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<b>Applicability:</b>	<i>St. Vincent Evansville</i>

## Institutional Review Board

### Policy Statement

St. Vincent Institutional Review IRB (IRB) is responsible for safeguarding the rights and welfare of human subjects involved in research activities. Accordingly, no grant, contract, or personal clinical research involving humans shall be made unless approved by the IRB. The IRB shall determine that the rights and welfare of the subjects are adequately protected; that the risk to the individual is outweighed by the potential benefits or knowledge to be gained; and the informed consent is to be obtained in an appropriate manner. The IRB shall also provide continuing review of all approved activities.

**See Procedure Section: A-H** for specific information for IRB committee members

**See Procedure Section: I-P** for specific information for investigators

**See Procedure Section: Q** for additional information for students

**See Procedure Section: R** for specific information regarding Humanitarian Use Devices (HUD)

### Definitions

- A. Exempt review- Studies that qualify for exempted status from the IRB are studies that do not qualify as research or do not include live human subjects. Exempt status may be placed on research conducted in established or commonly accepted educational settings, involving normal educational practices, test, survey procedures, interview procedures or observation of public behavior unless the data is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk for civil or criminal liability, or be damaging to the subject's financial standing, employability or reputation. Exempt status may be placed on research involving collection of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available and the information is recorded in a manner that the subject cannot be identified, directly or through identifiers linked to the subjects.

Performance improvement (PI) activities qualify for exempt status except in the case where the purpose of the project is to develop generalizable knowledge or establish a clinical practice standard where none exists. An IRB review is required if the PI project applies a new intervention that is beyond current standard practice, randomizes subjects into groups or imposes risks or burdens to patients beyond those associated with standard of practice.

The investigator does not determine exempt status; therefore all projects that meet the criteria for research are submitted to the IRB. A more detailed description of levels of IRB review is provided in the appendices.

- B. Expedited review - This is a quick review (turn around time approximately seven days) when the research involves no more than minimal risk or in the case of minor changes in a prior approved application. The application will be reviewed at the next IRB meeting and the principal investigator will be expected to attend if the expedited review is requested on a new application. Temporary approval is given until the next IRB meeting. A more detailed description of levels of IRB review is provided in the appendices.
- C. Full IRB review-This review applies to all studies not considered exempt or have greater than minimal risks. A more detailed description of levels of IRB review is provided in the appendices.
- D. Adverse event-- involves untoward or unfavorable medical occurrences in human subjects including any abnormal sign, symptom, or disease that may be associated with the subject's participation in the research.
- E. Unanticipated risk- Involve occurrences that are unexpected, related to or possibly related to study activities, and significant enough to suggest that the research may place subjects or others at a greater risk of harm than was previously known or recognized.
- F. Serious adverse event-- is any adverse event that occurs while participating in the study or perceived to be associated with recent participation in the study that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in a persistent or significant disability or incapacity, results in congenital anomaly/birth defect, or based on appropriate medical judgment may jeopardize the subject's health and may require medical or surgical intervention to prevent one of outcomes outlined above.
- G. Informed consent process- the end result of the informed consent process is the signed consent form. The form itself is not the process. No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. In the case of subjects less than 18 years of age, the consent process includes an age appropriate description of the study and the child's assent to participate in addition to the written informed parental consent.. A consent template is provided in the appendices.
- H. Waiver of written informed consent- The IRB may grant a waiver of written informed consent if sufficient evidence is provided by the investigator that clearly shows that the research involves no more than minimal risk to the subjects, will not adversely affect the rights and welfare, cannot be practicably carried out without the waiver, and there is no link directly or through identifiers linked to the subjects. A waiver may be granted if the only link to the research data is the consent document and the only risk is the breach of confidentiality related to the consent document. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
- I. IRB continuation renewal- The IRB must approve continuation of a research study on an annual basis unless the investigator is directed otherwise. The investigator provides sufficient evidence to the IRB regarding subjects recruited, adverse events, benefit/risk ration and changes in informed consent process. A continuation of a previously approved project template is provided in the appendices.
- J. IRB Closure-Once the study is completed, the investigator must close the study and provide the IRB sufficient evidence of subjects recruited, adverse events, benefit/risk ratio, and a document summarizing the

study outcomes. The summary document may be in the form of an abstract or manuscript. PowerPoint slides are not sufficient. A Final Closure template is provided in the appendices.

- K. Key personnel-include all personnel responsible for the research design, collection, and implementation of the study protocol. This includes the Principal Investigator and all Co-Investigators, any persons responsible for subject recruitment or enrollment, any persons who consent patients or provide interventions.
- L. Humanitarian Use Device (HUD)- a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4, 000 individuals in the United States in a calendar year. The FDA authorizes the marketing of HUDs through the issuance of a Humanitarian Device Exemption (HDE). HDEs are intended to encourage the discovery and use of devices intended for the treatment or diagnosis of diseases or conditions that afflict small numbers of individuals who would be left without satisfactory treatment options in the absence of the availability of such devices. HDEs accomplish this goal by allowing device manufacturers to market a HUD in the absence of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. Rather, the manufacturer must only provide information indicating that the device will not expose patients to an unreasonable or significant risk, the probable benefit to health outweighs the risks associated with its use, and there is not comparable device available. See Section R of this document.

## Equipment & Supplies

- A. For a more detailed description of IRB levels of review, see *Levels of Board Review (Appendix A)*.
- B. For new applications, see template: *New Application for Research Study to be conducted with patients of St. Vincent Evansville (Appendix B)*.
- C. For obtaining certification for human subjects' protection, see **Appendix C**.
- D. To create a consent form, see template *St. Vincent Consent Template Form (Appendix D)*.
- E. To obtain 6 month continual renewal, see template, *IRB Initial 6 Month Report, (Appendix E)*.
- F. For continuation renewal, see template: *Application to Continue (Renew) a Previously Approved IRB Project (Appendix F)*.
- G. To report adverse events, see template: *Adverse Event Report (Appendix G)*.
- H. For final closure, see template: *Study Final Closure (Appendix H)*.
- I. To modify an existing approved study, see template: *Application for Revisions of or Changes in research Protocol and/or Informed Consent Form (Appendix I)*.
- J. For the student non-research projects, see template: *Student (non-research) Project Descriptors (Appendix J)*.
- K. For the HUD application and consent template, see **Appendix K**.
- L. All templates are available on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>

## Procedure

- A. IRB committee members
  - 1. St. Vincent Chief Executive Officer (CEO) will designate at least six, but no more than fourteen IRB members. The CEO shall select one Member to serve as Chairman of the IRB. Each member of the IRB shall be appointed for a three (3) year term.
  - 2. The IRB will be composed of members with varying backgrounds and experiences that will enable them to review applications in terms of St. Vincent commitments and regulations, applicable law,

standards of professional maturity, and community attitudes. The members should possess the maturity, experience and expertise necessary to ensure respect for the advice and counsel of the IRB. Both genders shall be represented.

3. The IRB will have at least the following areas being represented: medical staff, administration, nursing, legal counsel, clergy, pharmacy, and community. At least one of the members shall have expertise in a nonscientific area and one shall not be otherwise affiliated with the Medical Center. More than one requirement may be fulfilled by one member.
4. If research involving a category of vulnerable subjects (e.g. prisoners, mentally disabled, employees) is regularly reviewed, the IRB shall include one member whose primary concern is the welfare of these subjects. The IRB may, at its discretion, request assistance from persons with specialized knowledge. These persons may not vote with the IRB.
5. No member shall participate in the review of a proposal in which the member has a conflicting interest. During the review, the member shall recuse him/herself from the review discussion and voting process.
6. Each member of the IRB shall have the right at every meeting to cast one vote. A simple majority of IRB members represented in person shall constitute a quorum of the IRB, inclusive of at least one community member.

#### B. Authority and Responsibility of the IRB

##### 1. Conduct and Frequency of Reviews.

Whenever practical, IRB meetings shall be conducted pursuant to Robert's Rules of Order. Convened IRB meetings shall be held (s) at the call of the Chair as deemed appropriate, or (b) at the call of the Chair upon receipt of a joint written request of three or more members.

##### 2. IRB Review and Approval of Research.

In reviewing proposals, the IRB shall consider the following guidelines:

- a. No person may be obliged to take part in a medical or surgical procedure which s/he judges in conscience to be immoral; nor may St. Vincent or any of its staff be obliged to provide a medical or surgical procedure which violates their conscience or the Ethical or Religious Directive for Catholic Health Facilities.
- b. Any procedure potentially harmful to the patient is morally justified only insofar as it is designed to produce a proportionate good. Ordinarily, the proportionate good that justifies a medical or surgical procedure should be the total good to the patient himself.
- c. Unnecessary procedures, whether diagnostic or therapeutic, are morally objectionable. A procedure is unnecessary when no proportionate reason justifies it. Any procedure that is contraindicated by sound medical standards is unnecessary.
- d. Each person has the right and the duty to protect the integrity of his/her body with all of its bodily functions.

In order to approve research covered by these regulations, the IRB shall determine that all of the following requirements are satisfied:

- e. Risks to subjects are minimized:
  1. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  2. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- f. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonable be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits the may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
  - g. Selection of subjects is equitable. In making this assessment the IRB should take account the purposes of the research and the setting in which the research will be conducted.
  - h. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. In the case that the subject is a child less than 18 years of age, a separate assent form, written in age appropriate language is included along with the written informed consent of the child's legally authorized representative.
  - i. Informed consent will be appropriately documented, in accordance with, and to the extent required by IRB policy.
  - j. Where appropriate the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
  - k. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
3. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.
  4. IRB procedures for review of research applications:
    - a. Investigator submits proposal to the IRB Administrative Assistant by the deadlines set forth. The application should be complete and a clean copy of the consent (for a stamped approved version) should be submitted.
    - b. Proposal is reviewed by Chair and the IRB analyst/liaison for completeness. If complete, the proposal is placed on the agenda for the next meeting.
    - c. Each IRB member receives notification of review, review deadline, and access to the online IRB server.
    - d. The IRB meeting must consist of a quorum that includes at least one community member.
    - e. The investigator presents a short (5 minute) overview of the study at the IRB meeting and will respond to questions/concerns of the IRB.
    - f. After the investigator leaves, the IRB votes on application, outlines any provisos.
    - g. The investigator will be notified of the IRB decision/provisos, supplied with a start date and a copy of the approved (stamped) informed consent.
  5. Documentation of Informed Consent

The IRB shall require written documentation of informed consent from all subjects of any research proposal unless the IRB has granted the waiver of written informed consent. The IRB may observe, or have a third party observe, the informed consent process or the research.

#### 6. Waiver or Alteration of Written Informed Consent

The IRB may waive the requirement of written informed consent, and may substitute a written statement regarding the research, if it finds:

- a. The consent form will be the only record linking the subject and the research, and principal risk is the harm to the subject resulting from a breach of confidentiality, in which case, the wishes of the individual subject shall govern, or;
- b. The research presents no more than minimal risk and involves no procedures for which written consent is normally required.

