research procedures pose more than minimal risk to subjects or when subjects are, as a group, belonging to a vulnerable population. The IRB is particularly concerned with research involving the following:

1. subjects under the age of 18
2. pregnant subjects
3. frail elderly subjects
4. incarcerated subjects or persons under a correctional sentence (parolees)
5. mentally impaired subjects
6. false or misleading information to subjects
7. withholding information such that subjects' consent is in question
8. procedures for debriefing subjects
9. biomedical procedures
10. procedures that are novel or not accepted practice

11. risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information, or information creating legal vulnerability

INFORMED CONSENT

Prospective participants in a research study must understand the purpose, the procedures, the potential risks and benefits of their involvement, and their alternatives to participation. While a consent document gives this information, the opportunity to discuss any questions or concerns with a knowledgeable research team member is also important. Informed consent is about one's understanding and willingness to participate in a study and not about signing a form. Informed consent for minor children (under the age of 18) must be obtained from their parents or legal guardians. In addition, if the minor is between the ages of 13 and 17, the child must give informed assent. Making an informed decision about participating in research includes subjects' having an understanding of the possible risks and benefits to their involvement, and knowing that they do not have to volunteer and can withdraw at any time.

I. Definitions

To discern the key components of informed consent, it is necessary to understand the ethical issues of research involving human subjects. The principles of autonomy, beneficence, and justice are basic to these ethical issues and are worthy of considerations as described below:

Autonomy: Autonomy means that each person should be given the respect, time, and opportunity necessary to make his or her decisions. Prospective participants must be given the information they will need to decide to enter a study or not to participate. They should not be pressured to participate. The principle of autonomy requires that protection be given to potentially vulnerable populations such as children, the elderly, the mentally ill, or prisoners. Individuals in these groups may be incapable of understanding information that would enable them to make an informed decision about study participation. They are considered potentially "vulnerable." Consequently, careful consideration of their situation and needs is required and extra care must be taken to protect them.

Beneficence: Beneficence obligates the researcher to secure the well-being of all study participants. It is the researcher's responsibility to protect participants from harm, as well as ensure that they experience the possible benefits of involvement.

Justice: The concept of justice may be questioned when decisions are being made regarding who will be given the opportunity to participate and who (and for what reason) will be excluded. Participants should not be selected due to class, gender socioeconomic status, or race unless justified by study objectives. See the Selection of Subjects section of The Belmont Report.

Basic elements of informed consent as defined in Section 46.116 of the federal code must be described in all protocols:

1. The consent begins with key information why one might or might not want to participate in the research;
2. The consent contains information that a reasonable person would want to have in order to make an informed decision about whether to participate;
3. Statement of the purpose of the research, duration of subject's participation, procedures and identification of any experimental procedures;
4. Foreseeable risks or discomforts;
5. Reasonable benefits to the subject or others;
6. Alternative procedures;
7. How confidentiality will be maintained;
8. Compensation, including whether and what type of medical treatment is available in case of injury;
9. Names and phone numbers of persons to contact for clarification about the research, the subject's rights and whom to contact in case of injury; and
10. Statement that participation is voluntary, refusal to participate involves no penalty and that subject may withdraw at any time without penalty.

Additional elements of informed consent that may be appropriate for certain types of studies:

1. Statement that the treatment may involve risks to subject or fetus if pregnant subject or may become pregnant during study;
2. Circumstances under which subject may be dropped from study without regard to subject's consent;
3. Additional costs to subject from participating in study;
4. Consequences of subject's decision to withdraw from study and procedures for orderly termination;
5. Statement that significant new findings of the study which might affect subject's willingness to continue will be provided to the subject; and
6. Approximate number of subjects in study.

II. Child Assent

In cases in which the research subject or participant is a child (defined as under the age of 18,) the researcher shall obtain the consent of the parents or guardian and the assent of the child. Assent is the agreement of the child to participate. The process for obtaining assent should follow the procedures for obtaining consent by the parents, with the form for assent written in age-appropriate language and sufficient attention given to explaining the study and answering the child's questions.

III. Waiving Consent

The IRB may waive some or all of the elements provided there is documentation that the research is to be conducted by or subject to approval by state or local government officials. In addition, it is possible to waive consent when the following conditions apply:

1. Risk is minimal;
2. No adverse effects on the rights of subjects;
3. Research could not practically be carried out; and
4. Subjects would be provided with additional pertinent information after participation.

