1.0 Policy:
All research proposals that intend to enroll human subjects must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and respect for persons (autonomy) as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Sparrow may apply and must be met as well.

Specific Policies
1.1 Minimal Criteria for Approval of Research
In order for a research project to be approved, the IRB must find that:

A. Risks to subjects are minimized:
   By using procedures, as outlined in the IRB Protocol Review Worksheet (RR 402-A) that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
   - In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that 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.

C. Selection of subjects is equitable.
   - In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as (but not limited to) children, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations. Under certain conditions a Waiver of Informed Consent may be approved by the IRB.

E. Informed consent will be appropriately documented as required by local, state and federal regulations.

F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

G. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Data stored electronically must be kept in accordance with the Security Guidelines for Clinical Research at Sparrow Health System procedures (FO 301-D).

H. When some or all of the subjects, such as children, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
I. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.

1.2 Other Criteria
The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.

The criteria used to determine whether third-party verification is required may include:
- Investigators that conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators that conduct studies that involve large numbers of subjects, and
- Investigators selected at the discretion of the IRB.

Outside reviewers may perform reviews as requested by the IRB Chairperson which may include ethical, research design, or statistical analysis among other types of reviews.

1.3 Reliance on Other IRBs for Review and Approval of Research Conducted at Sparrow Health System facilities.
Under authority granted by the Institutional (Signatory) Official of Sparrow Health System, the Sparrow Health System’s IRB may enter into joint review arrangements, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort as allowed and upon modification of the institutional Federal-wide Assurance agreement (FWA).

The Sparrow IRB has entered into contractual reliance agreements with, but not limited to, the following institutions for specified studies conducted at Sparrow facilities (also See SOP FO 306):

1.3.1. SHS/MSU IRB Reliance Agreement. The IRB Reliance is an agreement between Michigan State University’s Biomedical & Health Institutional Review Board (BIRB) and Sparrow Hospital which, if accepted under facilitated review by the Sparrow IRB, allows an MSU-paid faculty/staff member, intending to conduct research at a Sparrow facility, to have a research project undergo IRB review through BIRB, with the IRRC accepting the subsequent review by BIRB.

1.3.2. SHS/MSU IRB Collaborative Authorization Agreement. The IRB Collaborative Authorization Agreement, with MSU’s Community Research Institutional Review Board (CRIRB), provides CRIRB review of collaborative, multi-community research projects, with IRRC-appointed member representation on this committee. The Sparrow IRB retains the right to facilitated review and acceptance for conduct at Sparrow facilities of CRIRB-approved studies.

1.3.3. Michigan Cancer Research Consortium’s OCIRB Agreement. The SHS contractual agreement with Michigan Cancer Research Consortium’s Oncology Central Institutional Review Board (OCIRB) provides for OCIRB review of MCRC research projects for the Sparrow Regional Cancer Center. The IRRC provides appointed member representation on the OCIRB. The Sparrow IRB retains the right to facilitated review and acceptance for conduct at Sparrow facilities of OCIRB-approved studies.

1.4 Qualifications of Principal Investigators.
The IRB shall review the Investigator’s qualifications in relation to the research proposal.
Where the Investigator conducts research involving human subjects, the IRB shall consider the following:

1.4.1. The IRB shall consider whether the investigator is qualified in the area of the proposed research by reviewing information submitted by the Investigator including the Investigator’s references, resume, and/or curriculum vitae.

1.4.2. The IRB shall consider whether the Investigator has the appropriate professional experience in the field to be researched.
1.4.3. The IRB shall consider whether the Investigator has access to appropriate facilities to conduct the research, including the Investigator's medical staff privileges at Sparrow Health System. An Investigator shall not conduct clinical research without the appropriate medical staff privileges.

1.4.4. The IRB shall consider the Investigator's previous research activities.

1.4.5. The IRB shall consider the nature of the research protocol. If the protocol requires skills or qualifications beyond those of the proposed Investigator: (i) the protocol should be modified to match the Investigator's skills; (ii) qualified Investigators should be added; (iii) the protocol should be tabled; or (iv) the protocol should be denied.