The IRB may waive requirement of consent or may approve a consent procedure if it finds:

- c. The research is to be conducted to demonstrate or evaluate:
  1. Federal, state or local benefits or service programs which are not themselves research programs;
  2. Procedures for obtaining benefits or services under these programs; or
  3. Possible changes in or alterations to these programs and the research cannot be carried out practicably without the waiver or alteration; or
  4. The research involves no more than minimal risk to the subjects;
  5. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  6. The research cannot be carried out practicably without the waiver or alteration; and
  7. When appropriate, the subjects will be provided pertinent information after participation.

#### 7. Information Dissemination and Reporting Requirements

- a. The following are promptly reported to the IRB for review. The principal investigator is also required to report to the appropriate research sponsors or federal agencies including the Food and Drug Administration, the Directors of St. Vincent Evansville, or the appropriate representative:
  1. Any serious or non adherence with IRB requirements;
  2. Any information concerning injuries to subjects;
  3. Any information concerning problems to subjects or others;
  4. Any information considered to be an adverse event or serious adverse event.

#### 8. Supervision of Active Protocols

- a. For newly approved studies, progress reports are required at six (6) months after initial study approval and every twelve (12) months for approval of continuance of the study. The IRB reserves the right to increase frequency of progress reports if deemed necessary depending on the nature of the study, the degree of risk involved, and the vulnerability of the study subject population.
- b. For example, the IRB may consider increasing frequency for reporting for studies that may involve implantation of device, increased risks of infection, and/or patient population more susceptible to complications. Under any of these circumstances, the IRB will require more frequent progress reports and reviews of research study on a six (6) month basis; and if felt risks are even greater, may require review every three (3) months.
- c. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements; that has been associated with unexpected serious harm to subjects, or when scientific merit does not warrant continued investigation. Any suspension or termination of approval shall include a statement of the reasons

- for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the granting agency.
- d. The IRB may require verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
  - e. The IRB shall develop and maintain a system for determining the status of approved studies and for assuring that on-going studies are reviewed within the time intervals set by the IRB at the time of initial review and approval.
9. Since it is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug or device development, the IRB shall review both the amount of payment and the proposed method of disbursement to assure that neither present problems of coercion or undue influence. All information concerning payment, including the amount and schedule of payment, should be set forth in the informed consent form.
10. If advertising is used to recruit subjects, the IRB shall review such ads and determine whether the information is misleading to subjects, especially when a study will involve persons with acute or severe physical or mental illness or persons who are economically or educationally disadvantaged. The IRB shall be responsible for assuring that appropriate safeguards exist to protect the right and welfare of research subjects recruited through the use of advertising.

#### C. Appeals Procedure

1. Any person aggrieved by a decision of the IRB may request that the IRB reconsider its decisions. A request for such reconsideration is submitted in writing and must be received by the Chairman of the IRB by the close of business on the fifth (5<sup>th</sup>) working day after notification of the IRB's initial decision.
2. The aggrieved person shall include with such request for review a statement of his or her position, with copies of any supporting documents or new information for the IRB's consideration. Failure to submit a request for reconsideration as herein provided shall be deemed a waiver of the aggrieved party's right to request the same. If a request for reconsideration is made and heard by the IRB, the IRB's decision thereon shall be final and binding on all parties.

#### D. Emergency Use of Investigational Drugs, Devices, and Procedures

1. When a principal investigator is considering emergency use of an investigational drug, device, and/or procedure, a written informed consent and explanatory letter are submitted to the IRB. The IRB will review within five (5) working days. The chair, if any IRB member has concerns, will call an emergency meeting.
2. The following is considered by the IRB before approval:
  - a. There is no other reasonable protocol– or FDA-approved alternative therapy;
  - b. The patient is in a life-threatening situation;
3. The following is expected of the principal investigator if approval is obtained for emergency use of an investigational drug, device, and/or procedure:
  - a. The informed consent process is completed;
  - b. A report of the outcomes of the therapy is sent to the IRB;
  - c. Subsequent use of the therapy is subject to IRB review.

#### E. Levels of IRB review

1. Three levels of IRB review are possible. This includes exempt, expedited, and full. The criteria are described in **Appendix A** but are briefly outlined here:

- a. Exempt- Applications may be exempted from IRB oversight if
  1. The activity does not constitute research
  2. The activity does not include human subjects
  3. The activity qualifies as existing records, survey research and both without risk
- b. Expedited- Application may have expedited review if
  1. The research involves no more than minimal risk
  2. The proposal involves only minor changes in previously approved research.
- c. Full- All applications are reviewed by the IRB if more than minimal risk exists, or has previously obtained an expedited review.

F. IRB Records and Reports

1. The IRB shall prepare and maintain adequate documentation of IRB activities. This includes:
  - a. Copies of all research protocols;
  - b. Copies of all renewals and any progress reports;
  - c. Minutes of IRB meetings in sufficient detail to describe actions, supporting evidence, and resolution of controversial issues. All recused members shall be noted that they did not participate in review or voting;
  - d. Copies of all correspondence;
  - e. A list of IRB members and representative capacity;
  - f. A list of all IRB procedures and policies;
  - g. Statement of significant new finding provided to subjects as required by law;
  - h. All such records are to be maintained for at least three (3) years following the completion of approved clinical research.

G. The IRB shall report to the appropriate research sponsors or federal agencies, St. Mary's IRB of Directors any serious or continuing noncompliance with requirements, injuries to subjects or actions deemed as a problem for subjects or others.

H. If the IRB suspends or terminates approval of a research protocol, it shall include a statement of the reasons for its actions and shall report the action promptly to the appropriate research sponsors or federal agencies, the Directors of St. Vincent Evansville, and/or the appropriate departmental representative.

I. IRB procedure-for Investigators

1. All persons wishing to conduct research must submit an application to the IRB by the deadlines set forth by the Administrative Assistant to the IRB. All continuation renewals and final closure documents must be submitted to the Administrative Assistant by the deadlines set. Documents received are placed on the agenda for the next IRB meeting. IRB meetings are held quarterly in the Administrative IRB Room at 7:00 am. Unless otherwise noted, meetings are on the second Friday of March, June, Sept, and December.
  - a. Principal investigators of new applications are expected to be present to give a 5 minute overview of the study design, data to be collected, and process for protection of human subjects.
  - b. Students who submit research projects are asked to be accompanied by university adviser or designee.



2. Physicians submitting new research projects to the IRB are to use the template *New Application for Research Study to be conducted with patients of St. Vincent* provided in **Appendix B** or if participating in a multi-center study, submit the IRB application from the study's principal investigator, template *New Application for Research Study to be conducted with patients of St. Vincent Evansville* in **Appendix B**.
3. All allied healthcare professionals are required to submit research projects to the IRB using the
4. All key personnel in research studies must require proof of completion of a human subjects' protection course. **Appendix C** has specific requirements for obtaining this certification.

J. Information to be submitted to the IRB for new applications

1. The completed *New Application for Research Study* outlining the study purpose, procedures, and protection of human subjects. This shall be referred to as the project descriptor;
2. Copies of all instruments;
3. Copies of all intended recruitment material;
4. Two copies of the written informed consent;
5. Copies of completion of a human subjects protection course;
6. Any other pertinent information;
7. If the investigator has applied for external funding a copy of the grant application shall be included.

K. Written informed consent

Consent to participate in human subject research is a process that must be clearly identified in the project descriptor as the investigator's duty is to protect the rights and welfare of the subject volunteering to participate. The person collecting the consent, his/her capability of completing the informed consent process, the manner, place, and time where the consent process is completed must all be addressed in the project descriptor. The investigator must clearly show that the informed consent process is duly completed and that the subject has voluntarily consented to the study. In the case that the subject is a child less than 18 years of age, a separate assent form, written in age appropriate language is included along with the written informed consent of the child's legally authorized representative. If a subject chooses to withdraw from the study, the procedures to do so and what will be done with his/her information to date must be clearly explicated. The consent template is available in **Appendix D**.

L. Emergency Use of Investigational Drugs, Devices, and Procedures

1. Should the emergency use of an investigation drug, device, or procedure is deemed necessary, it is the principal investigator's responsibility to obtain approval for said drug, device, or procedure.
2. A letter to the Chair of the IRB requesting approval, the reasons for the therapy, how consent will be obtained and by whom, and expected cost to patient and organizational.
3. The Chair will notify the IRB members and request an emergency review of the request.
4. Unless impending death is expected, the IRB will provide the decision within five working days.
5. The investigator is expected to present outcomes of the therapy according to the time limits set forth by the IRB.
6. Subsequent use of treatment will require approval from the IRB.

M. Levels of IRB review for Investigators

1. Three levels of IRB review are possible. This includes exempt, expedited, and full. The criteria are described in **Appendix A** but are briefly outlined here:

- a. Exempt- Applications may be exempted from IRB oversight if:
  1. The activity does not constitute research;
  2. The activity does not include human subjects;
  3. The activity qualifies as existing records, survey research and both without risk;
  4. It is the purview of the IRB to determine if an application is exempted from review. A full IRB application is required;
  5. No study can be initiated before approval is awarded.
- b. Expedited- Application may have expedited review if:
  1. The research involves no more than minimal risk;
  2. The proposal involves only minor changes in previously approved research;
  3. It is the responsibility of the investigator to outline in the application the risks, benefits, and risk/benefit ratio so that IRB can deem application an expedited review;
  4. An investigator may request an expedited review between full IRB meetings and may be granted temporary approval so that the study may be started;
  5. The investigator is required to attend the next full IRB meeting to present a 5 minute overview of the study design, data to be collected, and process for protection of human subjects;
  6. No study can be initiated before approval is awarded;
  7. The date on the letter of approval is the official start date of the study.
- c. Full- All applications are reviewed by the IRB if more than minimal risk exists, or has previously obtained an expedited review.
  1. A complete IRB application is required;
  2. It is the responsibility of the investigator to outline in the application the purpose, how the sample will be obtained, all measures to protect subjects and data, risks and benefits to the subject and society as well as the risk/benefit ratio;
  3. The investigator is required to attend the full IRB meeting to present a 5 minute overview of the study design, data to be collected, and process for protection of human subjects;
  4. No study can be initiated before approval is awarded;
  5. The date on the letter of approval is the official start date of the study.

#### N. Reports to the IRB-for Investigators

1. During the first year of the study, unless directed otherwise by the IRB, the investigator will submit a 6-month continuation report.
2. Annually, unless directed otherwise by the IRB, the investigator will submit a yearly continuation report. No study may continue unless the IRB grants continuing approval. The reports to the IRB include:
  - a. Six month continue renewal. Use the *Application to Continue (Renew) a Previously Approved IRB Project* template in **Appendix E**. A template is available on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>
  - b. Annual continue renewal. Use the IRB Continue Renewal template available on the intranet (**Appendix F**) <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>. For investigators in multi-center studies that submit annual continuation forms to other IRBs may submit those forms as long as the appropriate information is included.