IV. Documentation of Informed Consent

Written consent signed by the subject or guardian is necessary for most studies. The consent form must have all appropriate elements specified in the IRB Instructions to Researchers. Consent forms and assent forms must be submitted for IRB review. There are two consent/assent forms with original signatures, one for the subject and one for the researcher.

V. Waiver: Written Signed Consent

The IRB may waive the requirement for a written signed consent in either of the following cases:

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 breach of confidentiality. In this case the subject shall be asked whether he or she wants to sign a consent form.

2. The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. (Example would be a questionnaire in which consent is implied by the fact of the subject returning the questionnaire.)

In either case, the researcher should provide the subject with a written description of the study that includes the elements of informed consent.

VI. Use of Consent Forms in Exempt Research

Under Section 46.117, the requirement for a signed consent form for some or all subjects **are exemJ!!** following the guidelines below:

1. No consent form is necessary if that document is the only identifier. A subject must, however, be given a consent form to sign if that is his/her wish.
2. In the event that a consent form is signed, it must be separated from other information that the participant has filled out in order to avoid identification.
3. Where no consent form is used, an informational sheet must be provided to the participant giving the same information that a signed consent form would (i.e., information about the study, risks, and benefits, etc.).

If there are any questions regarding interpretation of any of the above guidelines or federal regulations, please notify the Chair/Co-chairs of the IRB.

CONTINUING REVIEW

Under the revised Common Rule, continuing review is not required for:

- Research that is eligible for expedited review
- Exempt research conditioned on limited IRB review,
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,
- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

Amendments to Approved Studies

Any significant changes to the methodology or key personnel must be approved by the IRB in writing prior to their initiation. Researchers proposing to change any aspect of an approved study should contact the IRB to determine if the changes require approval of an amended protocol. If they do require review, a representative or representatives will be designated to act as reviewers. Usually these are individuals in the same capacities as the reviewers of the original protocol. The proposed amendment should include all pertinent sections of the protocol, with explanations of how and why the researcher requests to amend the original methodology.

The IRB may request verification from sources other than the investigator that no significant changes have occurred since previous IRB review. This decision will be made by the IRB Chair/Co-chairs or board on a case-by-case basis, depending on the likelihood that the investigator cannot offer an adequate verification.

Unanticipated Problems

If unanticipated risks or hazards are discovered during the course of the research, the Principal Investigator (Pl) shall immediately suspend research activities and notify the IRB in writing. The Chair/Co-chair will consult with the original IRB reviewer or reviewers to determine what actions to take. The researcher may not continue research activities until receiving permission from the IRB.

PROCEDURES FOR APPLICATION AND REVIEW PROTOCOLS

1. Prior to development of an IRB application, the Principal Investigator (Pl) should review the Human Subjects Research Office (IRB) web site, irb.rmu.edu, for the latest policies, procedures and forms (since updates are made on a regular basis) and complete the training modules as specified on the site. Questions about policies and procedures should be directed to any IRB committee member, IRB Chair/Co-chairs or irb@rmu.edu.

2. The PI must complete IRB awareness training via the CITI website as instructed on the IRB web page before the application may be submitted. (Section 2 of the online application form is designated for uploading the CITI training completion certification.)

3. The Pl should complete the IRB online application located on the IRB web page and submit the form electronically to the IRB office. If the PI is a student, the advisor's approval is also required in the application. Once the PI hits submit, the advisor's screen appears requesting the name and email of the advisor.

4. In exempt and expedited cases, the IRB reviews the proposal, requests revisions if needed, and when the protocol meets IRB requirements, approval will be granted. Researchers may not begin contact with subjects, soliciting them or collecting data, until after receipt of the approval letter from the IRB.

5. For full reviews, the IRB meets to discuss the study and vote as a group that human subject protections are adequate. It is acceptable for the PI to be available for questions, but this is not always necessary. After discussion, the vote is taken; a majority carries the vote. The approval letter is sent after the vote or, in the case of disapproval, informs the PI of required revisions. Communications about changes to protocols for student research will be copied to the faculty advisor. If the IRB requires further revisions or does not approve the research, the IRB shall communicate with the PI and advisor (if the PI is a student) as soon as possible after the meeting.

