SECTION 3
IRB Membership

3.1 IRB Membership (Reviewed 7/1/10)
IRB will conduct its business with the participation of voting members and if needed, ad hoc reviewers.

3.2 Composition of IRB (Revised 7/1/10)
The IRB is an appropriately constituted administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities. In accordance with the Federal regulations (45 CFR 46) of the Department of Health and Human Services (DHHS) and the applicable regulations (21 CFR 50 and 56) of the Food and Drug Administration (FDA) the IRB has the authority to approve, require modification in (in order to approve), or disapprove all research activities involving humans that fall within its jurisdiction. Federal regulations 45 CFR 46.107 and 21 CFR 56.107 outline the requirements for the composition of institutional review boards.

The IRB will have at least seven regular, voting members, including the chairperson, with varying backgrounds to promote complete and adequate review of research activities. The number of members may be expanded beyond the minimum of seven. The members shall be selected based on experience and expertise, diversity (including race, gender and ethnic origin) and sensitivity to community attitude and shall include representatives from nursing, pharmacy, risk management and the community.

The IRB will include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in the non-scientific area.

The IRB will include in its membership at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

At least one scientific member of the IRB will have had experience in research involving human subjects.

One non-scientist member will have expertise in human rights issues and/or ethical and legal issues considered to be relevant to human subject research.

The IRB will ascertain that its membership possesses the professional competence necessary to review human subject research and can judge the acceptability of the research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
Non-voting members will include a representative from the Finance Department and Regulatory Readiness Coordinator.

No IRB member may participate in the IRB's initial or continuing review of any study in which the member has a conflicting interest, except to present or assist in presenting the protocol or provide information requested by the IRB.

The IRB, at its discretion, may invite scientists or non-scientists from within or outside of TMH who are not members of the IRB and who have special expertise to function as ad hoc reviewers of a project application to assist the IRB in its review process. These ad hoc reviewers will have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but may not vote with the IRB except in as indicated for research involving prisoners.

If the IRB reviews research-involving prisoners as subjects, at least one individual participating in the review of such research will have the appropriate experience to serve as a prisoner representative. This individual may be an ad hoc member, contributing to the quorum and vote only for projects involving prisoners.

3.3 Appointment Chairperson (Reviewed 7/1/10)

The IRB will have a chairperson who has the qualifications of a scientist member of the IRB, is concerned about human rights and ethical issues, is well-informed in regulations relevant to the use of human subjects in research, and has served on the IRB for at least twelve months.

The chairperson will be appointed by the President/Chief Executive Officer (CEO) for renewable two-year terms beginning in July. This is indicated in the appointment letter.

The process for the renewal of the term of appointment of the chairperson will be initiated by the majority of the voting IRB members. The request for renewal will be submitted by the IRB membership to the President/CEO for approval. If the current chairperson does not wish to extend his/her appointment, or the IRB or President/CEO does not approve the reappointment, the procedures for the selection of a new chairperson will be activated. The IRB may provide, or the President/CEO may request, the nomination of more than one eligible member of the IRB. The President/CEO will approve one of the nominees for appointment.

The IRB Chair is evaluated by the President/CEO, with input from the IRB Administrative Liaison on an annual basis. The major criteria for the evaluation are knowledge of IRB regulations, attendance at Board meetings and leadership of the IRB, support of the IRB staff, and availability to deal with IRB related issues from investigators.

The Chair will appoint a Vice-Chair. This role is filled by a senior member of the IRB to assume the responsibilities of the chairperson during any period of the chairperson’s absence. Whenever the chairperson or vice-chairperson is not available, the
chairperson may designate a senior member of the IRB to assume the responsibilities of the chairperson during the period of his/her absence.

3.3.1 Terms and Conditions of Service (Reviewed 7/1/10)

The Chair has full voting rights, with the exception that s/he may not participate in a committee decision on a matter in which s/he has a conflict of interest, as defined in Conflict of Interests.

Upon appointment to the IRB, a current copy of Chair's Curriculum Vitae (CV) must be provided to the IRB and maintained on file. Updated copies of members’ CVs are requested as re-appointments are made to the IRB.

The Chair of the IRB is expected to read all new protocols, continuing review protocols, amendments/revisions/adverse event reports, ethical issues pertinent to human subject protections and other administrative meeting materials before a meeting and to facilitate the meeting discussions.

The Chair of the IRB is expected to act on behalf of the IRB in reviewing and approving the expedited and exempt study materials submitted between IRB meetings, provide consultation to Board and Office of Research/IRB staff regarding research topics.