1.4.6. The IRB may ask Investigators to address the topic in supplemental application materials.

1.4.7 All Resident, Fellow, and Student research projects must be sponsored by a responsible principal Investigator qualified in the area of the research to be conducted (also see SOP RI 801, 1.7).

2.0 Scope:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sparrow Hospital</td>
<td>This policy and procedure applies to the Sparrow research community.</td>
<td>✓</td>
</tr>
</tbody>
</table>

3.0 Responsibilities & Procedures

3.1 The IRB Administrator/Coordinator is responsible for ensuring that IRB reviewers have all the tools and resources they need to complete their research reviews.

3.2 The IRB Chairperson (or IRB Administrator) is responsible for providing IRB members adequate submission review training and ongoing guidance, and for selecting the primary reviewers with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB.

3.3 The IRB Reviewer is responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IRB.

3.4 Process Overview

3.4.1 Reviewers (primary review team, entire committee, and outside reviewers, if applicable) will look at research design, the risk level of the study, and the consent form as outlined in the Protocol Review Worksheet (RR 402-A) and the Informed Consent Form Checklist (IC 701-A). The primary reviewers may complete the forms prior to the IRB meeting. At the convened IRB meeting, the primary reviewers are asked to present the results of their review to the entire committee. Then the committee discusses the project and makes further comments before a decision is made as to approval/non-approval.

3.4.2 For new studies requiring full IRB review, the principal investigator, or their designee, is required to come before the committee to briefly present their proposed project and answer any questions the IRB members may have. Once discussion is competed, the principal investigator, or their designee, is excused and does not remain present for formal discussion or action(s) taken by the IRB.
3.4.3 At the discretion of the IRB Chairperson or upon request by committee members, the principal investigators, or their designee, may be asked to come before the committee to discuss other IRB review issues.

3.4.4 Under the terms of the collaborative/reliance agreements, studies submitted to the IRB receive expedited-like review by the IRB Chairperson, or designee. The IRB is notified of these decisions in an upcoming agenda.

3.4.5 The IRB office will notify the principal investigator, in writing, of the IRB’s decision.

3.5 Procedures Employed to Implement this Policy

<table>
<thead>
<tr>
<th>Who</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Chairperson or IRB Administrator</td>
<td>Select reviewers with appropriate expertise for the research to be reviewed.</td>
</tr>
<tr>
<td>IRB Chairperson</td>
<td>Ascertain whether the evidence exists that third party verification (outside reviewer) of submitted information is needed.</td>
</tr>
<tr>
<td>IRB Member (Reviewer)</td>
<td>Review research proposal and summarize findings on appropriate protocol review worksheet (RR 402-A) and Informed Consent Checklist (IC 701-A) if they wish to use those forms. Ascertain whether any special considerations exist that may influence the review of a proposal.</td>
</tr>
<tr>
<td>IRB Member (Reviewer)</td>
<td>Prepare summary of findings and recommendations for presentation at the next convened IRB meeting.</td>
</tr>
</tbody>
</table>

4.0 Other Documentation

- 45 CFR 46.111
- 21 CFR 56.108, 56.111

5.0 Other Attachments

- RR 402-A Protocol Review Worksheet: Primary Reviewer
- RR 402-B Risk Assessment Checklist for Research Studies
- RR 402-C Significant and Non-Significant Risk Checklist (Medical Devices)
- IC 701-A Informed Consent Checklist
### Protocol Review Worksheet: Primary Reviewer

**Project Title:**

**IRB Tracking #:**

**Type of Study:**
- Drug □
- Device □
- (requires SR/NSR risk determination)
- Other □

**Principal Investigator:**

**To Attend Meeting?**
- □ No
- □ Yes

### Criteria for Approval

1. **Risks to subjects are minimized**
   - □ Research procedures are consistent with sound research design
   - □ Research procedures do not unnecessarily expose subjects to risk
   - □ Researcher is qualified to conduct study
   - □ Routine or standard procedures to be performed on subjects for the purposes of the study whenever possible
   - □ The research plan makes adequate provision for monitoring the data to ensure the safety of subjects