6. All official approvals are issued by the IRB Office. The PI may not collect data before receiving official approval from the IRB Office. Every attempt will be made to review protocols in a timely yet thorough manner. Ordinarily the PI will receive notification of the decision within 15 business days of the protocol's final submission to the IRB Office in exempt and expedited cases (excluding Holiday breaks and the months of June, July and August) and within two weeks after IRB committee meetings in full-review cases.

7. It is the responsibility of the PI to inform the IRB Office of termination of the study or changes in methodology or personnel.

RELIANCE AGREEMENT

When multiple IRBs are involved in the same research study, a single IRB may become the lead IRB to reduce duplication and oversight for the same protocol. RMU IRB offers an IRB Reliance Agreement (also called an Authorization Agreement) which is an agreement that permits a single IRB to review human subject research for more than one site. RMU IRB can cede review to another institution (Relying IRB) or act as the Reviewing IRB or IRB of Record for other institutions. The roles and responsibilities for the collaborating institutions are defined in the agreement. To request reliance, please go to RMU IRB Reliance Agreement.

Appendix A

IRB APPLICANT CHECKLIST

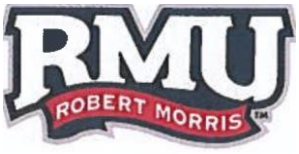
Before submitting your application, please make sure that:

Description	Yes
Collaborative Institutional Training Initiative (CITI)	
The principal investigator, co-investigators and advisor have completed human-subject training (CITI program) at the time of submission.	
Research Information	
You have adequately explained the purpose of the research.	
Informed Consent	
• Contact information for you, your faculty advisor, and your IRB office. You may use the following statement for the IRB office: If at any time you have questions regarding your rights as a research subject, queries may be forwarded to the RMU IRB Office at 412-397-6227 or irb@rmu.edu.	
• Information explaining that the subject is being asked to participate in research, including the purpose of the study, how long the study will last, and a detailed description of the tasks involved (including any interventions).	
• Risks or discomforts the participant may experience.	
• Potential benefits to subjects or others.	
• The degree of confidentiality a subject can reasonably expect, which includes who will have access to the data, where and how you will store data, how you will report data/results (for example, in aggregate or using pseudonyms), how long you will keep the data, and how you will use results (such as in reports, publications, or presentations).	
• Any appropriate alternative treatments that may be advantageous to the subject instead of the research.	

• For research greater than minimal risk, an explanation about available compensation and/or medical treatments if injury occurs, as well as where participants may obtain further information.	
• Signature/Date lines included for research participant and principal investigator. No signature is required for online surveys.	
Research Occurring Off-Campus	
• If research will take place off site, proper documentation (permission letter) hasbeen obtained and uploaded to the application.	
Data Collection	
• Your faculty advisor should have access to any data collected as part of your research project. All data should be fully deidentified and transferred to your faculty advisor's possession prior to graduation.	
Review	
• Check for completeness, accuracy, and best practices in human subject protections.	

Additional information can be found at rmu.edu/irb.

Appendix B



IRB ADVISOR CHECKLIST

To assist you in ensuring your student's IRB submission is complete and facilitate a smooth IRB process for the student, below is a checklist for you to help your student throughout the IRB submission process.

Description	Yes
IRB Process	
• Advise your student that they cannot begin their research until FINAL approval is granted from the RMU IRB. You and your student will receive a formal approval letter through email.	
• Remind students that the initial review can take up to 15 days and subsequent reviews, if necessary, can extend the timeframe for review. Plan accordingly.	
Collaborative Institutional Training Initiative (CITI)	
• Ensure that you, the student, and any co-investigators have completed human subject training (CITI program) prior to the submission.	
Research Information	
• There is a clear method of recruiting participants. See the RMU recruitment policy.	
Informed Consent	
• Provide guidance on the consent form. See the student's checklist and IRB consent templates for details.	
Research Occurring Off-Campus	
• If research will take place off site, proper documentation (permission letter) has been obtained and uploaded to the application.	