The Chair of the IRB is expected to attend all scheduled meetings of the IRB. When the Chair is unable to attend a scheduled meeting of the IRB, arrangement should be made in advance with the Vice-Chair or another senior Board member to facilitate the meeting. This information should be provided to the Office of Research/IRB.

A chair who is absent without notifying the Office of Research/IRB two meetings in a row or who is unable to attend at least 20% of the meetings in a rolling year may have her/his membership on the Board terminated.

The Chair will receive a parking voucher for each meeting attended and may receive an honorarium of $160. The honorarium is to recognize the work done PRIOR to the Board meeting in preparation for the meeting. It is not for merely attending the meeting. The Consent Agenda is to be completed PRIOR to the meeting. The form “Institutional Review Board (IRB) Protocol Review Standards” on colored paper used for reviewing new studies is to be completed PRIOR to the meeting. These forms are turned in and archived.

When the Chair is not able to attend a scheduled meeting of the IRB sufficient advance notice should be provide to the Office of Research/IRB of the intended absence(s), preferably at least ten working days. No IRB Review book will be distributed. A suitable substitute should be appointed to chair the meeting.

However, if an urgent unexpected situation arises after the IRB meeting material has been reviewed, contact the Office of Research/IRB promptly to notify the Board of the unexpected absence, turn in the completed Consent Agenda and Institutional Review Board (IRB) Protocol Review Standards sheet to the Office of Research/IRB. This
documentation will be attached with the guideline to document the approval for processing the honorarium. It is expected that such instances will be infrequent.

3.4 Voting Members (Reviewed 7/1/10)

The IRB solicits nominations. A nominating sub-committee will be assembled as needed.

It is incumbent upon the individual nominating the candidate for review to discuss the submission and determine the candidate’s interest in the position. The candidate should be informed of the obligations of being a Board member prior to the nomination. The CV/Resume of the recommended candidate(s) is submitted to the Board for approval. The nominated member is submitted to the President/Chief Executive Officer (CEO) of TMH for appointment to the IRB.

3.4.1 Terms and Conditions of Service (Revised 7/1/10)

Members are appointed for three-year terms. This is indicated in the appointment letter. The term of membership will be renewable for additional three-year periods without limit, as long as a member continues to possess the required qualifications. In case a member is chosen to become the chairperson, the duration of his/her membership will be extended automatically, to allow completion of the term of appointment as a chairperson.

In the case of reappointment, the IRB chairperson will review with a member in the last year of a three-year term the suitability of continuation into the next three-year term. If the consensus is continuation, the chairperson will recommend the reappointment to the President/CEO.

Each regular IRB member has full voting rights, with the exception that a member may not participate in a committee decision on a matter in which he/she has a conflict of interest, as defined in Conflict of Interests. The Prisoner Representative ad hoc member will only contribute to a quorum and may vote only when studies that involve prisoners are undergoing review.

Upon appointment to the IRB, a current copy of each member’s Curriculum Vitae (CV) must be provided to the IRB and maintained on file. Updated copies of members’ CVs are requested as re-appointments are made to the IRB.

All IRB members are expected to read all new protocols, continuing review protocols, amendments/revisions/adverse event reports, ethical issues pertinent to human subject protections and other administrative meeting materials before a meeting and to participate in meeting discussions.

Voting members of the Board are provided a parking voucher for each meeting attended and may receive an honorarium of $160. The honorarium is to recognize the work done
PRIOR to the Board meeting in preparation for the meeting. It is not for merely attending the meeting. The Consent Agenda is to be completed PRIOR to the meeting. The form “Institutional Review Board (IRB) Protocol Review Standards” on colored paper used for reviewing new studies is to be completed PRIOR to the meeting. These forms are turned in and archived.

Members of the IRB who are not able to attend a scheduled meeting of the IRB should provide sufficient advance notice of the intended absence(s), preferably at least 15 working days, to the Office of Research/IRB. No IRB Review book will be distributed when and absence is expected.

However, if an urgent unexpected situation arises after the IRB meeting material has been reviewed, contact the Office of Research/IRB promptly to notify the Board of the unexpected absence, turn in the completed Consent Agenda and Institutional Review Board (IRB) Protocol Review Standards sheet to the Office of Research/IRB. This documentation will be attached with the guideline to document the approval for processing the honorarium. It is expected that such instances will be in frequent.

Members of the IRB are expected to attend all scheduled meetings of the IRB. Members who are absent without notifying the Office of Research/IRB three meetings in a row or who are unable to attend at least 50% of the meetings in a rolling year may have their membership on the Board terminated.

When the agenda includes protocols that involve vulnerable populations, the Office of Research/IRB staff is responsible for ensuring that at least one member attending the meeting has knowledge and experience in working with the study population.