- c. Unanticipated events- any medical occurrence whose nature, severity or frequency is not consistent with existing information regarding the risk profile of the study procedure. Report within 5 working days. Use Adverse Event Report form shown in **Appendix G**. This template is also available on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>. For investigators in multi-center studies that submit unanticipated events to other IRBs may submit those forms as long as the appropriate information is included.
  - d. Serious adverse events- an event that is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in a persistent or significant disability or incapacity; results in congenital anomaly/birth defect or based on appropriate medical judgment may jeopardize the subject's health and may require medical or surgical intervention. Death is a serious adverse event. Report within 24 hours. Use Adverse Event Report form (**Appendix G**). A template is also located on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>. For investigators in multi-center studies that submit serious adverse events forms to other IRBs may submit those forms as long as the appropriate information is included.
  - e. Final study closure. Once approved study is completed, the investigator submits a final report. Included with Final Closure Report is an overview of the study findings. The study findings can be described in a one page document, an abstract submitted for a research presentation, or a manuscript submitted for publication that explains study and findings. In whatever manner, it is the responsibility of the investigator to provide a summary document for IRB review summarizing study findings. Use the Final Closure form shown in **Appendix H**. A template is also located on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>. For investigators in multi-center studies that submit closure forms to other IRBs may submit those forms as long as the appropriate information is included.
- O. No changes to the research study protocol, consent process, recruitment, advertising or addition of key personnel may be done unless approved by the IRB. Before a modification can be put into practice, the investigator will submit for review the proposed changes. The changes must be clearly shown on the current approved protocol indicating the changes requested along with completion of the *Application for Revisions of or Changes in Research Protocol* shown in **Appendix I**. A template is also located on the intranet: <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>. For investigators in multi-center studies that submit changes to the study protocol to other IRBs may submit those forms as long as the appropriate information is included.
- P. Appeals Procedure for Investigators
1. If the IRB suspends or terminates approval of a research protocol, it shall include a statement of the reasons for its actions and shall report the action promptly to the appropriate research sponsors or federal agencies, and the Directors of St. Vincent Evansville, or the appropriate departmental representative.
  2. A request for a review of the decision must be submitted in writing and must be received by the Chairman of the IRB by the close of business on the fifth (5<sup>th</sup>) working day after notification of the IRB's initial decision.
  3. The aggrieved person shall include with the request for review a statement of his or her position, with copies of any supporting documents or new information for the IRB's consideration. Failure to submit a request for reconsideration as herein provided shall be deemed a waiver of the aggrieved party's right to request the same. If a request for reconsideration is made and heard by the IRB, the IRB's decision thereon shall be final and binding on all parties.

- Q. Student projects whether they include human subjects or not, considered research or not are required to be reviewed and approved by the IRB prior to the student embarking on the project. The IRB approval from the student's university must be included in the IRB application along with certificate of human subject protection course. Complete the *New Application for Research study to be conducted with patients at St. Vincent Evansville* (Appendix B) for projects that meet the requirements for research. See **Appendix J** for the application template for projects that do not meet the criteria for research.
- R. For providers wishing to employ a HUD, complete the face page and application found in **Appendix K**. St. Vincent Evansville IRB will require an informed consent and a clear description on the procedure for the informed consent process

## References

- A. 21CFR 56 Institutional Review IRBs
- B. 21CFR 50 Informed Consent
- C. 21CFR 312 Investigational New Drug Application
- D. HIPAA Privacy Standards Manual Section 7.9: HIPAA Privacy B Uses and Disclosures for Which Consent, and authorization or opportunity to agree or object is not required; 45 CFR 164.512 (l).
- E. <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm110194.htm>

## Appendix A Levels of IRB Review

### I. Exempt Review.

Some research activities involving little or no risk to human subjects may qualify for exempt status under federal regulations for the protection of human subjects. Federal guidelines require that an institutional officer other than the investigator determine the eligibility of studies for exempt status.

#### A. Activities that qualify for exempt status:

1. Activity does not constitute research: According to 45CFR46.102(d), *research* is defined as "a systematic investigation...designed to develop or contribute to generalizable knowledge". Systematic investigation used for internal program evaluation or quality assurance does not constitute "research" under this definition, because it is intended only to evaluate a particular program.
2. Activity does not involve human subjects: Investigations may constitute research, but qualify for exemption because they fail to involve human subjects as defined in the federal regulations at 45CFR46.102(f). This section defines a *human subject* as a "living individual about whom data are gathered for research purposes". Research involving dead individuals is exempt from IRB oversight. The definition of human subject does not apply when data does not contain "private identifiable information" or individual identity of persons cannot be "readily ascertained" by the investigator. Although there is some confusion about the meaning of "readily ascertained", it is generally agreed that it applies to data that comes to the investigator in genuinely anonymous form, i.e., when no remaining linkage can be made between the data and the individual identity of the persons whose data is used.
3. Activity qualifies as existing records, survey research without risk: Under section 45CFR46.101(b) of the federal regulations, studies using existing records, data or specimens where data used are already in existence at the time that the study is initiated. In addition, the information collected must

be "recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects". According to this regulation, records research is exempt provided that the investigator records the data on worksheets in such a fashion that the information can no longer be linked to identifiable individuals, even if the records form which the information is drawn contain individual subject identifiers.

4. Another category of exempt research frequently undertaken involves interview or survey procedures. The federal regulations exempt such studies unless they involve recording the individual identity of subjects **and** the information gathered might, if publicly disclosed, place subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Even if the subjects' names were collected on the survey instrument, the study would remain exempt if nothing disclosed in the answers would place them at risk of harm.

## II. Expedited Review.

### A. Expedited review is permitted when:

1. The research involves no more than minimal risk and appears on the list of categories of research eligible for expedited review.
2. The proposal involves only minor changes in previously approved research.  
Expedited review will be conducted by the IRB Chair or, in his/her absence, a designee. Upon issuance of an approval by the Chair or designees, the project may be initiated; however, the protocol must be reviewed by the full IRB at its next regularly scheduled meeting. In the event the IRB requires modification or revision in a protocol at that time, the approval will be rescinded temporarily and the investigator shall cease to work on that portion of the project involving him and subjects. The approval may be reinstated upon the investigator's satisfactory compliance with IRB's modification requests. Expedited review procedures may not be used to disapprove the proposed research. A research activity may be disapproved only after a non-expedited review.

### B. Categories eligible for expedited review include:

1. Collection of hair and nail clippings in a non-disfiguring manner, deciduous teeth or permanent teeth.
2. Collection of excreta and internal secretions, including sweat, saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects, eighteen (18) years of age or older, using non-invasive procedures routinely employed in clinical practice; including the use of Physical sensors applied to the body that do not involve the input of matter or significant amounts of energy or invasion of the subject's privacy, weighing, testing sensory acuity, electrocardiography, electroencephalography, detection of naturally occurring radioactivity, diagnostic echography and electroretinography; but does not include exposure to MRI and x-rays.
4. Collection of blood samples by venipuncture in amounts not exceeding 450 ml in an eight (8) week period and no more than two (2) times per week from subjects eighteen (18) years of age or older who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque and calculus.
6. Voice recordings made for research purposes.
7. Moderate exercise by healthy volunteers.
8. A study of existing data, documents, records, pathologic specimens or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, gain theory or test development where the investigator does not manipulate the subject's behavior and the research will not involve stress to the subjects.
10. Research on drugs or devices for which an investigational new drug exemption or investigational device exemption is not required.

## Appendix B

### New Application for Research Study to be conducted with patients of St. Vincent Evansville

#### Application and Instructions for Completion of Project Descriptors

All research studies that involve human subjects and/or tissue for investigative purposes must be reviewed and approved by St. Vincent Evansville Institutional Review IRB (IRB). This document guides researchers through the application process.

This new application form must be completed for all applications qualifying for proposed research IRB review. Submissions to the IRB must contain all required materials. Incomplete submissions will be returned to the investigator without IRB review.

#### A complete submission must contain the following:

- I. Face Sheet with all signatures;
- II. IRB New Application (Project Descriptors);
- III. Informed Consent (2 copies. One for review and one for approval stamp) A proposed consent form containing all elements of informed consent, genetic consent, and/or repository consent, if applicable, (see the consent form templates in **Appendix D** of the Institutional Review IRB policy # 160812);
- IV. Formal Research Protocol; either prepared by the investigator or research sponsor, if applicable
- V. Any investigator brochures for studies of investigational drugs or devices
- VI. Investigational New Drug (IND) or Investigational Device Exemption (IDE): Completion of this field on the face/route sheet is required on all IND or IDE studies. If not applicable, provide a letter from yourself, if investigator initiated, or the sponsor, addressing why an IND or IDE is not required (indicating the applicable regulatory citation) for the drug(s) or device in question and this letter must accompany the IRB application.
- VII. Package inserts for study drug or medical, dental or physical therapy devices.
- VIII. If the research is being conducted under a grant, a complete copy of the grant application to federal or non-profit organizations.
- IX. Copies of all questionnaires, surveys, forms that will be used to collect data.
- X. Include a copy of the proposed advertisement for recruitment.
- XI. If the Principal Investigator (PI) is a student or non-medical staff member, a letter of support from a faculty member or medical staff that will be involved in the study must be submitted. This letter contains the stated responsibilities of the student or non faculty member as well as the stated responsibilities of the sponsoring faculty or medical staff member (This is in addition to the cover letter).
- XII. All key personnel for the study are required to provide proof of completion of a "Human Subjects Certification Course." **Appendix C** of the Institutional Review IRB policy # 160812 has specific requirements for obtaining this certification.
- XIII. All items are to be sent electronically to the IRB office. Please do not send multiple electronic files unless you have indicated in the document file name the order in which the files should be compiled. If at all

possible make the IRB application one continuous file. In this way, the IRB will be able to clearly follow your application. Start the name of each document with the number of the file, name of document, and last name of PI (i.e. 1Face Sheet\_Smith; 2ProjectDescriptor\_Smith; 3Appendix1\_Smith;). Do not submit in partial electronic and partial hard copies. Send electronic copies to [shawes@stmarys.org](mailto:shawes@stmarys.org). If you are unable to submit file electronically, contact the IRB administrative assistant [shawes@stmarys.org](mailto:shawes@stmarys.org)

**Instructions for preparation of the New Application, referred to as the "Project Descriptors":**

1. Each item must be titled as described below and addressed succinctly in the listed sequence.
2. If any item is not applicable, this should be so stated.
3. Attachment of applicable sections of the research protocol and/or grant application is **not** acceptable as a substitute for completion of each item. Please include sufficient information to facilitate an efficient IRB review.
4. Provide a cover letter to the IRB Chair stating the name of your study and that you will attend the IRB meeting to give a brief overview and answer questions/concerns. An example of a cover letter can be found on the intranet <http://intranet.stmarys.org/body.cfm?id=794&oTopID=0>
5. The face page should be completed and is the first page of your project descriptors.
6. Insert a brief title, principal investigator first initial and last name in the header of the subsequent project descriptor pages. Place preparation date in the footer of the Project Descriptors.
7. Insert page numbers.
8. Be sure that appendices are appropriately labeled and in the order in which they are cited in text.
9. Appropriate use of citations and reference list should be included.

Please see the attached file.

## **St. Vincent Evansville Project Descriptors for New Application**

**I. PURPOSE OF THE STUDY.**

- A. State concisely and realistically what the research project is intended to accomplish.