### Comments on Part 1:

2. **Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result**
   - □ Purpose of study is clear and acceptable
   - □ Results of any related studies are included
   - □ Number of subjects and duration of participation is stated and appropriate
   - □ Duration of the study is clear and appropriate
   - □ Compensation paid to subjects is appropriate

   **Is there a washout period?**
   - □ No
   - □ Yes
   - □ If so, is it appropriate, and are safeguards in place to assure subject will be adequately monitored?

   **Is there a placebo / no treatment control?**
   - □ No
   - □ Yes
   - □ If yes, is use of placebo appropriate and does not put subjects at risk?
Comments on Part 2:

3. **Selection of subjects is equitable**
   - [ ] Justification for use of vulnerable groups provided
   - [ ] Additional safeguards have been included in the study to protect the rights and welfare of these groups
   - [ ] Presence of any special community attitudes that may affect subject participation has been addressed where applicable
   - [ ] Selection of subjects reflects purposes of the research and group that will benefit from research outcome

Comments on Part 3:

4. **Legally effective informed consent is obtained**
   - [ ] Informed Consent will be sought from each subject
   - [ ] Informed Consent procedures and documentation appear to be appropriate
   - Does the protocol call for waiver of informed consent? [ ] No  [ ] Yes
   - If yes, is waiver appropriate? [ ] No  [ ] Yes

5. **There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data**

Comments on Part 4 to 5:
### 6. Review of Required Protocol Elements

Note: Protocols for Phase 1 studies may be less detailed than for Phase 2 and 3 studies

<table>
<thead>
<tr>
<th>Required Protocol Elements</th>
<th>Present?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of objectives and purpose of the study</td>
<td>□ No</td>
</tr>
<tr>
<td>Name, address, and statement of qualification (e.g., CV) of each Investigator and Sub-investigator</td>
<td>□ No</td>
</tr>
<tr>
<td>Name and address of each research facility to be used</td>
<td>□ No</td>
</tr>
<tr>
<td>Name and address of each IRB to be used</td>
<td>□ No</td>
</tr>
<tr>
<td>Patient selection criteria, exclusion criteria and estimated number to be studied</td>
<td>□ No</td>
</tr>
<tr>
<td>Summary of study design, including control(s) and steps to reduce bias risks</td>
<td>□ No</td>
</tr>
<tr>
<td>For drug studies, methods to determine dosing, expected maximum dosage, and duration of exposure to drug</td>
<td>□ No</td>
</tr>
<tr>
<td>Observations and measurements to be made during the study</td>
<td>□ No</td>
</tr>
<tr>
<td>Clinical procedures, laboratory tests and other measures to be taken to monitor the test article’s effects and minimize risks to subjects</td>
<td>□ No</td>
</tr>
<tr>
<td>Summary of data analysis and statistical methods to be used</td>
<td>□ No</td>
</tr>
</tbody>
</table>

**Comments on Part 6:**

---

### 7. Criteria For Review Schedule

Studies that are considered high risk will generally be reviewed at least semiannually.

Studies may be reviewed semiannually if the IRB believes that the study population is especially vulnerable.

Studies may be reviewed more frequently if the IRB believes that previous studies indicate high incidence of adverse events.

Studies may be reviewed more frequently if the IRB believes close monitoring is indicated.
If the IRB determines that a study that had been approved for an annual review requires closer monitoring, the IRB may make a determination to review that study on a more frequent basis. The reasons for such a determination will be included in the minutes and communicated to the Investigator.

