

# Maintaining Credibility in the Use of Commercial Institutional Review Boards

Diana W. Lenhardt, CIM  
Clinical Trials Specialist  
Columbia St. Mary's  
Milwaukee  
dlenhardt@columbia-stmarys.org

Mark Repenshek, Ph.D.  
Healthcare Ethicist  
Columbia St. Mary's  
Milwaukee  
mrepensh@columbia-stmarys.org

*Editor's Note: We invite our readers to share their thoughts about the following article. Please submit your comments to Ron Hamel at [rhamel@chausa.org](mailto:rhamel@chausa.org).*

Leonard Weber, in his article reprinted in the "From the Field" section of the spring 2011 issue of *Health Care Ethics USA*, argues that "...commercial IRBs need to have effective measures in place to ensure that they investigate submissions thoroughly and adhere to subject protection requirements."<sup>1</sup> Although correct, Weber's locus of accountability is only partially accurate. The responders to this piece make the same misstep. None adequately addresses the locus of accountability for human subjects research review remaining with the local health care institution, whether that institution chooses to outsource the institutional review board (IRB) function or not. In doing so, these authors have attributed a level of responsibility to the commercial IRB that is equal to, if not more than, the proper responsibility of the local health care institution. The conclusions drawn by these authors are problematic both from an argumentation standpoint (i.e., their arguments critical of commercial IRBs are often predicated on the health care institution's lack of oversight of human subjects research) and from a pragmatic one (i.e., these arguments are silent on the health

care institution's abdicating this responsibility).

In this essay we will realign the obligations between a health care institution and its commercial IRB through an examination of the Federalwide Assurance (FWA) language pertaining to human subjects research. We will discuss a number of implications for a more proper understanding of this relationship, including responses to critiques of commercial IRBs in response to Weber's article in *HCEUSA* by Jack Gallagher, Ph.D., corporate director, ethics, Catholic Health Partners, and Sr. Patricia Talone, RSM, Ph.D., vice president, mission services, CHA. Finally, we will establish a set of recommendations for health care institutions that seek to utilize a commercial IRB for review of human subjects research.

## Federalwide Assurance

All human subjects research is to be guided by ethical guidelines governing the protection of human subjects involved in the research. Regardless of whether the research is subject to the U.S. Federal Policy for the Protection

of Human Subjects (also known as the Common Rule), ethical principles are to guide research subjects' protection, principles similar to those found in the World Medical Association's Declaration of Helsinki or the Belmont Report, for example. This obligation

holds for the institution engaging in human subjects research, a point that is critically important for institutions that wish to engage another IRB through a Federalwide Assurance (FWA) for review of a proposed protocol for human subjects research. The U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), in its terms for the FWA for the Protection of Human Subjects, is explicit in the obligations incumbent upon an institution engaging in human subjects research:

When the Institution becomes engaged in research to which the FWA applies, the Institution *and* institutional review boards (IRBs) upon which it relies for review of such research will comply with the Common Rule (emphasis added).

When the Institution becomes engaged in research to which the FWA applies, the Institution *and* IRBs upon which it relies for review of such research at a minimum will comply with one or more of the following:

- The Common Rule;
- The U.S. Food and Drug Administration regulations at 21 CFR parts 50 and 56; and

[Four additional guidance

documents unrelated to this article]<sup>2</sup>

Both the Common Rule and the FDA's regulations form the basis for human subjects protocol review for IRBs across the United States. The focus of these regulations is to create a uniform set of rules for the protection of human subjects. These regulations are based in large part on the Belmont Report and as such reflect similar approaches to the protection of human subjects. Of greatest importance here is that regardless of whether the health care institution chooses to utilize a commercial IRB for its review of human subjects research or maintains that review in-house, the health care institution itself is ultimately accountable vis-a-vis the FWA to adhere to the obligations set forth in the Common Rule in order to protect human subjects enrolled in research.

Beyond the regulations based in the Belmont report, the FWA requires the *Institution submitting the FWA* have established written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research (or designee), and OHRP of any (emphasis added):

- (1) Unanticipated problems involving risks to subjects or others;
- (2) Serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s); and
- (3) Suspension or termination of IRB approval.