**II. BACKGROUND AND CURRENT STATUS OF WORK IN FIELD.**

- A. This section must provide a justification and rationale for conducting the study.
- B. For studies involving drugs or devices, in all cases, provide the regulatory status of the test article. For example, are the drugs or devices Federal Drug Agency (FDA) approved and if so for what indications. Especially indicate if the test articles are approved in children.

**III. METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS**

- A. Describe the study design (e.g., randomized, blinded, placebo controlled, etc.) and all procedures (sequentially) to be applied to subjects. For studies that include multiple study visits, list in chronological order, using bullet points, what will be done at each visit and what length of time will be required for each visit.
- B. Clearly indicate which procedures and/or treatments are being performed solely for purposes of the research study, and which procedures and/or treatments would be performed even if the subjects were not participating in the research study. If a blood draw is included in the study, indicate the amount of blood that will be drawn each time and during the entire study.

#### IV. CHARACTERISTICS OF SUBJECT POPULATION.

- A. Describe the characteristics of the subject population.
- B. Include the anticipated number of subjects to be studied (locally and in aggregate for multi-center studies), age ranges, sex, race, and health status.
- C. Identify the criteria for inclusion and exclusion.
- D. Justify the utilization of any special classes of subjects such as pregnant women, fetuses, children, mentally disabled, prisoners or others who are likely to be vulnerable.
- E. Estimate the time required to complete the entire study.
- F. Explain how the recruitment of subjects is intended to satisfy National Institutes of Health (NIH) or FDA requirements for the inclusion of women, racial/ethnic groups and children in human subjects' research. This item **MUST** be addressed. These policies may be found at:
  1. **NIH Guidelines on the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects:**  
[http://grants1.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants1.nih.gov/grants/funding/women_min/women_min.htm)
  2. **FDA Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs:**  
<http://www.fda.gov/cder/audiences/women/default.htm#gender>
  3. **NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects:**  
<http://grants1.nih.gov/grants/funding/children/children.htm>

#### V. METHOD OF SUBJECT SELECTION.

- A. Describe the method(s) to be employed in the identification/recruitment of potential subjects and **attach** any proposed advertising copies (posters, news ads, etc.). If advertising materials will be developed later, this will require completion and submission of an amendment to the IRB application.
- B. If applicable, indicate that you will be recruiting subjects from the St. Vincent Evansville staff and employees. Include a statement that the decision to participate or to continue participation in a study will not affect employment status.

#### VI. STUDY SITE.

- A. State the location(s) where the study will be conducted.

#### VII. POTENTIAL RISKS TO THE SUBJECT.

- A. Describe all potential risks and discomforts associated with each procedure. These include physical, psychological, social, legal and other risks and discomforts associated with the procedure.
- B. Assess the probability, magnitude (severity), potential duration and reversibility of each risk.
- C. The probability of risk of harm should be described quantitatively with percentages (if available). Otherwise, qualitative assessment is acceptable using terms such as "very rarely", "frequently", "usually", etc.
- D. Primary attention should focus on risks (particularly side effects) associated with the research intervention, research article or other procedures that are being performed solely for purposes of the research study.
- E. Identify those risks which are minimal and those which are more than minimal.
- F. If there are no risks or discomforts associated with the research procedures, then this should be stated.



## VIII. PROTECTION AGAINST RISKS.

- A. Describe the procedures utilized to prevent/minimize potential risks.
- B. Describe the criteria for removal of subjects from the research.
- C. Provide a description of the data and safety monitoring plan for this project. The National Institutes of Health has issued policies on data and safety monitoring of all intervention studies. The policies require oversight and monitoring of all intervention studies to ensure the safety of participants and the validity and integrity of the data. These policies may be found at:
  1. **NIH Policy for Data and Safety Monitoring:**  
<http://grants1.nih.gov/grants/guide/notice-files/not98-084.html>
  2. **NIH Further Guidance on a Data and Safety Monitoring for Phase I and Phase II Trials:**  
<http://grants1.nih.gov/grants/guide/notice-files/not-OD-00-038.html>
- D. Indicate if there will or will not be a Data and Safety Monitoring IRB (or equivalent) associated with the project.

## IX. POTENTIAL BENEFITS TO THE SUBJECT.

- A. Describe the potential benefits that may accrue directly **to the subject** as a result of participation in the research. The description of potential benefits to the subjects should not include benefits that the subjects might realize from procedures that they would undergo even if they were not participating in the research.
- B. Indicate the probability, magnitude, and duration of these potential benefits.
- C. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.
- D. Do not list payment or free services as potential benefits to the subjects.

## X. POTENTIAL BENEFITS TO SOCIETY.

- A. Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.

## XI. RISK/BENEFIT ASSESSMENT.

- A. The risk/benefit assessment should be made separately for therapeutic and non-therapeutic procedures used in the study.
- B. Acceptability of the risk/benefit ratio for therapeutic procedures used in the research study requires satisfaction of two conditions. First, the risk to individual subjects must be outweighed by the potential benefits. Second, the risk/benefit ratio of the procedures used must not be known to be significantly less favorable than any alternative interventions available to subjects, including those available outside the research context. The risk/benefit assessment should address each of these points.
- C. For randomized clinical studies, satisfaction of the second condition requires that it not be known beforehand that one of the therapies being compared has a significantly less favorable risk/benefit ratio than other therapies used in the study or alternative therapies available in the non-research studies. That is, it must not be known that receiving placebo has a significantly less favorable risk/benefit ratio than receiving therapy used in the research study or a treatment available in the non-research setting. The risk/benefit assessment should carefully explain how this criterion is satisfied by the study, based on what is currently known about available treatments.

- D. For any non-therapeutic procedures used in the study, it must be explained why the risk of the non-therapeutic procedures is sufficiently low to be outweighed by the potential benefits to society of the knowledge to be gained in the study.

XII. ALTERNATIVES TO PARTICIPATION.

- A. For studies evaluating therapeutic interventions, describe any therapeutic alternatives available to the subjects outside the research setting.
- B. Indicate whether subjects may undergo study intervention(s) without participating in the research study. If the therapeutic interventions are being added to standard care, indicate that subjects will receive standard care whether or not they participate in the study.
- C. If study interventions are non-therapeutic in nature, indicate that subjects will not have to undergo these procedures if they do not participate in the study.

XIII. CONFIDENTIALITY.

- A. Explain how individual identifiers will be used in maintaining the research records. For example, indicate whether records will be labeled with the subject's name, or whether they will be labeled with a code number, with a master key that links name and code number maintained in a separate and secure location.
- B. Indicate that the HIPAA authorization will be included in the confidentiality section of the consent form.
- C. If the study involves the use of a federal Certificate of Confidentiality, this should be indicated.
- D. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's **medical** record (as contrasted with the **research** record), then this should be explained.
- E. State that individual subjects will not be identified in any presentation or publications based on the results of the research study.

XIV. PAYMENT FOR PARTICIPATION.

- A. Describe any economic incentives or other rewards for participation and any prerequisite condition that must be fulfilled by subjects in order to receive compensation, including prorated payments for partial participation, if applicable.

XV. FINANCIAL OBLIGATIONS.

- A. Describe any costs to the subject as a result of the research procedures that exceed what would be incurred with standard treatment (e.g., additional diagnostic tests, additional hospitalization, drugs, devices, etc.)
- B. State if the study medication will be provided free of charge.

XVI. RESEARCH INJURIES.

- A. Describe the procedure for treatment of any research-associated injury both in regard to the plan for medical care and responsibilities for payment of costs associated with the delivery of the care for such injuries. Specifically, describe the extent to which the sponsor of the research will be responsible for the costs associated with research related injuries.
- B. If it is the case, indicate that the subject and/or the subject's insurer will be billed for the costs associated with the medical care of a research-related injury.

XVII. FINANCIAL CONFLICT OF INTERESTS.

- A. Report specific outside activities that may or may not represent conflicts of interests.

- B. Explain whether any key research personnel have a reportable economic interest in any outside entity, or act as officers, directors, employees or consultants for such an entity, whose financial interests may be affected by the research study. If so, describe in detail the nature of the interest or involvement in the outside entity. Key research personnel include the principal investigator, co-investigators, research coordinators, and any persons involved in securing the informed consent of prospective subjects.
- C. For any key research personnel who have reportable financial interests or involvement as described above, explain whether these interests can be managed without constituting a prohibited conflict of interests that affects the design, conduct, or reporting of the research study.
- D. Explain whether reportable financial interests or involvement as described above will be disclosed to prospective subjects in the informed consent process.

#### XVIII. INFORMED CONSENT

- A. Describe the circumstances under which informed consent will be obtained, the process, and who will seek consent.
- B. List the names of all individuals who will be participating in the research project and include their date of completion of a course on human subject protection in biomedical research. Separately list the names of those individuals who will participate in the informed consent process including the informed consent interview and documentation of informed consent and their relationship to the study.
- C. If minors will be utilized as subjects, the process of assent (when appropriate) should be described. Include the statement, "Assent will be obtained from all subjects capable of assent, with complexity of the disclosure geared to their ability to understand the information. The objection of any subject in word or action to the performance of study procedures will be sufficient for their withdrawal or exclusion from the study."
- D. If applicable to the study, the use of legally authorized representative must be described.
- E. Requests for **waiver or alteration of the informed consent procedure** or for **waiver of documentation of informed consent** will be reviewed in accordance with federal regulations. If a waiver or alteration of informed consent is requested, please document within this section how your study meets the guidelines for waiver of written informed consent.
  - 1. The consent form will be the only record linking the subject and the research, and principal risk is the harm to the subject resulting from a breach of confidentiality, in which case, the wishes of the individual subject shall govern, or;
  - 2. The research presents no more than minimal risk and involves no procedures for which written consent is normally required.
  - 3. If the study evaluates a federal, state or local benefits or service programs which are not themselves research programs or;
  - 4. Procedure for obtaining benefits or services under these programs or;
  - 5. Possible changes in or alterations to these programs and the research cannot be carried out practicably without the waiver or alteration or;
  - 6. The research involves no more than minimal risk to the subjects;
  - 7. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - 8. The research cannot be carried out practicably without the waiver or alteration and;
  - 9. When appropriate, the subjects will be provided pertinent information after participation.

- F. Special considerations for informed consent are required for research involving genetic analysis and for the collection of human biological materials for research repositories. These special requirements are listed with the repository and genetic consent form examples.

XIX. MEDICAL DEVICE RESEARCH.

- A. Provide IDE number, investigator's brochure, package inserts and manufacturers instructions, where applicable.
- B. For clinical investigations of **devices (medical, dental, physical therapy)** the application must be **accompanied by a letter from the sponsor** which addresses the regulatory status of the medical device in question. This letter must address at least the following information applicable to the medical device being studied.
1. Has a pre-market notification been submitted to the FDA?
  2. Has the device been determined by the FDA to be a "510(k)" device? Or does the sponsor anticipate that the FDA will issue such a determination?
  3. Does the sponsor consider that the clinical investigation of the device may be exempt from IDE regulations [21 CFR 812.2(c)]?
  4. If the clinical investigation is for a **marketed** device, did the device receive pre-market approval as a 520(k) device or through the IDE process? If so, provide the appropriate regulatory references.
  5. If the clinical investigation is for a **marketed** device, will the results of the study be submitted to the FDA in support of additional indications and/or labeling changes?
  6. Does the sponsor of this investigation consider the device to be "significant risk" or assessment and the rationale used in making the risk determination. The sponsor should also provide information in regard to the determinations made by other IRB's; if applicable.
  7. Does the sponsor consider that the study may be conducted in accordance with the "abbreviated requirements" of the IDE regulations [21 CFR 812.2(b)]?