Data Collection	
• You should have access to any data collected as part of your student's research project. All data should be fully deidentified and transferred to your possession prior to graduation.	
Attachments to IRB Application	
• Confirm that the student has the necessary attachments (if applicable): 1. CITI training completion report for the researcher 2. Site permission(s) 3. Informed consent document(s) 4. Instruments (survey or interview questions) 5. HIPAA form for Retrospective Chart Reviews	
Review	
• Check for completeness, accuracy, and best practices in human subject protections.	

Additional information can be found at rmu.edu/irb.

Appendix C

IRB MEMBER REVIEW CHECKLIST

RMU researchers and IRB members share responsibility for ensuring that human research conducted under RMU's jurisdiction meets the ethical principles of the Belmont Report and federal criteria for IRB approval of research and informed consent. Below is a checklist that outlines the criteria for IRB approval.

Description	Yes
Collaborative Institutional Training Initiative (CITI)	
• The researcher has completed CITI program training.	
Research Information	
• The research contributes to generalizable knowledge	
• There is an adequate description of the activities involving human subjects.	
• The study instruments have been provided.	
• The subjects are not likely to be vulnerable to coercion or undue influence.	
• Any compensation/incentives are reasonable.	
• There is no conflict of interest.	
Informed Consent	
• Contact information is provided for researcher, advisor and IRB.	
• Purpose of study, how long the study will last, and a detailed description of the tasks involved (including any interventions) are included.	

• The risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	
• Both risks and anticipated benefits are accurately identified, evaluated and described.	
• Signature/Date lines included for research participant and principal investigator.	
Research Occurring Off-Campus	
• If research will take place off site, proper documentation (permission letter) has been obtained and uploaded to the application.	
Data Collection	
• There is a detailed description of the data collection and methods of recording.	
• There are adequate provisions to protect the privacy interests of participants.	
• There are adequate provisions to protect the confidentiality of data.	
Attachments to IRB Application	
• Confirm that the student has the necessary attachments (if applicable): 1. CITI training completion report for the researcher 2. Site permission(s) 3. Informed consent document(s) 4. Instruments (survey or interview questions) 5. HIPAA form for Retrospective Chart Reviews	
Review	
• Check for completeness, accuracy, and best practices in human subject protections.	

Additional information can be found at rmu.edu/irb.

APPENDIXD

SAMPLE CONSENT FORM (STANDARD)

(This document serves as guidance in the preparation of your Participant Consent form. Your actual consent form may differ depending on the nature of your study]

Robert Morris University Institutional Review Board

Approval Date: (To be filled in by researcher after final IRB approval)
IRB Number: (To be filled in by researcher after final IRB approval)

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: (Insert title)
PRINCIPAL INVESTIGATOR: (Name and contact information)
CO-INVESTIGATORS: (Names and contact information)
FACULTY ADVISOR: (Name and contact information)

1. **Description** -This study is designed to (explain why the research is being conducted, why they are being asked to participate, how long the study will last and the tasks involved).
2. There is minimal risk to you as a participant in this study. However, if you feet uncomfortable, you may withdraw from this (survey, interview, etc,) at any time.
3. There is no direct benefit to you in this study participation. (If it is possible that subjects may benefit directly from study participation, disclose this to the subject).
4. There is no monetary compensation for this study, there is no fee to complete this study.
5. Any information about you obtained in this study will be kept strictly confidential. The data collected will be stored in a (password protected computer) for (3 years) and then safely destroyed. You will not be identified by name in any publication.
6. Your participation is voluntary, you may withdraw from this study at any time by contacting the investigator listed above. Your decision to withdraw from this study will have no effect on your current or future relationship with Robert Morris University.

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 his 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

_____ _____
Researcher's Signature Date

APPENDIX E

SAMPLE CONSENT FORM (FOR ONLINE SURVEY)

Robert Morris University Institutional Review Board

Approval Date: (To be filled in by researcher after final IRB approval)
IRB Number: (To be filled in by researcher after final IRB approval)

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

[This document serves as guidance in the preparation of your Participant Consent form. Your actual consent form may differ depending on the nature of your study]

TITLE OF STUDY:

Dear (Student):

You are being asked to participate in a research study designed to (explain why the research is being conducted and why they are being asked to participate). You will be asked (number) questions and it will take approximately (number) minutes to complete the questionnaire.