(b) The Institution will ensure that the IRB(s) that reviews research to which the

FWA applies has established written procedures for:

- (1) Conducting IRB initial and continuing review (not less than once per year), of research, and reporting IRB findings to the investigator and the Institution;
- (2) Determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
- (3) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.<sup>3</sup>

While Weber notes that “the responsibilities of all IRBs are the same, whether commercial or organizational, and the government regulations that they are to follow and to implement are the same,”<sup>4</sup> he fails to note that the oversight of the IRB still remains with the institution that issued the FWA in minimally all of the above areas. This point is all the more important in light of Weber’s conclusion that in order for health care professionals and the public to maintain confidence in the work of commercial IRBs and IRBs in general, “...ongoing attention to their quality and professionalism is required.”<sup>5</sup> The locus of this ongoing attention to quality and professionalism is precisely that of the institution. In other words, taking the liberty

to restate Weber’s conclusion: If we—health care professionals and the public—are going to have confidence in the work that IRBs are doing, *then whether or not the health care institution utilizes a commercial IRB, it is the health care institution that remains responsible for ongoing attention to their quality and professionalism.*

Using this redrafted conclusion, light may be shed on Jack Gallagher’s two critiques of commercial IRBs. First, Gallagher makes the point that commercial IRBs may not know well the mission of the hospital for which it reviews human subjects research.<sup>6</sup> Yet, if our redrafted conclusion is a more appropriate understanding of the relationship between commercial IRBs and the institution utilizing their services, then the question should be: *Has the institution required the commercial IRB to know the mission of its hospital and the implications of that mission for review of human subjects research?* This question sets the stage for a shift in responsibility of the Catholic hospital related to the *Ethical and Religious Directives (ERDs)* and human subjects review. To Gallagher’s second critique, the question should more properly shift away from assurance that the IRB is sufficiently familiar with the ERDs to: *Has the institution (Catholic hospital) sufficiently educated the IRB on its obligations to the ERDs with regard to human subjects research?*<sup>7</sup> In both instances, Gallagher’s critiques of the relationship between commercial IRBs and the institution that utilizes its services misses an important shift from an accountability on the commercial IRB to that of an accountability of the institution itself.<sup>8</sup> (*See Addenda A and B at the end of this article or in attached PDFs.*)

Sr. Patricia Talone’s critique rightly focuses on the intersection between regulatory

obligations for community representation and commercial IRB membership. Like previous authors, however, Talone places the onus for this obligation on the commercial IRB.<sup>9</sup> This is misplaced. The administrative oversight for review of human subjects research can never be surrendered to a commercial IRB and, consequently, warrants local control *and* representation from the community in which the institution lies.<sup>10</sup> It is the recommendation of the authors that the local administrative body maintain a research oversight committee as the administrative review body for local community representation. In this way, to answer Talone's critique of commercial IRBs, membership is from the community and certainly will be required to "know and embrace the history and philosophy of the hospital and organization"<sup>11</sup> engaged in human subjects research. Although Talone does conclude her piece by noting an "opportunity" for Catholic organizations to evaluate their IRB processes to insure community participation,<sup>12</sup> this seems inadequate. Given the responsibility that a Catholic health care organization has to its vulnerable, especially those in human subjects research, there lies an *obligation* to ensure that its community has a voice in the process of review of human subjects research protocols. Of note, however, is that this obligation lies with the Catholic health care organization and not necessarily with the commercial IRB.

### Reliance on an External IRB

It seems these authors conclude that because an institution has shifted review of human subjects research protocols to a commercial IRB, there also exists a shift in ethical accountability from the institution to the

commercial IRB for human subjects research in general. This is inaccurate. All institutions, for which the FWA applies, must ensure that a written document exists outlining the commitments of the commercial IRB and the institution in which human subjects research occurs. This agreement includes a commitment that the IRB will adhere to the requirements of the institution's FWA.