8. **Risk Assessment:**
This study is  □ Low Risk  □ Moderate Risk  □ High Risk
Do you believe the monitoring plan described is adequate for the risk?
Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred? □ No  □ Yes
Do you believe that this study requires full IRB review more often than annually □ No  □ Yes
Is an interim report required? If yes, how often? □ in 3 months  □ in 6 months  □ other ______________

Primary Reviewer (print) ___________________________________________  Date ____________________________

_______________________________________________________________

Signature
Project Title:

IRB Tracking #:

Principal Investigator: ____________________________________________

To Attend Meeting? □ No  □ Yes

Criteria for Approval

1. Risks to subjects are minimized?
□ Research procedures are consistent with sound research design
□ Research procedures do not unnecessarily expose subjects to risk
□ Researcher is qualified to conduct study
□ Routine or standard procedures to be performed on subjects for the purposes of the study whenever possible
□ The research plan makes adequate provision for monitoring the data to ensure the safety of subjects

Comments on Part 1:

2. Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result
□ Purpose of study is clear and acceptable
□ Results of any related studies are included
□ Number of subjects and duration of participation/follow-up is stated and appropriate
□ Duration of the study is clear and appropriate
□ Compensation paid to subjects is appropriate

Is there a control group? □ No  □ Yes
□ If yes, use of controls is appropriate and does not place any subjects at risk

Comments on Part 2:
3. Selection of subjects is equitable

☐ Justification for use of vulnerable groups provided
☐ Additional safeguards have been included in the study to protect the rights and welfare of these groups
☐ Presence of community attitudes that may affect subject participation has been addressed where applicable
☐ Selection of subjects reflects purposes of the research and group(s) that will benefit from research outcome

Comments on Part 3:

4. Legally effective informed consent is obtained

Informed Consent will be sought from each subject ☐ No ☐ Yes
Informed Consent procedures and documentation appear to be appropriate ☐ No ☐ Yes
Does the protocol call for waiver of any elements of informed consent? ☐ No ☐ Yes
If yes, is waiver appropriate, that is:
1 the research involves no more than minimal risk to the subjects?
2 the waiver or alteration will not adversely affect the rights and welfare of the subjects?
3 whenever appropriate, the subjects will be provided with additional pertinent information after participation?
Is a debriefing form provided? ☐ No ☐ Yes

Comments on Part 4:

5. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data described in protocol? ☐ No ☐ Yes

Comments/recommendations on Part 5:

6. Review of Required Protocol Elements

Required Protocol Elements Present?
Statement of objectives and purpose of the study ☐ No ☐ Yes
Name, address, and statement of qualification of each Investigator and Sub-investigator ☐ No ☐ Yes
Name and address of each facility where research will be performed by Investigator ☐ No ☐ Yes
Protocol Review Worksheet (Social): Primary Reviewer

Name and address of each facility where research will be performed by other, non-institution/Organization employees □ No □ Yes
Name and address of each IRB to be used (if research sites above have IRBs) □ No □ Yes
Patient selection criteria, exclusion criteria and estimated number to be studied □ No □ Yes
Summary of study design, including control(s) and steps to reduce risk of bias □ No □ Yes
Observations and measurements to be made during the study described □ No □ Yes
Measures to be taken to monitor the research effects and minimize risks to subjects □ No □ Yes
Summary of data analysis and statistical methods to be used □ No □ Yes

Comments on Part 6:

Part 7 Review of the Informed Consent Document (use Form IC 701-A and attach)

Comments on Part 7:

8. Criteria For Review Schedule
Is the study population is especially vulnerable? □ No □ Yes
Is the information being obtained especially sensitive? □ No □ Yes

Risk Assessment:
This study is □ Minimal Risk □ Low Risk □ Moderate Risk □ High Risk

Do you believe that this study needs verification from sources other than the Investigator that no material changes have occurred? □ No □ Yes

Is an interim report required? If yes, how often?
□ in 3 months □ in 6 months □ Other ________________ □ No □ Yes

For how long should the IRB approve this study?
□ 1 year □ 6 months □ 3 months □ Other ________________

Reviewer (print) ___________________________ Date ___________________________
Signature ___________________________
Protocol Review Worksheet: regular Reviewer

Project Title: ____________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
IRB Tracking # ________________________________________________________
Principal Investigator: _________________________________________________