XX. REFERENCES.

- A. Insert citations within text of application preferably using AMA Manual of Style; however APA 6<sup>th</sup> edition is acceptable.
- B. List references here as stated in AMA Manual of Style or APA 6<sup>th</sup> edition.

## Appendix C

# General Requirements for Human Subjects' Certification

I. **Prior to initiating a study, key personnel shall complete a course in human subjects protection:**

1. Key personnel shall be defined at this time, the principal investigators and persons recruiting and consenting subjects.
2. The course entitled "Protecting Human Subjects in Biomedical Research" is located on St. Mary's elearning site. Proof of completion of this course must be on file with the IRB prior to initiating study.
3. Access to the online course is by permission only. Requests for enrollment are made through the IRB office (485-6500) .
4. Once enrollment occurs, the individual will be notified that access to the course is available.

5. Print a completion document and submitted to the IRB within your application. Keep a copy of the form for your records as each new study will require proof of certification.
6. At this time, once the course is completed, no further certifications are required.  
**Contact Dr. Winsett if you need assistance with a human subject protection course**  
[rpwinsett@ascension.org](mailto:rpwinsett@ascension.org)

## Appendix D

# St. Mary's Consent Template Form

General instructions for writing the consent form:

- \* Must be addressed.
- \*\* Addressed if applicable.
- Use lay language. Reading level should be 6<sup>th</sup> grade.
- Add subject initials space (or legally authorized representative) on each page.
- The signature page does not need subject initials space.
- Add a brief title and principal investigators name at the top of all pages (except the title page).
- Add to the bottom of **each** page of the consent form a "preparation date \_\_\_\_\_". (This date would change whenever a revision is made to the consent)
- Write the Consent Form in the 2<sup>nd</sup> person (you), except the sections entitled "Compensation and Treatment for Injury" and "Consent of Subject" which should be written in the 1<sup>st</sup> person (I).
- Number and title each section as shown below.
- -----

Consent to Participate in [name of study here] Research Study

Principal Investigator: Name and address.

Co-Investigators: Names (no addresses)

### 1. INTRODUCTION:

- a. Statement indicating that the subject is being given the opportunity to participate in a **research** study.
- b. Purpose of the research study. A clear and concise statement indicating the reason the research is being conducted.
- c. If applicable, a description of the investigational agent (pharmaceutical or device) and/or investigational procedures to be studied. Add a brief description of any comparative (i.e. standard or control) agents or devices, if any, to be used in the project.
- d. Approximate number of subjects to be enrolled into the research project at this I institution and, for multicenter studies, the approximate number of subjects in aggregate.
- e. Specific location(s) (institutions, clinics, offices, etc.) in which the research will be performed.
- f. Anticipated duration of subject's participation as well as the time required to complete the entire study. For some studies, this may be minutes or hours with or without subsequent short or long-term follow-up participation by the subject. For others, participation (such as treatment) may require days, weeks, or months of "active" participation with short and/or long-term follow-up participation. In any event, the total duration of required involvement of the subject in the research study must be addressed.

### 2. PROCEDURES TO BE FOLLOWED:

- a. A clear and concise description of the procedures to be performed, usually in chronological order.
- b. Identify any additional or extra procedures that are being performed only because the subjects are participating in a research study. These include extra venipunctures, additional diagnostic or monitoring procedures, or increased time in the hospital, etc. Conversely, clarify what procedures would normally be performed even if subjects did not participate in the research study, if applicable.
- c. If applicable, the significance of placebos, randomization and double-masked (double- blind) clinical trials should be explained. Subjects should be given an explanation of "randomization." Telling them that the assignment to treatment will be done randomly, mathematically, or by lottery may not be sufficient. Instead, more of an explanation should be given. In a two-arm trial, for example, subjects should be told that there is a fifty percent chance of receiving one of two treatments thought to be beneficial for patients with their particular kind of disease; that one is the standard treatment and the other is the experimental treatment; that the experimental treatment is thought to be at least as good as the standard treatment; and that the investigator will not be the person who decides which treatment they receive.

If the study involves the use of placebos, subjects should be told the chances of receiving the various possible treatments, including the chance of receiving a placebo. A placebo should be described as an "an inactive substance."

It is important that prospective subjects understand that a double-mask design means that neither they, their physicians, nor the investigators treating and evaluating them will know which treatment they are to receive or have received. It is important to the research design that neither the investigators nor the subjects know about the assignment to each treatment.

- d. Developing trends in the data. The fact that such development will not affect their assignment during the course of the study should be communicated to perspective subjects prior to enrollment.

### 3. RISKS ASSOCIATED WITH PARTICIPATION:

- a. A description of any reasonably foreseeable risks or discomforts to the subject. This should include potential physical risks and, if applicable, psychological, social, or economic risks.
- b. Include potential risks of investigational agents, devices, procedures and treatments, as well as known risks of standard (comparative) agents, devices, procedures and treatments.
- c. To the extent possible, risks of harm or discomfort should be characterized as to their probabilities of occurrence, potential seriousness, duration and reversibility. For example, a potentially serious and irreversible risk, even with a **low** probability of occurrence, should be prominently displayed in the consent form. Likewise, minimal risk (e.g., nausea associated with investigational agents) with a **high** probability of occurrence requires more description than minimal risk with low probabilities of occurrence, etc.
- d. The probability of risk of harm should be described quantitatively with percentages (if available). Otherwise, qualitative assessment is acceptable using terms such as "rarely", "frequently", "usually," etc.
- e. A statement that the research treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- f. A statement that any significant new findings developed during the course of the research project, which may impact upon the safety and efficacy of the procedure or treatment under study and consequently influence the subject's willingness to continue participation, will be provided to the subject.
- g. Procedures used to prevent or minimize potential risks and/or discomforts may also be described.

### 4. BENEFITS ASSOCIATED WITH PARTICIPATION:

- a. A description of any benefits to the subject or to others (i.e., society) which may reasonably be expected from the research. The description of potential benefits to the subjects should not include benefits that subjects might realize from procedures they would undergo even if they were not participating in the research.
- b. Indicate the probability, magnitude, and duration of these potential benefits.
- c. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.
- d. Do **not** list compensation for participation or free services as a benefit.

5. ALTERNATIVES TO PARTICIPATION:

- a. When the research involves evaluation of a therapeutic intervention, alternative procedures or treatments that might be advantageous to subjects should be disclosed. It is sufficient to briefly indicate the types of standard treatments available. If palliative or end of life care is an appropriate alternative (e.g., an alternative to participation in a phase I trial of a cancer drug), this should be indicated as well.
- b. Indicate whether subjects may receive treatments used in the research without participating in the study.
- c. If therapeutic interventions evaluated in the study are being added to standard care, indicate that subjects will receive standard care whether or not they participate in the study.
- d. If study interventions are nontherapeutic in nature, indicate that subjects will not have to undergo these procedures if they do not participate in the study.

6. CONFIDENTIALITY:

- a. Provide a statement explaining how individual identifiers will be used in maintaining the research records (e.g., "Your research record will be labeled with your name." **or** "Your research record will be labeled with a code number. A master key that links your name and code number will be maintained in a separate and secure location.")
- b. Insert the HIPAA subject authorization language provided below. The language in this template should be precisely followed. The material in block form is the required authorization language. The *italicized* material in parentheses provides directions for including material that may or may not be relevant for particular studies.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or PHI). PHI collected in this study may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the researchers at St. Vincent Evansville to have access to your PHI collected in this study (*if the study will use PHI in the possession of another covered entity, add*) and to receive your PHI from (**either**) your physician (**and/or**) facilities where you have received health care. (*if any of the following individuals or entities will also be reviewing the PHI collected or received for the study, then add the following sentence.*) In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including (*if the study is multi-institutional, add*) researchers at (*name of the institutions*); (*if a cooperative group study, add*) the (*name of the cooperative group*); (*if the research involves an FDA-regulated drug, device or biologic, add*) the Food and Drug Administration (FDA); and (*if claims for some of the procedures performed during the study will be submitted to third party payers, add*) your medical insurance carrier. (*if the research is sponsored, add*) Your PHI may also be shared with (*name of sponsor*), which sponsors and provides funds for this research; (*name of Chief Research Office, if applicable*) which has been hired by the sponsor to coordinate the study; and

a Data and Safety Monitoring Committee (if applicable). (If the previous sentence was used, add the following sentence as well.) However, these latter organizations may not have the same obligations to protect your PHI. The Institutional Review IRB (IRB) at St. Vincent Evansville may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used (**either**) until the study is completed (**or if the research is FDA regulated**) for as long as the sponsor reports study data to the FDA (**or if the research is without a foreseeable end-point, such as a repository or a registry**) indefinitely.

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. (If the research study includes treatment of subjects, add the following sentences.) However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

- c. If the study involves the use of a federal Certificate of Confidentiality, provide the information regarding the certificate and how it protects subject information from disclosure.
- d. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's **medical** record (as contrasted with the **research** record), then this should be explained. Indicate that information placed in the medical record may be available to the subject's employer or insurer.
- e. State that individual subjects will not be identified in any presentations or publications based on the results of the research study.

#### 7. COMPENSATION AND TREATMENT FOR INJURY:

- a. A statement indicating whether any compensation and medical treatments are available if injury occurs and, if so, what they consist of and who will provide the compensation (often the study sponsor) and the treatments. If not, include a statement that the subject or the subject's insurance carrier will be billed for the costs associated with the medical treatment of a research related injury.

#### 8. QUESTIONS:

- a. A statement indicating a contact [the investigator or others with telephone number(s)] to answer questions about the research study.
- b. A statement indicating a contact [preferably the principal or co-investigator with 24 hour - 7 day telephone number(s)] in the event of research related injury.
- c. A statement indicating that subjects may contact the Chairman of the IRB at (812) 485-7134 or (812) 485-6500 if they have any questions about their rights as a participant in this study or their rights as a research subject.

#### 9. PAYMENT FOR PARTICIPATION:

- a. A statement indicating if there will or will not be payment (money or gifts) to the subject for participation.



- b. If applicable, a statement that payment will or will not be prorated for incomplete participation and if prorating is applicable regardless of the reasons for incomplete participation.
- c. If the subject is a minor, a statement that payment will be made to the subject **or** to the parent.

10. COSTS OF PARTICIPATION:

- a. A statement indicating if there will be any additional costs to the subject that may result from participation in the research.
- b. If applicable, address costs of study procedures and/or treatments, tests, physician fees, out-patient visit charges, and **additional** hospitalization costs attributable to participation.
- c. For studies in which some or all of the research costs will be billed to insurance carriers, and in the event of carrier denial, the subject would be held responsible for these costs, then a statement as follows is appropriate.  
"In some cases, insurers may not reimburse claims submitted for medical procedures or treatments performed as part of a research study. Therefore, you could incur some additional, uninsured expenses as a result of participating in this research study. You may wish to consult your insurer regarding the extent of your coverage for procedures and treatments performed in the study."