To illustrate, we include a sample contract of an IRB Services Agreement that highlights the importance of contractually obligating the commercial IRB at the insistence of the institution in which the research will be conducted (Addendum C). This includes, but is certainly not limited to, the ERDs and the Mission, Vision and Values of the Catholic healthcare institution.

### Recommendations for Seeking a Commercial IRB

Regardless of institutional sponsorship or affiliation, the health care institution in which human subjects research is done should utilize a Request for Proposals (RFP) with explicit criteria guiding the commercial IRB applicants. For this RFP, the term "protocol" research review shall include, but not be limited to, the research protocol, informed consent documents, conflicts of interest disclosures, adverse event reports, subject recruitment plans, and any other related documentation necessary to perform these services. To that end, the commercial IRB should:

1. Conduct initial, expedited, and continuing review and approval of submitted protocol, protocol amendments, protocol updates for

regulatory compliance, including but not limited to, FDA, OHRP, Good Clinical Practice, HIPAA, and other federal or state regulatory compliance;

2. Review the scientific and ethical merits of the study and the protocol design, including the inclusion/exclusion criteria, consistent with the *Ethical and Religious Directives*;
3. Review the credentials and determine the qualifications of principal investigators, sub-investigators and clinical research coordinators to perform a protocol;
4. Monitor any reportable adverse events, conduct data safety monitoring, and report information to [institution] to ensure the highest level of protection for patient safety;
5. Identify, document, mitigate and monitor actual, perceived or potential conflicts of interests, including the review of financial disclosure statements;
6. Design community education programs or activities necessary to support waivers of informed consent;
7. Provide written documentation to [institution] of the review and decision-making process for each protocol, including any conflicts of interest concerns identified; and
8. Identify and report to [institution] any other issues with the protocol

identified through the review process, regardless of its source, that could reasonably impact the rights of human subjects participating in research.

### Proposal Elements and Selection Criteria

Proposals should address and/or provide:

1. The commercial IRB policies and procedures for performing the Scope of Services contained in the RFP, including an approach for transitioning the current open research studies;
2. The commercial IRB's policies and procedure for communicating with [institution], the principal investigators, and research staff about protocols under review and adverse events that are reported, specifically indicating whether the commercial IRB will designate a primary contact person for [institution];
3. The knowledge and experience of the commercial IRB, and its principals, in providing IRB services;
4. The knowledge and experience of the members of the IRB panel that would perform the Scope of Work, including a list of outside experts or other resources used by the IRB;
5. The actual average response time for protocol review and approval, specifically from the point the commercial IRB receives the protocol to [institution's] receipt of documentation of review decision;

6. The commercial IRB's policies and procedures or ability to customize its processes and forms, specifically informed consent forms, to [institution's] requirements, including the *Ethical and Religious Directives*, local community standards, etc.;
7. The commercial IRB's documentation and report policies and procedures, including any sample formats, for receiving protocols, reporting the IRB review and approval process, notification of adverse events, etc., specifically whether reports will be received or submitted in an electronic format;
8. Proposed fee schedule, including but not limited to, fees for continuing progress reports, amendment review, studies that were withdrawn prior to full review completion, and the transition of existing studies;
9. A list of any registrations and/or accreditations issued to the commercial IRB by any regulatory agencies or reviewing bodies;
10. A list of any negative citations issued against the commercial IRB by any regulatory agency; and
11. A list of the commercial IRB's references to include the names and telephone numbers, and identification of any integrated health system clients.<sup>13</sup> (See *Addendum C at the end of this article or in attached PDF.*)

## Conclusion

Utilizing a commercial IRB to review human subjects research does not condone abdicating complete ethical oversight for human subjects research to the commercial IRB. In fact, the institution in which human subjects research is conducted may not do so. Many of the critiques raised by Weber's article and those of the responders seem to be mistaken in this regard. We have discussed the importance of the FWA in ensuring that the institution in which human subjects research takes place maintains a proactive role in the conduct and oversight of that research. In the case of Catholic health care institutions, we highlighted a number of areas where ethical oversight must be maintained through the FWA and written agreements. Finally, we provide an example of an RFP reflective of the commitments that must be maintained between the Catholic health care institution and the commercial IRB. Recognizing these commitments prior to selecting a commercial IRB allows the Catholic health care provider to effectively extend and obligate the commercial IRB to the Mission, Vision, Values and the *Ethical and Religious Directives* for the Catholic health care institution for the review of human subjects research.