Your participation in this study is completely voluntary. There are no foreseeable risks associated in taking this survey. However, if you feel uncomfortable answering any questions, you can withdraw from the survey at any point. There will be no compensation of any kind in exchange for participating in this study. Your survey responses will be strictly confidential and data from this research will be reported only in the aggregate. Your information will be coded and will remain confidential. The information collected will be stored in a password protected computer for 3 years and then safely destroyed.

If you have questions at any time about the survey or the procedures, you may contact (Researcher's name) at (phone) or by email at _____. If you have questions regarding your rights as a human subject research participant, please contact the Robert Morris University Institutional Review Board at 412-397-6227 or irb@rmu.edu.

Thank you very much for your time and support.

By clicking on the "Continue" button below, I am indicating that I understand the nature and purpose of this research and I agree to participate in this study. I understand that I am free to withdraw at any time.

(Researcher's name)

Appendix F

Sam2le Site Permission Letter

This is just a sample. Please adjust your letter accordingly.

PLEASE NOTE that site permission letters must be printed on the site's letterhead, and must include a real signature (cannot be a typed signature). This letter will need uploaded to #8. Researching in an Organization of the IRB application.

Company/Institution Letterhead

Robert Morris University
6001 University Boulevard
Moon Township, PA 15108

Insert Date

Dear Robert Morris University Institutional Review Board:

On behalf of (insert name of site), I am writing to grant permission for (insert name of PI), a (insert description) at Robert Morris University, to conduct her/his research titled, "(insert title of study)". I understand that (insert name of PI) will recruit up to (insert recruitment number) of our clients and conduct interviews at (insert name of site) over the next (insert length of study period). Any data collected will be kept confidential and will be stored on a password protected computer until the end of the study where all information will be safely destroyed.

We are happy to participate in this study and contribute to this important research.

Sincerely,

Signature
Title

Appendix G

IRB CLOSURE REPORT

Upon completion of your study, please complete the following:

Principal Investigator: _____

Email: _____

Project Title: _____

IRB Protocol Number: _____

Date Study Completed: _____

Will the results of your study be published? **Yes**__ _ **No**___ _

Signature of Principal Investigator: _____

Email completed form to: RMU IRB Office, ir.Q..@.r mu.edu.

Questions may be directed to: RMU IRB Office at ir.Q..@.rmu.edu or 412-397-6227.

Upon receipt of this form, the RMU Institutional Review Board will inactivate your study.

Appendix H

Institutional Review Board (IRB) Reliance Agreement

Reviewing Institution: Name of Institution or Organization Providing IRB Review

IRB Registration #:_____ Federalwide Assurance (FWA) #, if any:_____

Relying Institution: Name of Institution Relying on the Designated IRB

The Officials signing below agree that_____ may rely on the designated IRB for review and continuing oversight of its human subject research described below:

This agreement is limited to the following specific protocol(s):

Title of Research Project:_____

Research ID Number: .....

Name of Principal Investigator:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Name of Co-Principal lnvestigator(s):_____

_____

Sponsor or Funding Agency:_____

Award Number, if any: _

The review performed by the designated IRB will meet the human subject protection requirements of applicable regulatory agencies. The Reviewing Institution will follow its internal written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. Relevant documents, including but not limited to IRB minutes, will be made available to the Relying Institution upon request. The Relying Institution remains responsible for ensuring compliance with the Reviewing Institution IRB's determinations and with the Terms of its Office of Human Research Protections (OHRP)-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Reviewing Institution)

_____ Date:_____

Print Full Name:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Institutional Title: _____

Signature of Signatory Official (Relying Institution)

_____ Date:_____

Print Full Name:_____

Institutional Title: _____

Appendix H

Division of Responsibilities

I. Reviewing Institution/lRB agrees that for the research covered by this Agreement it will:

1.1. Provide initial and continuing reviews of submitted research, reviews of amendments; reviews of unanticipated problems that may involve risks to subjects or others; reviews of noncompliance that may represent serious or continuing noncompliance; reviews of local context information provided by Relying Institution; and reviews of other documents, requests, or information related to the approval and continuing oversight of the research, as applicable. The review and oversight of the research by the Reviewing IRB will be performed in accordance with the human subjects protection requirements of the Relying Institution's(s') FWA(s), any applicable federal human subjects research regulations and ethical principles referenced therein and any other applicable federal human subjects research regulations or policies.