11. PREMATURE TERMINATION:

- a. A statement indicating the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- b. The potential medical consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject.

12. VOLUNTARY PARTICIPATION:

- a. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- b. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- c. If recruiting employees or students include the following statements: "If you are a student, you understand participating or not participating in this study will in no way influence your grade in any course. If you are an employee of the hospital, you should realize that participating or not participating will not affect your employment status."

13. CONSENT OF SUBJECT:

Include the following statements:

- a. I have read or have had read to me the description of the research study as outlined above. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts, side effects and adverse reactions as well as the possible benefits (if any) of the study.
- b. I freely volunteer to participate in the study. I understand that I do not have to take part in this study and that my refusal to participate will involve no penalty or loss of rights to which I am entitled. I further understand that I am free to later withdraw my consent and discontinue participation in this study at any time. I understand that refusing to participate or later withdrawing from the study will not adversely affect my subsequent medical care.
- c. State that the subject will receive a copy of the consent form.  
Include spaces for signatures and dates for the following:  
Research Subject

Person Conducting Consent Interview or Person Obtaining Consent  
Witness

Principal Investigator

Assent of Minor (If the research study includes children who are between the ages of 8 and 17, then an assent line/date is required)

Legally Authorized Representative and Relationship (If the research study includes individuals who have a legally authorized representative, then the signature of legal representative and relationship is required)

## Appendix E

### Initial 6-Month Report

Date Report Submitted: \_\_\_\_\_

Name of Sponsor: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

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

Co-Investigator(s): \_\_\_\_\_

Study Location: \_\_\_\_\_

Study Duration: Open Date: \_\_\_\_\_ Date Closed: \_\_\_\_\_

#### LOCAL DATA REPORT: (for multi-centered studies)

Total patients enrolled locally: \_\_\_\_\_

New enrollments since last report locally: \_\_\_\_\_

Number completed planned study treatment locally: \_\_\_\_\_

Number of patients withdrawn from study locally: \_\_\_\_\_

Reason:

Number of patients in follow-up locally: \_\_\_\_\_

#### OVERALL DATA REPORT:

Overall total patients enrolled: \_\_\_\_\_

Overall new enrollments since last report: \_\_\_\_\_

Overall number completed planned study treatment: \_\_\_\_\_

Overall number of patients withdrawn from study: \_\_\_\_\_

Reason:

Overall number of patients in follow-up: \_\_\_\_\_

Have any serious adverse reactions occurred? \_\_\_\_\_

Have these events been reported to the Manufacturer? \_\_\_\_\_

Have all amendments been submitted to the IRB and approved? \_\_\_\_\_

Is the IRB consent form approved? \_\_\_\_\_

Comments:

\_\_\_\_\_

Principal Investigator / Date

The IRB reviewed the above information and the IRB accepts this report.

\_\_\_\_\_

IRB Chair / Date

## Appendix F

# Application to Continue (Renew) a Previously Approved IRB Project

Date: Date of Original IRB Approval \_\_\_\_\_ Most recent continuing approval \_\_\_\_\_

Title of Proposal: (Use original full title) \_\_\_\_\_

Principal Investigator:

DEPARTMENT \_\_\_\_\_ PHONE#: \_\_\_\_\_ FAX#: \_\_\_\_\_

CAMPUS ADDRESS: \_\_\_\_\_

E-MAIL ADDRESS: \_\_\_\_\_

### Section A - Protocol Summary

1. Provide a summary (one page or less) of the research project including, the purpose, subject population, investigative methodology, research procedures applied to subjects, and potential for subject risk. **Attach a separate sheet.**
2. Provide a summary (one page or less) of all substantive revisions to the research project since the most recent approval. If there were no any revisions, this should be stated. **Attach a separate sheet.**

### Section B - Demographic Information

(Questions in this section apply only to your local site.)

1. Has the research project been initiated? Yes \_ No\_\_ If no, explain on a separate sheet.
2. Provide the number and gender of subjects accrued since activation of the study.

Total Number \_\_\_\_\_ Male \_\_\_\_\_ Females \_\_\_\_\_

3. Provide the number and gender of subjects accrued since most recent continuing (renewal) approval (not applicable if this request is for first renewal).

Number \_\_\_\_\_ Male \_\_\_\_\_ Females \_\_\_\_\_

4. Provide the number of subjects by ethnic origin accrued since activation of the study.

Caucasian \_\_\_\_\_; Black \_\_\_\_\_, not of Hispanic origin; Hispanic \_\_\_\_\_;

Asian/Pacific Islander \_\_\_\_; American Indian/Alaska Native \_\_\_\_; Other or Unknown \_\_\_\_

5. Provide an explanation of whether subject recruitment has complied with NIH and FDA requirements for the inclusion of women, racial/ethnic minorities and children in human subjects research. **Attach a separate sheet.**

### Section C - Problems, Complications, Subject Withdrawal

(Questions in this section apply only to your local site and pertain to the period since the most recent IRB approval to initiate or continue the research.)

1. Did any subjects express complaints about their participation in the research project?  
Yes \_\_\_\_ No \_\_\_\_ If yes, describe on a separate sheet these complaints and corrective measures taken, if any.
2. Did any subjects voluntarily withdraw from the study for non-medical reasons?  
Yes \_\_\_\_ No \_\_\_\_ If yes, describe on a separate sheet any known reasons for each subject's withdrawal.
3. Were any subjects prematurely terminated by the investigator from the research study for non-medical reasons (such as poor compliance)? Yes \_\_\_\_ No \_\_\_\_ If yes, describe on a separate sheet the reasons for each subject's withdrawal.
4. Was there an unusually high frequency of serious but **anticipated** (expected) adverse events? Yes \_\_\_\_ No \_\_\_\_ If yes, describe this finding on a separate sheet.
5. Did any subject suffer an unanticipated (unexpected) adverse event, serious adverse event, or death that was reported to the IRB since the last IRB review? Yes \_\_\_\_ No \_\_\_\_  
If yes, describe on a separate sheet the number of such events and their nature and significance.
6. Were any subjects withdrawn from the study because of medical problems or complications? Yes \_\_\_\_ No \_\_\_\_ If yes, describe on a separate sheet the medical problem or complication for each subject who was withdrawn.

### Section D - Study Results and Risk-Benefit Assessment

(Questions in this section apply to all study sites and pertain to the entire period since initiation of the study.)

1. What results (preliminary or final) have been obtained in the study? If the study is a multi-center trial, this should be stated and any available results provided, including interim summary reports of data and safety monitoring IRBs. If there are no results that can be reported to the IRB at this time, this should be stated and explained. **Attach a separate sheet.**
2. Have any external unanticipated problems, unanticipated (unexpected) adverse events, serious adverse events, or deaths been reported?  
Yes \_\_\_\_ No \_\_\_\_ If yes, **summarize** on a separate sheet the reportable adverse event(s) and include what, if any, impact these had on the research.
  1. Have any clinical or laboratory research results been published or presented which are relevant to the modification or continuation of this study? Yes \_\_\_\_ No \_\_\_\_ If yes, explain these developments on a separate sheet.
  2. Has anything occurred since the last IRB review which may have altered the risk/benefit assessment? Yes \_\_\_\_ No \_\_\_\_  
Answers provided in Section C, #1-6 and Section D, #1-3 should be considered in addressing this question.

If the answer is "yes", describe on a separate sheet the current risk/benefit assessment and how it differs from the original assessment.

3. If there are any **unreportable** adverse events received since the previous continuing review application which, considered in aggregate, may have relevance to the research such should be summarized on a separate sheet.

### Section E - Informed Consent Evaluation

1. Attach a copy of the current IRB stamped approved consent form for this study.
2. Did any problems occur in obtaining and documenting informed consent? Yes \_\_\_\_ No \_\_\_\_ If yes, explain on a separate sheet.

3. Did this study receive waiver/alteration of consent? Yes \_\_\_\_ No \_\_\_\_

4. Is the most recent version of the consent form still acceptable? Yes \_\_\_\_ No \_\_\_\_

1. Have informed consent documents and information pertaining to the identity of the subjects been securely stored? Yes \_\_\_\_ No \_\_\_\_ If not, explain on a separate sheet.

1. Have any significant new findings developed in the course of the research which may relate to the willingness of **current** subjects to continue participation? Yes \_\_\_\_ No \_\_\_\_ If yes, explain on a separate sheet plans implemented to inform subjects of this information.

2. What is the status of the study? (Check the appropriate blanks)

A. \_\_\_\_ open to active enrollment

B. \_\_\_\_ closed to enrollment (participants **are** receiving research interventions).

C. \_\_\_\_ closed to enrollment (participants **have completed** all research interventions) and

\_\_\_\_(a) the research remains active only for long-term follow-up of participants

OR

\_\_\_\_(b) the remaining research activities are limited to data analysis

If you checked blanks B or C, do you need a stamped approved consent form?

Yes \_\_\_\_ No \_\_\_\_

Signature of Investigator \_\_\_\_\_ Date: \_\_\_\_\_

## Appendix G

### Adverse Event Report

### Unanticipated, Serious

### Serious Adverse Event

### Death

Complete the narrative form and table. Send both to IRB in one document.

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Initial report \_\_\_\_\_

Follow-up \_\_\_\_\_

Study title (complete): \_\_\_\_\_

Type of report: \_\_\_\_\_ Unanticipated, serious (UA)

\_\_\_\_\_ Serious adverse event (SAE)

\_\_\_\_\_ Death

Subject identifier \_\_\_\_\_ Date of event \_\_\_\_\_

Describe the UA, SAE, or death:

Was the event related to use of the research protocol, device, or procedure? Describe completely the documented evidence that it was unrelated, unlikely, possibly, probably, or clearly caused.

Was the event life-threatening, required prolonged hospitalization, created persistent or significant disability, resulted in death, etc.?

Was study intervention stopped (Yes or No)? If yes, date intervention stopped. \_\_\_\_\_

If study intervention was stopped, was it re-started (Yes or No)? If yes, provide date \_\_\_\_\_

1	3	4	5	6	7	8	10	11
Patient ID #	AE or Problem Description	Relation to Research	Seriousness	Unanticipated Event	Type of Report	Date of Injury	Intervention Stopped	Intervention Re-started

# Appendix H Study Final Closure Report

Complete the information requested for the entire study period. Include with this form a summary of study findings. This may be in abstract form with graphs or tables, a narrative that summarizes the study findings or a manuscript submitted or accepted for publication. PowerPoint slides are insufficient.

