

INSTITUTIONAL REVIEW BOARD BY-LAWS FOR
CHARLESTON AREA MEDICAL CENTER, INC.
CAMC HEALTH EDUCATION AND RESEARCH INSTITUTE
ROBERT C. BYRD HEALTH SCIENCE CENTER AT WEST
VIRGINIA UNIVERSITY CHARLESTON DIVISION

A. Mandate

The Institutional Review Board (IRB) for the Protection of Human Subjects for the Charleston Area Medical Center, Inc (CAMC, Inc.), the Robert C. Byrd Health Sciences Center of West Virginia University Charleston Division (WVU–Charleston Division) and the CAMC Health Education and Research Institute (CAMC Institute) functions under the mandate of the Board of Directors of the CAMC Institute with the leadership and direction of the Associate Vice President (AVP) of WVU-Charleston Division and the President of the CAMC Institute (hereafter referred to as the Institutional Official). The IRB is responsible for reviewing all research involving human subjects conducted at CAMC facilities, by members of CAMC’s Medical Staff or at or by other health care, government or educational organizations in CAMC’s service area to ensure that it follows ethical principles and that it is carried out in accordance with applicable regulations.

B. The IRB

1. Membership

The IRB is composed of "regular" members, including the Chair and Vice Chair. Members have varying backgrounds to promote complete and adequate review of research activities. The number of regular members on the Board shall not exceed fifteen, some of whom must be non-scientific and /or non-affiliated members. “Alternate” members fill in for regular members when necessary. Alternate members are invited to attend all meetings and are required to attend at least one meeting per year.

2. Appointment and Term

The CAMC Institute Board of Directors appoints regular and alternate members of the IRB. The term of service is two (2) years with potential for renewed terms upon nomination as stated below

Whenever a vacancy occurs, the IRB Chair will send recommendation for nomination of new members and alternates to the Institutional Official. The Institutional Official will nominate new members and alternates to CAMC Institute Board of Directors. The Associate Vice President (AVP) for the West Virginia University Charleston Division will be consulted if nominees are faculty or staff members of WVU-Charleston prior to the submission to the Board of Directors.

When a regular member vacancy occurs, the member’s alternate may serve as a regular member until the CAMC Institute Board of Directors appoints a new regular member. The CAMC Institute Board of Directors and/or the Institutional Official may remove a regular or alternate member from service with or without cause.

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The Institutional Official will consult with the AVP before removing a regular or alternate member who is a WVU-Charleston faculty or staff member.

3. *Duties of Members*

IRB members have the following duties:

- Uphold federal and state regulations, institutional policies and procedures and ethical standards for the protection of human subject research.
- Attend IRB meetings.
- Perform review of projects as assigned.
- Interpret federal regulations, IRB guidelines and procedures to investigators.
- Participate in periodic revisions of the IRB guidelines.
- Request that the alternate attend a meeting in the event the regular member cannot do so.
- Inform the administrative staff if unable to attend a meeting.
- Keep confidential any information specific to human subjects and maintain general confidentiality with IRB business.
- Participate in continuing education on human subject research.

4. *Conflicts of Interest*

No IRB member may participate in the discussion of a protocol for which he or she is an investigator unless invited to do so by the IRB. No IRB member may vote on a protocol for which he or she is an investigator or has any conflict of interest.

5. *Duties of Alternate IRB Members*

Alternate members will be invited to all regular meetings and will have the following duties:

- Uphold federal and state regulations, institutional policies and procedures and ethical standards for the protection of human subject research.
- Attend at least one IRB meeting per year.
- Attend IRB meetings as requested when a regular member cannot attend.
- When the regular member is not in attendance than the alternate members assumes a proxy vote.
- Review IRB materials based on Federal regulations and Institutional Policies.
- Participate in continuing education on human subject research activities.