1.2. Suspend or terminate approval of all or part of the research that is not being conducted in accordance with the requirements of Reviewing Institution/lRB.

1.3. Notify the Relying Institution in writing of its findings and actions.

1.4. Ensure that an institutional mechanism exists by which complaints about the research can be made by local research participants or others to a contact at the Reviewing Institution/IRB.

1.5. Provide researchers at the Relying Institution the informed consent document to use for the research where the Reviewing Institution/lRB has determined that a consent form is required. The Reviewing lnstitution/IRB will permit a Relying Institution to customize limited site-specific sections of the consent form, generally the sections on the availability of treatment and compensation for research-related injury; payment or reimbursement of research costs incurred by participants; and local contacts. Any such modifications will be subject to approval by the Reviewing Institution/IRB, which will then provide a final approved consent document to the Relying Institution.

1.6. Report determinations of Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval to OHRP, FDA, or any other applicable agency, as required under applicable rules or regulations. Relying Institution shall be provided with a copy of any such report in advance of submission and provided with a reasonable amount of time to review and comment. Reviewing Institution/lRB shall take such comments into consideration in finalizing its report, however, Reviewing Institution/lRB will follow its Standard Operating Procedures regarding content and timing of these reports. Nothing in this section shall preclude the Relying Institution from making its own report to applicable agencies.

1.7. Make available relevant minutes of IRB meetings and other relevant documentation to the Relying Institution upon request.

1.8. Upon request, provide the Relying Institution with a copy of the Reviewing Institution's Human Research Protection Program (HRPP) Standard Operating Procedures.

1.9. When appropriate, conduct on site or remote post-approval monitoring or directed audits.

1.10. Obtain an assurance from Relying Institution of its conflict of interest ("COi")

review of research study personnel at Relying Institution and that a COi determination has been made. Review any research study personnel COi or financial conflict of interest ("FCOI") management plans specific to the research study submitted by the Relying Institution and decide whether the management plan is adequate to address the COi or FCOI identified by Relying Institution to permit the research to continue at the Relying Institution. Convey to Relying Institution any concerns Reviewing Institution may have regarding the management plan and work with Relying Institution to resolve those concerns.

2. **Relying Institution** agrees that for the research covered by this Agreement it will:

2.1. Comply with the terms of this Agreement and the terms of Relying Institution's OHRP approved FWA.

2.2. Cooperate in the Reviewing Institution/IRB's initial and continuing review of the research, including, but not limited to, providing Reviewing Institution/lRB with any non-compliance or protocol deviations or Data Safety Monitoring reports, not otherwise provided to Reviewing Institution/IRB as required under this Agreement and/or Reviewing Institution's HRPP Standard Operating Procedures.

2.3. Ensure compliance of its employees and agents with the Reviewing Institution's HRPP Standard Operating Procedures and determinations regarding the research, including, but not limited to, directives to suspend or terminate designated research activities.

2.4. Not approve research if it has not been approved by the Reviewing Institution/lRB, however, this does not preclude Relying Institution from conducting further review and approval or disapproval of research that has been approved by Reviewing Institution/IRB

2.5. Be responsible for safeguarding the rights and welfare of each research participant in performance of the research and acknowledges that the participant's rights and welfare take precedence over the goals and requirements of the research.

2.6. Provide the Reviewing Institution/lRB with any local context information applicable to the research.

2.7. The PI at the relying institution will oversee the conduct of the study at its institution. This includes but is not limited to:

2.7.1. Monitoring protocol compliance;

2.7.2. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;

2.7.3. Promptly reporting to the Reviewing Institution/IRE any proposed changes in the research and not initiating changes in the research without prior review and approval of Reviewing Institution/IRB, except where necessary to eliminate apparent immediate hazards to the participants;

2.7.4. Enrolling individuals in the research only after Reviewing Institution/IRB review and approval;

2.7.5. Obtaining, documenting, and maintaining records of consent and HIPAA authorization, as applicable, for each participant or each participant's legally authorized representative as stipulated by the

Reviewing Institution/IRB; and

2.7.6. Promptly notifying Reviewing Institution/IRB of new safety information that may represent Unanticipated Problems Involving Risk to Subjects or Others, or Serious or Continuing Noncompliance in accordance with Reviewing Institution's HRPP Standard Operating Procedures

2.8. Assist and cooperate with Reviewing Institution/IRB in the preparation of any report to notify OHRP, FDA, or any other applicable agency of determinations of Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval concerning incidents or safety information related to research at the Relying Institution.