Date Report Submitted: \_\_\_\_\_

Name of Sponsor: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

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

Co-Investigator(s): \_\_\_\_\_

Study Location: \_\_\_\_\_

Study Duration: Open Date: \_\_\_\_\_ Date Closed: \_\_\_\_\_

**LOCAL DATA REPORT: (for multi-centered studies)**

Total patients enrolled locally: \_\_\_\_\_

New enrollments since last report locally: \_\_\_\_\_

Number completed planned study treatment locally: \_\_\_\_\_

Number of patients withdrawn from study locally: \_\_\_\_\_

Reason:

Number of patients in follow-up locally: \_\_\_\_\_

**OVERALL DATA REPORT:**

Overall total patients enrolled: \_\_\_\_\_

Overall new enrollments since last report: \_\_\_\_\_

Overall number completed planned study treatment: \_\_\_\_\_

Overall number of patients withdrawn from study: \_\_\_\_\_

Reason:

Overall number of patients in follow-up: \_\_\_\_\_

Have any serious adverse reactions occurred? \_\_\_\_\_

Have these events been reported to the Manufacturer? \_\_\_\_\_

Have all amendments been submitted to the IRB and approved? \_\_\_\_\_

Is the IRB consent form approved? \_\_\_\_\_

Comments:

\_\_\_\_\_

Principal Investigator / Date

The IRB reviewed the above information and the IRB accepts this report.

\_\_\_\_\_

IRB Chair / Date

## Appendix I

# Application for Revisions of or Changes in Research Protocol and/or Informed Consent Form

PREPARATION DATE: \_\_\_\_\_ Date of Original IRB Approval \_\_\_\_\_

TITLE OF PROPOSAL: (Use original full title)

\_\_\_\_\_

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

DEPARTMENT \_\_\_\_\_ PHONE#: \_\_\_\_\_ FAX#: \_\_\_\_\_

CAMPUS ADDRESS: \_\_\_\_\_

E-MAIL ADDRESS: \_\_\_\_\_

DATE OF MOST RECENT CONTINUATION (RENEWAL) APPROVAL \_\_\_\_\_

(if applicable)

1. DESCRIPTION AND JUSTIFICATION OF PROPOSED REVISIONS IN THE SPONSOR PROTOCOL

(If your study originated outside of St. Mary's and needs to be revised, please send a summary of the revisions. With each change, refer to the page number within the old protocol where the changes occur. Attach the revised project descriptors with these changes highlighted. If the study does not originate outside of St. Mary's, then state N/A).

2. DESCRIPTION AND JUSTIFICATION OF PROPOSED PROJECT DESCRIPTORS REVISIONS

(If your study originates within St. Vincent Evansville and needs to be revised, please send a summary of the revisions. With each change, refer to the page number within the old project descriptors where the changes occur. Attach the revised project descriptors with these changes highlighted.

3. DESCRIPTION OF AND JUSTIFICATION OF PROPOSED REVISIONS IN THE INFORMED CONSENT FORM

With the changes in your project descriptor, be sure that the consent is revised appropriately. Attach two new consents, one with all the revisions highlighted and one that will be stamped for approval. Be sure each new consent has a revision date in the footer.

4. OTHER CHANGES (i.e., changes in investigator status, funding sources, etc.):

5. Do the revisions noted above have an adverse effect on the risk/benefit profile of the research?

Yes \_\_\_\_\_ No \_\_\_\_\_. If yes, an explanation is required.

6. LIST ATTACHMENTS (i.e., protocol, project descriptors, consent form, sponsor

correspondence, etc.):

\_\_\_\_\_  
SIGNATURE OF INVESTIGATOR / DATE

## Appendix J

# New Application for Student Projects to be conducted with patients or data from St. Vincent

### Application and Instructions for Completion of Project Descriptors

Projects that do not meet the criteria for research are still required to be reviewed and approved by the St. Vincent Evansville Institutional Review Board (IRB) prior to the student embarking on any phase of the project. This document guides project leaders through the application process. If the student project meets the definition of research, use the *New Application for Research for Patients at St. Vincent Evansville*. This application is for non-research, program evaluation, or medical record review without patient identifiers. If there is any question regarding a



project's research or non-research status, contact the IRB Chair Rebecca P Winsett PhD RN  
[rpwinsett@ascension.org](mailto:rpwinsett@ascension.org)

This new application form must be completed for all projects where the leader is a student or that the project does not meet the criteria for research. If, later, the project becomes a formal research project, a second research application must be completed. A student project that does not meet the criteria for research can be submitted for expedited review. Submissions to the IRB must contain all required materials. Incomplete submissions will be returned to the investigator without IRB review.

**A complete submission must contain the following:**

1. Cover letter- the cover letter must state that this is a student project, the name of the faculty who is advising the student, as well as the St. Vincent Evansville Employee who is supporting the student.
2. Face Sheet with all signatures
3. IRB New Application for Student Projects (Project Descriptors)
4. If the project is being conducted under a grant, a complete copy of the grant application to federal or non-profit organizations.
5. Copies of all questionnaires, surveys, forms that will be used to collect data.
6. The application must be accompanied by a letter of support from a faculty member or medical staff that will be involved in the project. This letter contains the stated responsibilities of the student or non faculty member as well as the stated responsibilities of the sponsoring faculty or medical staff member (This is in addition to the cover letter).
7. Send entire packet electronically, preferably as one single document, to the IRB Administrative Assistant [shawes@ascension.org](mailto:shawes@ascension.org)
8. If unable to create one single cohesive document, submit files labeled in the order in which they go in the IRB application so that the IRB can be printed and copied accurately. Start the name of each document with the number of the file, name of document, and last name of PI (i.e. 1Face Sheet\_Smith; 2ProjectDescriptor\_Smith; 3Appendix1\_Smith;). Please do not submit partial electronic and partial hard copies.

**Instructions for preparation of the New Application, referred to as the "Project Descriptor**

- A. Each item must be titled as described below and addressed succinctly in the listed sequence.
- B. If any item is not applicable, this should be so stated.
- C. Attachment of applicable sections of the research protocol and/or grant application is **not** acceptable as a substitute for completion of each item. Please include sufficient information to facilitate an efficient IRB review.
- D. The face page should be completed and is the first page of your project descriptors.
- E. Insert a brief title, principal investigator first initial and last name in the header of the subsequent project descriptor pages. Place preparation date in the footer of the Project Descriptors.
- F. Insert page numbers (i.e., 1 of 11; 2 of 11, etc.)
- G. Be sure that appendices are appropriately labeled and in the order in which they are cited in text.
- H. Appropriate use of citations and reference list should be included. Insert citations within text of application preferably using AMA Manual of Style; however APA 6<sup>th</sup> edition is acceptable.

# Students Non-research Project Descriptor

## 1. PURPOSE OF THE PROJECT

- State concisely and realistically what the project is intended to accomplish.

## 1. BACKGROUND AND CURRENT STATUS OF WORK IN FIELD

- This section must provide a justification and rationale for conducting the project.
- This section would be a short review of the literature providing the importance of your project.

## 1. METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS.

- Describe the project design and all procedures (sequentially) to be completed. For projects that include multiple visits, list in chronological order, using bullet points, what will be done at each visit and what length of time will be required for each visit.
- Clearly indicate which procedures and/or treatments are being performed solely for purposes of the project. Describe how this project differs from regular practice or procedures and provide supporting evidence that it does not meet the criteria for research.
- If your project is a chart review, please describe in detail how you have received permission for access to the data and the steps you will take to obtain the data.
- This section must provide a justification and rationale for conducting the project.
- This section would be a short review of the literature providing the importance of your project.
- State concisely and realistically what the project is intended to accomplish

## 4. CHARACTERISTICS OF SUBJECT POPULATION.

- Describe the characteristics of the subject population. (What do you know about the population from which you will be sampling for this project?).
- This section is about the group from which you will complete your project. Tell us about what the population looks like. That way, when you describe your subject selection in Section 5, the IRB will have a clear vision of your sample. If you need help in describing your population and your sample, discuss with your advisor or contact Dr. Winsett [rpwinsett@ascension.org](mailto:rpwinsett@ascension.org)
- If the project is changing a current practice or program, describe the current program and outcomes and the proposed changes to be made to the program. Include the measurement variables that will be used to assess the new/revised program.
- Include the anticipated number of subjects to be in the project, age ranges, sex, race, and health status.
- Identify the criteria for inclusion and exclusion.
- Justify the use of any special classes of subjects such as pregnant women, fetuses, children, mentally disabled, prisoners or others who are likely to be vulnerable. Nurses or employees are considered to be vulnerable populations.
- Estimate the time required to complete the entire study. Include the project timeline.

## 1. METHOD OF SUBJECT SELECTION.

- Describe the method(s) to be employed in the identification/recruitment of potential subjects and **attach** any proposed advertising copies (posters, news ads, etc.). If advertising materials will be developed later, this will require completion and submission of an amendment to the IRB application.
- If applicable, indicate that you will be recruiting subjects from the St. Vincent Evansville staff and employees. Include a statement that the decision to participate or to continue participation in a study will not affect employment status.

- If the project is changing/revising a program to be offered to all subjects, describe the circumstances in which patients/subjects will be offered the changed/revised program.
  - This section is about who (even if the who are charts) gets selected for your project.
2. STUDY SITE.
- State the location(s) where the project will be conducted.
3. POTENTIAL RISKS TO THE SUBJECT.
- Describe all potential risks and discomforts associated with each procedure. These include physical, psychological, social, legal and other risks and discomforts associated with the procedure. In order to qualify for expedited review as a student project, there must be less than minimal risk. Describe physical, emotional, financial, and legal risks separately.
  - Assess the probability, magnitude (severity), potential duration and reversibility of each risk.
  - The probability of risk of harm should be described quantitatively with percentages (if available). Otherwise, qualitative assessment is acceptable using terms such as "very rarely", "frequently", "usually", etc.
  - Use a table to help explain the identified risk, assessment, probability, magnitude, duration, and reversibility of each.
  - Identify those risks which are minimal and those which are more than minimal.
  - If there are no risks or discomforts associated with the research procedures, then this should be stated.
4. PROTECTION AGAINST RISKS.
- Describe the procedures used to prevent/minimize potential risks.
  - Describe the criteria for removal of subjects from the project.
  - Provide a description of the data and safety monitoring plan for this project. State how you will protect the data from viewing by others not associated with the study, where you will store and protect the data. Describe what you will do with the data once the project is completed.
5. POTENTIAL BENEFITS TO THE SUBJECT.
- Describe the potential benefits that may accrue directly **to the subject** as a result of participation in the project. The description of potential benefits to the subjects should not include benefits that the subjects might realize from procedures that they would undergo even if they were not participating in the project.
  - Indicate the probability, magnitude, and duration of these potential benefits.
  - If there are no direct benefits to subjects associated with participation, then this should be clearly stated.
  - Do not list payment or free services as potential benefits to the subjects.
6. POTENTIAL BENEFITS TO SOCIETY.
- Describe the potential societal benefits of the project in terms of human health/welfare, the advancement of knowledge or the good of society.
7. RISK/BENEFIT ASSESSMENT.
- The risk/benefit assessment should be made separately for therapeutic and nontherapeutic procedures used in the project.
  - Acceptability of the risk/benefit ratio requires satisfaction of two conditions. First, the risk to individual subjects must be outweighed by the potential benefits. Second, the risk/benefit ratio of the procedures

used must not be known to be significantly less favorable than any alternative interventions available to subjects, including those available outside the research context. The risk/benefit assessment should address each of these points.

- For any nontherapeutic procedures used in the project, it must be explained why the risk of the nontherapeutic procedures is sufficiently low to be outweighed by the potential benefits to society of the knowledge to be gained in the study.