## Endnotes

<sup>1</sup> Leonard J. Weber, "The Credibility of Institutional Review Boards," *Health Care Ethics USA* 19, no. 2 (Spring 2011): 12-15, 13.

<sup>2</sup> HHS OHRP Federalwide Assurance for the Protection of Human Subjects found at <http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html>. Accessed on August 15, 2011.

<sup>3</sup> Ibid, found at <http://www.hhs.gov/ohrp/policy/irbgd107.html>. Accessed on August 29, 2011.

<sup>4</sup> Weber, 13.

<sup>5</sup> Weber, 15.

<sup>6</sup> John Gallagher, “Response to Weber.” *Health Care Ethics USA* 19, no. 2 (Spring 2011): 18.

<sup>7</sup> Gallagher, 18-19.

<sup>8</sup> Examples that are relevant for the work of a Clinical Trials Office at an institution that engages a commercial IRB include, “SAMPLE Administrative Approval Form for Research Protocols” *Addendum A*; SAMPLE Policy and Procedure “Research Approval Criteria, Preliminary Evaluation, and Approval Process,” *Addendum B*.

<sup>9</sup> Sr. Patricia Talone, “Response to Weber.” *Health Care Ethics USA* 19, no. 2 (Spring 2011): 21.

<sup>10</sup> 45 CFR 46.112 found at:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.112>. Accessed on August 31, 2011.

<sup>11</sup> Talone, 22.

<sup>12</sup> Talone, 22.

<sup>13</sup> A scoring matrix may be beneficial for comparing RFP from each of the commercial IRB, see *Addendum D*.



## Administrative Approval Form for Research Protocols

Date: \_\_\_\_\_  
Study Title: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_

### Required Acknowledgments:

#### Manager, Clinical Trials Operations

This study meets the approval criteria, recommend approval ☐  
This study does not meet the approval criteria, recommend denial ☐  
based on the following:

##### Does not meet:

Mission and Vision Criteria	<input type="checkbox"/>	Operational Criteria	<input type="checkbox"/>
Documentation Criteria	<input type="checkbox"/>	Legal/Compliance Criteria	<input type="checkbox"/>
Budget Criteria	<input type="checkbox"/>	IRB Criteria	<input type="checkbox"/>

Date

Comments:

#### Healthcare Ethicist, if applicable

This study meets the approval criteria, recommend approval ☐  
This study does not meet the approval criteria, recommend denial ☐  
based on the following:

##### Does not meet:

Mission and Vision Criteria ☐

Date

Comments:

#### Director, Finance, if applicable

This study meets the approval criteria, recommend approval ☐  
This study does not meet the approval criteria, recommend denial ☐  
based on the following:

##### Does not meet:

Budget Criteria ☐

Date

Comments:

#### Administrative Executive

This study meets the approval criteria, recommend approval ☐  
This study does not meet the approval criteria, recommend denial ☐  
based on the following:

##### Does not meet:

Mission and Vision Criteria ☐ Operational Criteria ☐

Date

Comments:



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**Administrative Approval Form for Research Protocols**

**Date:** \_\_\_\_\_  
**Study Title:** \_\_\_\_\_  
**Principal Investigator:** \_\_\_\_\_

Documentation Criteria ☐ Legal/Compliance Criteria ☐  
Budget Criteria ☐ IRB Criteria ☐

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**Director, Legal/Compliance, if applicable**

This study meets the approval criteria, recommend approval ☐  
This study does not meet the approval criteria, recommend denial ☐  
based on the following:

Does not meet:  
Legal/Compliance Criteria ☐

**If after detailed analysis, the study does not meet Budget or Operational Criteria and the PI has requested the study proceed to the Operations Council for review:**