2.9. Cooperate with and provide reasonable assistance to the Reviewing Institution/IRB in conducting directed audits as applicable. Nothing in this Agreement shall preclude Relying Institution from conducting its own post-approval monitoring of the research.

2.10. Obtain disclosures of, and review and manage, in accordance with Relying Institution's conflict of interest policy(s) or as required by the funding or regulatory agency, COi or FCOI determinations for research study personnel involved in the research at the Relying Institution. Provide Reviewing Institution/IRB with an assurance documenting training, review, and determinations for all research study personnel and provide details of any associated management plan specific to the research study. This assurance shall be provided at initial review, annual review and/or at any interim time point determined necessary by the Reviewing Institution/IRR Relying Institution will expect its personnel to submit any changes in financial interests to the appropriate office at Relying Institution within 30 days and will provide updates to Reviewing Institution/lRB regarding any changes to research study personnel COi status as soon as possible thereafter.

2.11. Maintains responsibility for reporting any COi or/ FCOis as required by applicable funding or regulatory agencies.

2.12. Notify the Reviewing Institution/lRB immediately if there is a suspension or restriction of the Relying Institution PI in the conduct of the research.

2.13. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

2.14. Ensure that the relying institution's research personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, having any locally institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subjects protections, and background checks for their assigned role in the research. A relying institution's selection of appropriate education/training requirements and other qualifications for its research personnel is at its discretion. A relying institution shall provide information or documentation regarding its research personnel's education, training, and qualifications in connection with a ceded review as requested by the reviewing IRB.

3. **Both parties** agree to the following general provisions:

Appendix H

3.1. This Agreement will become effective upon full execution by the parties and will remain in effect for as long as IRB review for the above referenced research is required or until the Agreement is terminated pursuant item 3.2 below.

3.2. The Agreement will be terminated in its entirety in the event that:

3.2.1. The Parties mutually agree to termination;

3.2.2. The Reviewing or the Relying Institution terminates its participation under this Agreement upon thirty (30) business days' prior written notice to the other party.

3.2.3. The Reviewing Institution terminates IRB approval for the research.

3.2.4. The Reviewing or the Relying Institution's FWA is suspended, restricted, terminated, or expires; or

3.2.5. The Reviewing IRB fails to remain registered with OHRP.

Upon termination under this Section 3.2, the Parties will work together to determine the effect of such termination on the research and will work together to ensure an orderly transition of the research to another IRB, as applicable.

3.3. Each institution will be responsible for its own negligence in connection with its performance of this Agreement and the research specified in this agreement.

3.4. As permitted by the HIPAA Privacy Rule, Reviewing Institution/lRB shall serve as the privacy board for consideration of a waiver or alteration of authorization. The Reviewing Institution/lRB make no representation about the compatibility of a waiver or alteration of authorization with a Relying Institution's privacy practices, implementation ofHIPAA or obligations under state law. As an alternative, a Relying Institution, with the agreement of the Reviewing Institution/IRB, may retain responsibility for reviewing and approving waivers of or alterations of authorization for research ceded under this Agreement in accordance with the HIPAA Privacy Rule. If a separate HIPAA authorization form will be used for the research, the Relying Institution will ensure the accuracy of the information within the form, the compliance of the form with the HIPAA Privacy Rule and that the form permits PHI to be used by and disclosed to the Reviewing Institution/IRB as necessary for conducting, reviewing and overseeing the research. In the case of a combined consent and HIPAA authorization, the Reviewing Institution/IRB shall be responsible for ensuring that the form complies with applicable requirements in the HIPAA Privacy Rule and the Relying Institution will work with the Reviewing Institution/lRB to provide, as requested, any language specific to the Relying Institution.

3.5. This agreement must be kept on file by both parties and provided to OHRP upon request.

Contact Information

IRB Contact at External Institution:

Name:

_____

Appendix H

Title: _____

Phone: _____

Email: _____

IRB Contact at RMU:

Name: Sushil Acharya

Phone: 412-397-4023

Email: acharya@rmu.edu