C. The Chair and the Vice Chair of the IRB

The CAMC Institute Board of Directors appoints the Chair and Vice Chair from nominations made by the Institutional Official. The Institutional Official will obtain the approval of the AVP if the Chair or Vice Chair is a faculty or staff member of the WVU-Charleston Division.

The CAMC Institute Board of Directors and/or the Institutional Official can remove the Chair and or the Vice Chair from service. The Institutional Official will consult with the AVP before removing the Chair or Vice Chair if the Chair or Vice Chair is a faculty or staff member of the WVU-Charleston Division.

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The Chair has the following duties:

- Uphold federal, state and local regulations, institutional policy and procedures and ethical standards for the protection of human subjects in research.
- Chairs all regular meetings or special sessions of the IRB. Works with the Vice Chair to assist in meeting functions. The Vice Chair performs the Chair's duties when the Chair is not available or has a conflict of interest.
- Performs all functions of a regular IRB member. Act on behalf of the IRB, when appropriate, to suspend research pending IRB review of unanticipated problems involving risk to human subjects and/or noncompliance.
- Ensures prompt reporting to the Institutional Official, AVP for the WVU-Charleston Division, the federal Office of Human Subjects Protection and others as needed of any unanticipated problems involving risk to human subjects and/or noncompliance.
- Represents the IRB in dealings with the public when attendance of the total membership is not required.
- Participates in or designates others to participate in sessions designed to inform and educate WVU-Charleston Division faculty, and CAMC, Inc. staff concerning the aims and functions of the IRB.
- Appoints special consultants to review protocols and provide assistance to the IRB when deemed necessary.
- Has the authority to authorize emergency changes to a protocol to avoid an immediate hazard to subjects.
- Works with the Institutional Official to recommend and implement necessary or desirable change to the Bylaws.
- Evaluated potential IRB members and recommends new members to the Institutional Official for appointment.
- Schedules emergency meeting or cancels meeting when necessary.

The Vice Chair will substitute for the Chair to fulfill the above functions when necessary and as requested by the Chair. In the event that Chair or the Vice Chair are unable to perform the above functions the Chair will designate another member to serve in this role on a temporary basis.

D. Administrative Staff

The IRB administrative staff is drawn from the personnel of the CAMC Institute's Department of Research and Grants Administration. Administrative staff will work with the IRB and perform the following duties:

- Uphold federal and state regulations, institutional policy and procedures and ethical standards for the protection of human subjects in research.
- Serve as the administrator of the IRB to uphold federal regulations protecting human subjects participating in research
- Maintain accurate files, minutes and records for the IRB
- Maintain ongoing education in human subject research protections for IRB members, investigators and research personnel.

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- Provide guidance regarding federal regulations and institutional procedures to investigators, research staff and others.
- Screen all protocols for conformity with the required format.
- Determine whether research is exempt from IRB review on behalf of the IRB.
- Advise investigators of any additions or modifications, which are necessary before sending a protocol for review.
- Assign primary and secondary reviewers for protocols requiring IRB review.
- Provide timely copies of all appropriate materials to investigators, IRB members and study coordinators.
- Coordinate IRB meetings including preparation of the agenda and minutes.
- Maintain records concerning all protocols, continuing education credits for members and alternates and other IRB activities.
- Participate in on-site reviews by federal inspectors of IRB procedures and records.
- Forward copies of the minutes of each meeting to the Institutional Official the AVP of WVU-Charleston Division and Alternated Members.
- Keep confidential any information specific to human subjects and maintain general confidentiality with IRB business.

E. Special Consultants

The Chair may designate a consultant with special expertise to assist in the review of a particular protocol. The appointment of a special consultant is subject to the approval of the investigator whose protocol is being reviewed. If approval is not given, the IRB may refuse to act on the protocol.

F. Meetings

1. Date and Time

The IRB will set regular monthly meeting times at intervals necessary and acceptable. Special meetings may be requested by regular member/s or the Institutional Official and called by the Chair.

2. Agenda

The IRB will review, discuss and act on all protocols on the agenda.