#### 8. ALTERNATIVES TO PARTICIPATION.

- Describe any alternatives available to the subjects outside the project.
- Indicate whether subjects may participate in the project without participating in the data collection associated with the project. If therapeutic interventions are being added to standard care, indicate that subjects will receive standard care whether or not they participate in the project.
- If interventions are nontherapeutic in nature, indicate that subjects will not have to undergo these procedures if they do not participate in the project.

#### 9. CONFIDENTIALITY.

- Explain how individual identifiers will be used in maintaining the project records. For example, indicate whether records will be labeled with the subject's name, or whether they will be labeled with a code number, with a master key that links name and code number maintained in a separate and secure location.
- Indicate that the HIPAA authorization will be upheld.
- If information about the subject's participation or the results of procedures performed will be placed in the subject's **medical** record (as contrasted with a **project** record), then this should be explained.
- State that individual subjects will not be identified in any presentations or publications based on the results of the project.

#### 10. PAYMENT FOR PARTICIPATION.

- Describe any economic incentives or other rewards for participation and any prerequisite condition that must be fulfilled by subjects in order to receive compensation, including prorated payments for partial participation, if applicable.

#### 11. FINANCIAL OBLIGATIONS.

- Describe any costs to the subject as a result of the project procedures that exceed what would be incurred with standard treatment (e.g., additional diagnostic tests, additional hospitalization, drugs, devices, parking, etc.).

#### 12. PROJECT INJURIES.

- Describe the procedure for treatment of any project-associated injury both in regard to the plan for medical care and responsibilities for payment of costs associated with delivery of the care for such injuries. Specifically, describe the extent to which the sponsors of the project will be responsible for the costs associated with project related injuries.
- If it is the case, indicate that the subject and/or the subject's insurer will be billed for the costs associated with the medical care.
- If this section does not apply to your project, please state.

#### 13. FINANCIAL CONFLICT OF INTERESTS.

- Report specific outside activities that may or may not represent conflicts of interests.

- Explain whether any key research personnel have a reportable economic interest in an outside entity, or act as officers, directors, employees or consultants for such an entity, whose financial interests may be affected by the research study. If so, describe in detail the nature of the interest or involvement in the outside entity.
- For any key research personnel who have reportable financial interests or involvement as described above, explain whether these interests can be managed without constituting a prohibited conflict of interests that affects the design, conduct, or reporting of the project results.

#### 14. INFORMED CONSENT.

- Describe the circumstances under which a waiver of written informed consent is met.
- Describe in detail the following:
  - The research involves no more than minimal risk to the subjects;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - The research could not practicably be carried out without the waiver or alteration; and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- If this project does not qualify as research, then justify how the project meets the definition of non research

#### 15. REFERENCES

- Insert citations within text of application preferably using AMA Manual of Style; however APA 6<sup>th</sup> edition is acceptable.

## Appendix K Humanitarian Use Device (HUD)

### Policy Statement

St. Vincent Evansville Institutional Review Board (IRB) is responsible for safeguarding the rights and welfare of human subjects involved in research activities and accordingly, safeguard the rights and welfare of patients who may require a humanitarian use device (HUD). This policy is a supplement to the Institution Review Board Policy # 1756491.

### Definition

A humanitarian use device (HUD) is one that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4, 000 individuals in the United States in a calendar year. The FDA authorizes the marketing of HUDs through the issuance of a Humanitarian Device Exemption (HDE). HDEs are intended to encourage the discovery and use of devices intended for the treatment or diagnosis of diseases or conditions that afflict small numbers of individuals who would be left without satisfactory treatment options in the absence of the availability of such devices. HDEs accomplish this goal by allowing device manufacturers to market a HUD in the absence of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. Rather, the manufacturer must only provide information indicating that the device will not expose patients to an unreasonable or significant risk, the probable benefit to health outweighs the risks associated with its use, and there is not comparable device available.

This policy does not cover emergent use of a HUD for off label or non-FDA approved conditions.

## IRB responsibilities

Use of HUDs does not constitute research. The FDA regulations governing their use require that the healthcare provider who will use a HUD obtain IRB approval before the HUD is used to treat or diagnose patients. The IRB is responsible for both initial and continuing review of the HUD use. IN conduction its initial review, the IRB must determine that use of the HUD will be consistent with the approved labeling for the device. For continuing review, the IRB must follow the requirements at 21CFR56, but may use expedited review procedures unless it determines that full board review should be performed.

The IRB may also use its discretion in determining whether to approve the use of a HUD for a given period of time, for a specified number of patients, or on a case-by-case basis. However, the HUD regulations require that the use of the HUD be reviewed by the IRB no less frequently than once a year.

After approval by the IRB, the regulations require that the healthcare provider transmit to the IRB any medical device reports related to the occurrence of adverse events that must be submitted to the FDA in compliance with the reporting requirements of 21CFR803

## Informed Consent

The HUD regulations do not address informed consent requirements for the use of a HUD. St. Mary's IRB will require an informed consent and a clear description on the procedure for the informed consent process.

## Equipment & Supplies

- A. For application for use of a HUD, see Attachment 1
- B. For the consent template for HUD, see Attachment 2

## Procedure

- A. For providers wishing to employ a HUD, complete the face page and application found in Appendix A.
- B. Provide the following documents preferably in one streamlined document with clear notations and subheadings that will facilitate the review of the application:
  1. The FDA HDE letter that authorizes marketing of the HUD;
  2. The HUD manufacturer's product label, clinical brochure and/or other pertinent information regarding operation of the device;
  3. Any patient information packet for the device;
  4. A summary of safety and probable benefits from the device manufacturer;
  5. A written statement from the applicant specifying that use of the HUD will be limited to the clinical indications listed in the FDA-approved product labeling;
  6. Information describing the applicant's clinical experience with the device, any training completed or required, and a list of physicians who will be using the device;
  7. Prior annual reports of the manufacturer regarding the use of the device;
  8. An explanation of the costs that patients will incur with use of the device;
  9. Any advertisements or other descriptive materials that might be used in marketing the HUD;
  10. A written statement from the applicant specifying that the patient information packet will be given to the patient before the device is used.
  11. Include two copies of the informed consent that will be used.
  12. List who will be completing the informed consent process.

13. List dates of completion of the human subjects' protection course for **each person** who will be completing the informed consent.
14. Include copies of the human subject protection course certificates.

References

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm110194.htm>

## Attachment 1 - St. Vincent Evansville Institutional Review Board Application for a Humanitarian Use Device (HUD)

Face page and Descriptor

Provide the following face page and descriptors preferably in one streamlined document with clear notations and subheadings that will facilitate the review of the application.

1. Name of HUD device and manufacturer's model number
2. Principal Provider Name  
PhoneEmail  
Office Address  
List any additional contacts for the IRB  
NameRoleEmail
  - 1.
  - 2.
  - 3.
3. Device Manufacturer Name
4. Manufacturer Contact Name and numbers
5. Proposed use of HUD (how eligibility is determined i.e. inclusion/exclusion criteria)}
6. Clinical indication for device (short synopsis of indications and population)
7. List all personnel that will be authorized to insert/distribute/treat with the HUD described in this application

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Principal Provider Signature Date

## St. Vincent Evansville Institutional Review Board Application Humanitarian Use Device Descriptor

Include the following. Please refer to each of the 14 items in sequential order. If there is a manufacturer's protocol that gives this information, write a short synopsis and indicate the page number in the booklet where the item is discussed in more detail. Provide all information in one streamlined document.

1. The FDA HDE letter that authorizes marketing of the HUD;
2. The HUD manufacturer's product label, clinical brochure and/or other pertinent information regarding operation of the device;
3. Any patient information packet for the device;

4. A summary of safety and probable benefits from the device manufacturer;
5. A written statement from the applicant specifying that use of the HUD will be limited to the clinical indications listed in the FDA-approved product labeling;
6. Information describing the applicant's clinical experience with the device, any training completed or required, and a list of physicians who will be using the device;
7. Prior annual reports of the manufacturer regarding the use of the device;
8. An explanation of the costs that patients will incur with use of the device;
9. Any advertisements or other descriptive materials that might be used in marketing the HUD;
10. A written statement from the applicant specifying that the patient information packet will be given to the patient before the device is used.
11. Include one copy of the consent within the application and a separate file of the consent to have the IRB approval stamp placed. **Only the stamped consent may be used.**
12. List who will be completing the informed consent process.
13. List dates of completion of the human subjects' protection course for **each person** who will be completing the informed consent.
14. Include copies of the human subject protection course certificates.

## Attachment 2 Template for HUD Consent

Complete the template. Include a copy of your consent in the IRB application. In addition to having a copy of the consent for the IRB to review, send a separate file with the consent to have the approval stamp placed. **Only the stamped approved consent may be used.** If there are any changes in the consent, please resubmit your changes to the IRB to receive an approved revised consent. You may add St. Mary's logo or your office logo to the consent. The logo must be in place on the clean consent to receive approval.

Consent to Allow Use of a Humanitarian Use Device

This is not a research study

1. You are being asked by Dr. \_\_\_\_\_ to have a Humanitarian Use Device, called a HUD, placed in you. A HUD is a device that has been approved by the Food and Drug Administration but its use is rare. A HUD device helps treat or diagnosis a condition that is seen in less than 4,000 person each year. You are part of a group of patients that might benefit from a HUD. This is not a research study.  
Please take time and read this consent. Ask any questions about the device or how it will be used.
2. The Food and Drug Administration (FDA) has approved the use of [name of the device] for [treatment/ diagnosis] for patients who have [describe the treatment or condition in which this device is intended]. The effectiveness of [name of device] has not been demonstrated because this [treatment/condition] is not seen very often.
3. [Describe the HUD and how it is used.]  
You are eligible to receive this device because you have [name of treatment or condition] and have not improved with your current treatment.
4. [describe possible risks, side effects and /or adverse events. Use lay language at 6<sup>th</sup> grade level]



5. [describe any alternative treatments or procedures that your patient may wish to consider in lieu of the HUD. Describe process/procedure should the patient decide to discontinue use of device, if applicable. Use lay language at 6<sup>th</sup> grade level.]
6. The procedure will take place [describe the location, include address or suite number] and will take [describe length of procedure]
7. You will have the device in place [describe how long the patient's treatment will be in hours, days, weeks, months, years] and you will be followed by your doctors [describe the type of follow up the patient will have]
8. While the device is in place, Dr. \_\_\_\_\_ will collect information on your response to treatment. This includes [state what lab, procedures, exams; how often and if this is different from standard care]
9. I understand the need for a HUD and that I qualify for it.

I understand that the device has been approved by the FDA for use for my condition.

I can choose not to have the device.

I understand that this is not a research study.

I freely volunteer for the device.

\_\_\_\_\_  
Patient Signature Date

\_\_\_\_\_  
Consenter Signature Date

\_\_\_\_\_  
Principal Provider Signature Date



**Attachments:**

No Attachments

	Approver	Date
	Sheila Hawes: Asst, Executive	8/26/2015
	Rebecca Winsett: Scientist, Nurse	8/26/2015
	Rebecca Winsett: Scientist, Nurse	1/28/2016
	Sheila Hawes: Asst, Executive	1/28/2016