The TMH IRB reserves the right to reschedule protocols for review based on the experience and expertise of the members attending the IRB meeting and/or to seek expert consultation if deemed necessary.

3.5 Non-voting Members (Revised 7/1/10)

The IRB Chair and Regulatory Readiness Coordinator appoint non-voting members as needed to provide a particular expertise or consultation that may add to the benefit of the Board. Representatives from the Finance Department and Regulatory Readiness Coordinator serve as non-voting members.

Non-voting members do not count toward the meeting quorum.

Non-voting IRB members are not compensated for their service on an IRB (i.e., for attending meetings and for reviewing the protocol or other information).

Members are appointed for three-year terms. This is indicated in the appointment letter. The term of membership will be renewable for additional three-year periods without limit, as long as a member continues to possess the required qualifications.
In the case of reappointment, the IRB chairperson will review with a member in the last year of a three-year term the suitability of continuation into the next three-year term. If the consensus is continuation, the chairperson will recommend the reappointment to the Regulatory Readiness Coordinator.

Upon appointment to the IRB, a current copy of each member's Curriculum Vitae (CV) must be provided to the IRB and maintained on file. Updated copies of members’ CVs are requested as re-appointments are made to the IRB.

Members of the IRB are expected to attend all scheduled meetings of the IRB. All IRB members are expected to read all new protocols, continuing review protocols, amendments/revisions/adverse event reports, ethical issues pertinent to human subject protections and other administrative meeting materials before a meeting and to participate in meeting discussions.

Members of the IRB who are not able to attend a scheduled meeting of the IRB should provide sufficient advance notice (Preferably at least 15 working days to avoid making a review book,) to the Office of Research/IRB of the intended absence(s).

3.6 Removal of Member (Reviewed 7/1/10)

When a Board member consistently fails to attend IRB meetings or fails to meet expectations, the IRB Chair and Regulatory Readiness Coordinator or Administrative Liaison meet with the Board member to determine the cause. If the IRB member indicates an inability to continue to function effectively as an IRB member, the member will be thanked for her/his service on the Board and relieved of her/his post. The Board will be notified at the next scheduled IRB meeting of the vacancy. Nominations to fill the position will be sought and a subcommittee convened if necessary.

Members who do not adequately fulfill their responsibilities, as judged by the IRB Chair may be asked to step down from IRB membership by the Chair and/or IRB Administrative or Regulatory Readiness Coordinator.

Members of the IRB may be removed before the end of their term if their participation in IRB activities is deemed to be inadequate, inappropriate, or damaging to the reputation of TMH and its research activities.

3.7 IRB Performance Review (Revised 7/1/10)

The IRB is routinely evaluated for performance, composition, and attendance by the IRB Chair and the Regulatory Readiness Coordinator or IRB Administrative Liaison. The Regulatory Readiness Coordinator and IRB Administrative Liaison meets with the IRB Chair as needed for "state of the IRB" discussions and feedback is freely exchanged about what Board activities need to be addressed, updated, clarified, and the IRB Chair identifies administrative office issues that the Regulatory Readiness Coordinator and IRB Administrative Liaison need to address.
The IRB Administrative Liaison reports the findings of the IRB meetings to the Professional Affairs Committee on a quarterly basis to ensure communication to the TMH Board.

3.8 IRB Member Conflict of Interest (Reviewed 7/1/10)

No member of the IRB may participate in the initial, continuing review (may provide information or clarification as necessary but may not vote), or amendment of any protocol in which the member has a conflict of interest. Serving as an investigator or co-investigator on a study is always a conflict of interest. Conflicts of interest may be either financial or non-financial.

At a convened meeting of the IRB, any member who has a conflict of interest must leave the room and not participate in the vote on the relevant protocol. The absent IRB member does not count toward the meeting quorum. Absence from the meeting due to conflict of interest is documented in the minutes of the meeting. The same policies apply to an IRB Chair or Vice-Chair performing expedited reviews.

3.9 Orientation and Education (Reviewed 7/1/10)

New members of the IRB will receive a letter of appointment and meet with the IRB Chair and Regulatory Readiness Coordinator. The orientation session will review the functions of IRB members, discuss the confidentiality rules of the IRB, and review the member conflict of interest policy. Each new member is provided with an extensive outline of important topics and given various references for information on those topics. Opportunities for additional education are also provided.

IRB members must have the National Institute of Health IRB Computer Based Training certificate of Completion on file after 1/1/2007 if they did not complete one of the previously accepted courses. Relevant articles are routinely distributed to IRB members to further their knowledge and educational opportunities are provided at the IRB meetings enhance members’ knowledge of regulations and information relating to protection of human subjects.