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**CSM Operations Council**

This study meets the Budget and/or Operational criteria, recommend approval ☐  
This study does not meet the Budget and/or Operational approval criteria, recommend denial ☐  
Comments/Concerns Raised:

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**Date**

Comments:

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**Date of Meeting**

**Addendum B**

		<b>Policy and Procedure</b>
<b>Department</b>	<b>Title</b>	<b>Number</b>
Research	Research Approval Criteria, Preliminary Evaluation, and Approval Process	
<b>Board Approval Date</b>	<b>Executive Vice President/COO</b>	<b>Issue Date</b>
<b>Med Staff Approval Date</b>		<b>Review Date</b>

**POLICY STATEMENT:**

It is the policy of the institution to be notified of and to consistently and confidentially review all human subject research studies (“clinical research”) being conducted at an institution facility or utilizing an institution’s resources or personnel in order to determine if the study is being conducted in alignment with institution’s mission, vision, and ethical guidelines, and meets institution’s clinical research approval criteria.

The purpose of this policy is to outline:

- the approval criteria for research;
- the preliminary evaluation process for new research; and
- the approval/denial process for clinical research studies conducted at INSTITUTION.

**SCOPE:**

This policy applies to all clinical research conducted at institution.

**APPROVAL CRITERIA:**

All clinical research studies conducted at INSTITUTION or clinical research studies utilizing INSTITUTION’s resources or personnel must meet the following research criteria.

1. INSTITUTION Mission and Vision Criteria

The purpose and design of the clinical research study must be consistent with INSTITUTION’s mission to make a positive difference in the health status and lives of individuals and the community, with special concern for those who are vulnerable, in a manner that is committed to providing high quality, accessible, values-driven programs and services with equal attention to the physical, spiritual, and emotional dimensions of health. This includes, ensuring that all clinical research abides by the Ethical and Religious Directives for Catholic Healthcare Services.

## 2. Documentation Criteria

All documentation associated with the clinical research study shall be in finalized format, including, but not limited to, the study protocol, informed consent forms, regulatory submissions (IND, IDE), sponsor contract, grant agreements, investigator agreements, financial statements, privacy authorizations, schedule of events, etc.

## 3. Budget Criteria

The preliminary financial information must indicate that all professional fees, facility expenses, staff costs, and associated fees (i.e. IRB fees, recruitment costs, etc) are fully compensated at a reasonable and customary level, and a final budget must be approved by INSTITUTION's Finance Director.

## 4. Operational Criteria

A resource utilization plan must demonstrate the availability and commitment of all necessary and competent personnel (i.e. investigator, clinical research coordinator, data manager, pharmacist, nursing staff, etc.) and the accessibility of all necessary facilities and other resources needed to support the conduct of the clinical research study, and be approved by the appropriate INSTITUTION Administrative Executive.

## 5. Legal/Compliance Criteria

An approval must be obtained from INSTITUTION's Legal Department that the study documents, and operating arrangement between the participating parties comply with all applicable federal and state laws and regulations, and INSTITUTION policies.

## 6. IRB Criteria

A final, unconditional approval letter from the INSTITUTION authorized institutional review board must be obtained.

## **PRELIMINARY EVALUATION and INITIAL DETERMINATION of NEW RESEARCH:**

1. The Clinical Trials Office (CTO) conducts a preliminary evaluation of all proposed clinical research studies being conducted at INSTITUTION or utilizing INSTITUTION's resources or personnel to determine if the study is in alignment with INSTITUTION's established research criteria. The CTO uses the Preliminary Evaluation of New Research Project checklist and the established research approval criteria (as noted above) to conduct the preliminary evaluation.
2. The CTO identifies and notifies the appropriate Medical Staff member (i.e. Department Chair, Medical Director) of the proposed study.
3. The Principal Investigator (PI) must submit the following to the CTO for preliminary evaluation:
  - 3.1 All documents associated with the clinical research study, specifically the study synopsis, schedule of events, informed consent forms, and contracts; and
  - 3.2 A preliminary budget that indicates the amount the sponsor is willing to pay per

subject and the services the sponsor considers routine/standard care and those services designated as research-related/protocol specific.