3. Voting

A majority of the members of the IRB entitled to vote shall constitute a quorum and be required to conduct business. A majority of those eligible to vote and present at the meeting is required for IRB action. One unaffiliated, non-scientific member must be present. IRB members or alternate members may vote on research protocols or issues if they have a conflict of interest and must leave the room during discussion and voting on such projects.

4. Minutes

The minutes of the IRB meetings shall reflect the conduct of each meeting of the IRB Membership sufficient to document, at minimum, the attendance, the actions taken and votes on research protocols to include the number of members voting for, against and abstaining, the next review date, the basis for requiring changes in or disapproving

research, a written summary of the discussion and resolution of controversial issues and arrival and departure of members during the convened meeting. The minutes may also contain additional information that reflects the length of the meeting, decisions on protocols made outside of the IRB meeting, actions on other items of business and a listing of informational/educational items. The IRB minutes should also document determinations required by the regulations and specific information justifying each determinations (e.g., research involving pregnant women, children, prisoners, waiver of consent of waiver of documentation of consent).

After the minutes have been approved by the IRB, a copy is to be sent to the Institutional Official, the AVP of the WVU-Charleston Division and Alternate IRB Members.

G. Attendance of Investigators at Board Meetings

The Principal Investigator is required to be present at the IRB meeting for which his/her protocol is scheduled to be reviewed. If the Principal Investigator cannot be present, he/she may request to the Chair, in writing, that a designee (another investigator and/or research coordinator) attend the meeting to answer questions related to the research protocol. With approval of the Chair, the designee may attend the meeting. Protocols for which no investigator or designee is present may not be reviewed by the IRB.

H. Changes to the By-Laws

The Chair will work with the Institutional Official to recommend and implement necessary or desirable changes to these Bylaws. The CAMC Institute Board of Directors shall have the sole authority to amend these Bylaws.

The CAMC Institute Board of Directors approved changes at the August 13, 2003, February 13, 2002 and the August 14, 2002 meetings.

* Voted and approved by the CAMC Health Education and Research Institutes' Board of Directors on February 13, 2002

***Revised** on August 14, 2002 by CAMC Institutes' Board of Directors

***Revised** on August 13, 2003 by CAMC Institutes' Board of Directors

***Revised** on August 10, 2005 by CAMC Institutes' Board of Directors

***Revised** on February 8, 2006 by CAMC Institutes' Board of Directors

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A. Purpose

The Institutional Scientific Review Board (“ISRB”) for Charleston Area Medical Center, Inc. (“CAMC”), the Robert C. Byrd Health Sciences Center of West Virginia University/Charleston Division (“WVU-Charleston”) and CAMC Health Education and Research Institute, Inc. (“CAMC Institute”) was established to formally review all proposed “Investigator-initiated” research studies for scientific validity. The ISRB functions under the mandate of the Board of Directors of the CAMC Institute with the leadership and direction of the Associate Vice President (AVP) of WVU-Charleston Division and the President of the CAMC Institute (hereafter referred to as the Institutional Official). The ISRB serves is separate and distinct from the Institutional Review Board for the Protection of Human Subject (“IRB”) and was established to support and strengthen the scientific review process conducted at CAMC facilities, by members of CAMC’s Medical Staff, or at or by other health care, governmental or education organizations in CAMC’s service area.

B. The ISRB

1. Membership

The ISRB is composed of “regular” members, including the Chair and Vice Chair, who represent the research disciplines and other research professionals. Regular member has a designated “alternate” member who fills in for regular members when necessary. Members should have previous experience with Investigator-initiated research as a Principal Investigator or Co-Investigator. ISRB members may not serve concurrently on the Institutional Review Board. The number of regular members on the ISRB shall not be less than five (5) or more than eleven (11).

2. Appointment and Term

The CAMC Institute Board of Directors appoints regular and alternate members to the ISRB membership. The term of service is two (2) years with renewed terms upon nomination as stated below.