Criteria for Approval

1. Risks to subjects are minimized
   □ Research procedures are consistent with sound research design
   □ Research procedures do not unnecessarily expose subjects to risk
   □ Researcher is qualified to conduct study
   □ Routine or standard procedures to be performed on subjects for the purposes of the study whenever possible
   □ The research plan makes adequate provision for monitoring the data to ensure the safety of subjects

Comments on Part 1:

2. Risks to subjects are reasonable in relation to anticipated benefits (if any), and the importance of the knowledge that may be expected to result
   □ Purpose of study is clear and acceptable
   □ Results of any related studies are included
   □ Number of subjects and duration of participation is stated and appropriate
   □ Duration of the study is clear and appropriate
   □ Compensation paid to subjects is appropriate
   Is there a washout period? If yes, □ No □ Yes
   is it appropriate □ No □ Yes
   are there safeguards to assure subject will be adequately monitored? □ No □ Yes
   Is there a placebo / no treatment control? If yes, □ No □ Yes
   is use of placebo appropriate and does not put subjects at risk? □ No □ Yes

Comments on Part 2:
3. Selection of subjects is equitable

- Justification for use of vulnerable groups provided.
- Additional safeguards have been included in the study to protect the rights and welfare of these groups.
- Presence of any special community attitudes that may affect subject participation has been addressed where applicable.
- Selection of subjects reflects purposes of the research and group that will benefit from research outcome.

Comments on Part 3:

4. Legally effective informed consent is obtained

- Informed Consent will be sought from each subject
- Informed Consent procedures and documentation appear to be appropriate

Does the protocol call for waiver of informed consent?  
- No  
- Yes

If yes, is waiver appropriate?  
- No  
- Yes

5. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Comments on Part 4 to 5:

Reviewer (print)  

Date

Signature
<table>
<thead>
<tr>
<th>Federally Required Elements</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that the study involves research</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>An explanation of the purposes of the research</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Safety and efficacy defined as a purpose (required for FDA)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The expected duration of participation (include active &amp; follow-up)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Number of visits</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>A description of the procedures, including:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Procedures at each visit matches protocol</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Procedures clearly described (in lay language)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Laboratory adequately described</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Experimental procedures defined</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>The following described:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Reasonably foreseeable risks/discomforts of the study article</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Reasonably foreseeable risks &amp; discomforts of the procedures</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Reasonably expected benefits to subjects/others</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Appropriate alternative treatments defined</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Confidentiality Statement, including:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Sponsor / funder and/or CRO access to records</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>FDA access</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>IRB access</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other (e.g. interview service)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Injury statement (if more than minimal risk), including:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Description of available compensation</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Description of available medical treatments</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>What treatment consists of, if applicable</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Who to contact for a research related injury</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Participation statement, including:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Participation is voluntary</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Refusal to participate will involve no penalty or loss of benefits</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Subject may stop participation at any time - without penalty / loss of benefits</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Who to contact for information about research</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Contact for questions about research subject's rights</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>24-hour emergency contact number?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

Comments:
### INFORMED CONSENT CHECKLIST

<table>
<thead>
<tr>
<th>Additional Elements, as Appropriate:</th>
<th>Yes</th>
<th>No</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research may involve unforeseeable risks to the subject</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Risks to pregnant women/ embryo/ fetus or nursing baby</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Costs/additional costs to subject from participation</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Circumstances under which the subject's participation may be terminated</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>without regard to the subject's consent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payment for participation described (pro-rated, reasonable)</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Procedures for orderly termination of participation</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Medical /scientific terminology defined</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>A statement that significant findings during the course of research that</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>might affect the subject’s willingness to continue participation will be</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>provided to the subject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The approximate # of subjects in the study</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Legal guardian consent, if needed</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>IRB volunteer statement included</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Institutional/Organization Required Elements</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

See consent form template for suggestions for appropriate wording

<table>
<thead>
<tr>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Primary Reviewer ___________________________ Date ____________