4. After preliminary evaluation, the CTO will make the following initial determinations and notify the PI:
  - 4.1 Whether the proposed activity constitutes clinical research in accordance with the policy, “How to Identify Human Subject Research”; or
  - 4.2 Whether the proposed activity meets the criteria for Institutional Review Board exemption; and
  - 4.3 Whether the clinical research study is in alignment with INSTITUTION’s Research Criteria.
5. If the proposed clinical research study is determined to not constitute clinical research, the CTO will notify the PI that no further action is necessary.
6. If the clinical research study is determined to constitute clinical research and be in alignment with INSTITUTION’s research criteria, the study will pass the preliminary evaluation and proceed through the CTO for Detailed Analysis, as described below.
7. If the research study is determined to constitute clinical research, but the PI disagrees with the determination, the PI may request the INSTITUTION Research Oversight Committee to review the determination, as described in Section 9.
8. If the research study is determined to constitute clinical research, but not be in alignment with INSTITUTION’s research criteria, the study will be denied and the CTO will take no further action.
  - 8.1 In circumstances when the PI disagrees with the CTO’s initial determination that the proposed activity is not in alignment with INSTITUTION’s research criteria, except for Budget or Operational Criteria, the PI may request the INSTITUTION Research Oversight Committee to review the determination as described in Section 8.
  - 8.2 In circumstances when the PI disagrees with the CTO’s initial determination that the proposed activity is not in alignment with INSTITUTION’s research Budget or Operational Criteria, the CTO shall instruct the PI to follow the steps outlined in Section 2 of the Detailed Analysis.
9. In circumstances outlined in Section 7 above, when the study proceeds to the Research Oversight Committee for review:
  - 9.1 The Research Oversight Committee may review the initial determination at a special meeting called by the Chair or at the next regularly scheduled meeting.
  - 9.2 The Research Oversight Committee shall make a recommendation based on its review of initial determination.

- 9.3 The CTO will notify the PI of the recommendation of the INSTITUTION Research Oversight Committee.
- 9.4 Unless the CTO or PI disagrees with the recommendation, the CTO will follow the recommendation of the INSTITUTION Research Oversight Committee.
- 9.5 If either the CTO or PI disagrees with the recommendation of the INSTITUTION Research Oversight Committee, either party may request the Signatory Institutional Official to review the initial determination and recommendation. The decision of the Signatory Institutional Official shall be final.

#### **DETAILED ANALYSIS and FINAL DETERMINATION of NEW RESEARCH:**

1. If the proposed research study (i) passes the initial determination, (ii) is otherwise approved by the recommendation of the INSTITUTION Research Oversight Committee, or (iii) is approved by the Signatory Institutional Official, the CTO begins processing the research study in detail.
2. If during the detailed analysis (i.e. budget development, contract negotiation, reimbursement analysis, regulatory processing), the CTO determines that the research study no longer meets INSTITUTION's research criteria, then the Detailed Analysis stops. In that situation, the CTO immediately notifies the PI to try to rectify the situation.
  - 2.1 At this time, the PI will be advised to contact the Sponsor to discuss issues and make necessary changes to the study.
  - 2.2 If the study fails to meet INSTITUTION's Research Criteria, except for the Budget and Operational Criteria, and the Sponsor is unwilling to make necessary changes, the PI may request the INSTITUTION Research Oversight Committee to review the CTO's Detailed Analysis determination in accordance with Section 9 of the Preliminary Evaluation Section of this Policy.
  - 2.3 If the study does not meet the Budget criteria, and the Sponsor is unwilling to make necessary changes, the PI may consider seeking alternate funding sources, obtaining approval from a third-party payor to bill portions of the services, or making adjustments to the cost structure of the study. If funds are obtained, and/or changes are made to meet the Budget Criteria, the CTO will allow the study to proceed to the IRB for review.
  - 2.4 If all attempts to meet the Budget Criteria are exhausted, or the proposed research study does not meet the Operational Criteria, the PI may request INSTITUTION's Operations Council to review the CTO's initial determination or Detailed Analysis determination. INSTITUTION's