Whenever a vacancy occurs, the ISRB Chair will send recommendation for nomination to the Institutional Official. The Institutional Official will nominate new members and alternates to the CAMC Institute Board of Directors. The Associate Vice President (AVP) of the West Virginia Division will be consulted if nominees are faculty or staff members of the WVU-Charleston Division.

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When a regular member vacancy occurs, the member's alternate may serve as a regular member until the CAMC Institute Board of Directors appoints a new regular member. The Institutional Official will consult with the AVP before removing a member or alternate who is a WVU-Charleston Division faculty or staff member.

3. *Duties of Members*

ISRB members have the following duties:

- Uphold federal and state regulations, institutional policies and procedures and ethical standards for the protection of human subject research.
- Attend ISRB meetings.
- Interpret federal regulations, and ISRB policies and procedures to investigators.
- Participate in periodic revisions of the ISRB Policies and Procedures.
- Request the alternate attend a meeting in the event the regular member cannot do so.
- Inform the administrative staff if unable to attend a meeting.
- Carry out consultations as requested.
- Serve on the Appeals Committee when appointed by the ISRB.
- Keep confidential any information specific to human subjects and maintain general confidentiality ISRB business.

4. *Conflict of Interest*

No ISRB member may participate in the discussion of a protocol for which he or she is an investigator unless invited to do so by the ISRB. No ISRB member may vote on a protocol for which he or she is an investigator or has any conflict of interest.

5. *Duties of Alternate Members*

Alternate members will be invited to attend all meetings and have the following duties:

- Uphold federal and state regulations, institutional policies and procedures and ethical standards for the protection of human subject research.
- Attend at least one ISRB meeting per year.
- Attend ISRB meetings as requested when a regular member cannot attend.
- When the regular member is not in attendance than the alternate member assumes a proxy vote.

C. THE CHAIR AND VICE CHAIR OF THE BOARD

The CAMC Institute Board of Directors appoint the Chair and the Vice Chair from nominations made by the Institutional Official. The Institutional Official will obtain the approval of the AVP if the Chair or Vice Chair is either a faculty or staff member of the WVU-Charleston Division.

The CAMC Institute Board Directors and/or the Institutional can remove the Chair and/or the Vice Chair from service. The Institutional Official will consult with the AVP before removing the Chair or Vice Chair if the Chair or Vice Chair is a faculty or staff member of the WVU-Charleston Division.

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The Chair has the following duties:

- Chairs regular meetings or special sessions of the ISRB. Works with the Vice Chair to assist in meeting functions. The Vice Chair performs the Chair's duties when the Chair is not available or has a conflict of interest.
- Uphold federal and state regulations, institutional policy and procedures and ethical standards for the protection of human subjects in research.
- Performs the function of a regular ISRB member.
- Represents the ISRB in dealings with the public when attendance of the total membership is not required.
- Participates in or designates others to participate in sessions designed to inform and educate WVU-Charleston Division faculty, CAMC Institute staff and CAMC, Inc. staff concerning the aims and functions of the ISRB.
- Appoints special consultants to review protocols and provide assistance to the ISRB when that need is deemed necessary.
- Cancels meetings when there is no immediate business.
- Works with the Institutional Official to recommend and implement necessary or desirable changes to the Bylaws.
- Schedules emergency meeting or cancels meetings when necessary.

The Vice Chair will substitute for the Chair to fulfill the above functions when necessary and as requested by the Chair. In the event that the Chair or the Vice Chair are unable to perform the above functions the Chair will designate another member to serve in this role on a temporary basis.