Operations Council may approve or deny that the study meets the Budget and/or Operational Criteria, and its decision on these criteria will be final. The CTO will notify the PI of the INSTITUTION Operations Council decision,

- 2.4.1 In circumstances when the study proceeds to the INSTITUTION Operations Council, the CTO provides a study summary to the INSTITUTION Operations Council in advance of their meeting to discuss the study.
  - 2.4.2 If the INSTITUTION Operations Council has any concerns regarding the study after review, those concerns must be presented to the Research Oversight Committee.
3. At the conclusion of the Detailed Analysis processing, if the clinical research study meets the Research Criteria, or is otherwise approved by the INSTITUTION Operations Council, or Signatory Institutional Official, the CTO shall then grant INSTITUTION Operational approval and allow the study to proceed to the IRB for review and approval.
  4. Once IRB approval is granted, the CTO will be prepared to make a final determination approving the study.
  5. If the study fails to meet IRB approval, and the Sponsor is unwilling to make the necessary changes to meet IRB requirements, no further action will be taken. The CTO will notify the PI of the IRB's decision to deny the study and instruct the PI to NOT enroll any human subjects.
  6. The final determination approving or denying a study shall be recorded on the INSTITUTION Administrative Approval Form for Research Protocols.

#### **FINAL DETERMINATION of APPROVAL:**

1. The INSTITUTION Operational approval and the IRB approval must both be granted in order to receive a final determination approving the study.
2. Once the CTO is prepared to make a final determination, the CTO shall grant a final determination approving the study. Thereafter, the study may commence to enroll human subjects.
3. In order for a study to receive a final determination of approval, the study must receive INSTITUTION Operational approval and IRB approval. Operational or IRB approval alone does not constitute a final determination of approval. The operational approval shall be granted prior to obtaining IRB approval. If the PI would like the study to proceed to the IRB prior to receiving operational approval, the CTO notifies the PI that if the study does not receive operational approval, the PI remains responsible for any IRB fees associated with the IRB review.

**END POLICY**



**SCORING CRITERIA: 1-10**  
 0 = Not Provided or Addressed  
 1 = Poor  
 5 = Average  
 10 = Excellent

**Addendum C**

**IRB Proposal Evaluation Matrix**

	IRB 1	IRB 2	IRB 3			Notes
<b>1. Adherence to RFP Instructions</b>						
Timeliness						
Completeness						
Overall quality and professionalism						
Overall responsiveness						
Average Score						
<b>2. Thoroughness of Review - High Priority</b>						
Expertise						
Interaction with Site and PI						
Dedicated Contact Person						
Policies and Procedures						
Average Score						
<b>3. Timing - High Priority</b>						
Actual Response Time						
Score						
<b>4. Cost - Medium Priority</b>						
Costs						
Score						
<b>5. Customization - High Priority</b>						
Religious Directives						
Other						
Average Score						
<b>6. Reports and Documents - Medium Priority</b>						
Electronic Submission						

**SCORING CRITERIA: 1-10**  
 0 = Not Provided or Addressed  
 1 = Poor  
 5 = Average  
 10 = Excellent

<b>IRB Proposal Evaluation Matrix</b>	<b>IRB 1</b>	<b>IRB 2</b>	<b>IRB 3</b>			<b>Notes</b>
Supporting Information						
Average Score						

<b>7. Experience of Reviewers, Credentials - High Priority</b>						
Work with Other Health Systems						
List of References						
FDA Reports						
Accreditation						
Negative Citations						
Average Score						

<b>8. Transition of Studies - Lower Priority</b>						
Approach						
Timing						
Cost						
Average Score						

<b>9. Continuing Education of IRB - Lower Priority</b>						
Panel Bios						
Score						

<b>TOTAL SCORE:</b>					
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