D. ADMINISTRATIVE STAFF

The administrative staff is drawn from the personnel of CAMC Institute's Office of Research and Grants Administration. The administrative staff will work with the ISRB to perform the following duties:

- Serves as the administrator of the ISRB.
- Maintain accurate files, minutes and records for the ISRB.
- Maintain ongoing education in human subjects research protection and scientific review for ISRB members, investigators and research personnel.
- Uphold federal and State regulations, institutional policy and procedures and ethical standards for the protection of human subjects in research.
- Distribute ISRB Policies and Procedures to faculty, staff and students and provide guidance in the development of protocols.
- Screen all protocols for conformity with the required format.
- Advise investigators of any additions or modifications, which are necessary before sending a protocol for review.
- Assign primary and secondary reviewers for protocols requiring IRB review.
- Provide timely copies of all appropriate materials to investigators, ISRB members and study coordinators.
- Coordinate ISRB meetings including preparation of the agenda and minutes.
- Prepare and forward the Institutional Assurance of Scientific Review of a protocol to the Institutional Review Board.

- Maintain records concerning all protocols, continuing education credits for members and alternates and other ISRB activities.
- Forwards copies of the minutes of each meeting to the Institutional Official and the AVP of WVU-Charleston Division and Alternate Members.
- Keep confidential any information specific to the human subjects and maintain general confidentiality with ISRB business.

E. SPECIAL CONSULTANTS

The Chair may designate a consultant with special expertise to assist in the review of a particular protocol. The appointment of a special consultant will be made in consultation with the Investigator whose protocol is being reviewed. If the consultant cannot be agreed upon, the ISRB may refuse to act on the protocol.

F. MEETINGS

1. *Date and Time*

The ISRB will set regular monthly meeting times at intervals necessary and acceptable. Special sessions may be requested by member/s or the Institutional Official and called by the Chair.

2. *Agenda*

The ISRB will review, discuss and act on all protocols on the agenda.

3. *Voting*

A majority of the members of the ISRB entitled a vote shall constitute a quorum and shall be required to conduct business. The vote of a majority of those eligible to vote at a meeting at which a quorum is present is required for ISRB action. ISRB members or alternate members may not vote on research protocols or issues if they have a conflict of interest and must leave the room during discussion and voting on such projects.

4. *Minutes*

The minutes of the ISRB meetings shall reflect the conduct of each meeting of the ISRB membership sufficient to document, at a minimum, the attendance, the actions taken and votes on research protocols to include the number of members voting for, against and abstaining, the next review date, the basis for requiring changes in or disapproval of a research protocol, a written summary of the discussion and resolution of controversial issues and arrival and departure of members during the convened meeting. The minutes may also contain additional information that reflects the length of the meeting, decisions on protocols made outside of the ISRB meeting, actions on other items of business and a listing of information/educational items.

After the minutes have been approved by the ISRB, a copy is to be sent to the Institutional Official, the AVP of the WVU-Charleston Division and Alternate ISRB Members.

G. ATTENDANCE OF INVESTIGATORS AT BOARD MEETINGS

The Principal Investigator is required to be present at the ISRB meeting at which his/her protocol is scheduled for review. If the Principal Investigator cannot be present, he/she may request, in writing to the Chair, in writing, that a designee (another investigator and/or research coordinator) attend the meeting and answer questions related to the research protocol. With approval of the Chair, the designee may attend the meeting. Protocols for which no investigator or designee is present may not be reviewed by the ISRB.

H. CHANGES TO GUIDELINES/BY-LAWS

The Chair will work with Institutional Official to recommend and implement necessary or desirable changes to these Bylaws. The CAMC Institute Board of Directors shall have the sole authority to amend these Bylaws.

The CAMC Institute Board of Directors approved changes at the February 13, 2002 and the August 14, 2002 board meeting. Updated upon the next amendment.
Revised August 13, 2003

* Voted and approved by the CAMC Health Education and Research Institutes' Board of Directors on February 13, 2002

***Revised** on August 14, 2002 by CAMC Institutes' Board of Directors

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***Revised** on August 10, 2005 by CAMC Institutes' Board of Directors

***Revised** on February 8, 2006 by CAMC Institutes' Board of Directors