

Baystate Medical Center

Division of Academic Affairs

POLICY

INDUSTRY SPONSORED CLINICAL TRIAL AGREEMENTS

Baystate Medical Center, Baystate Health, Inc. and its affiliates (“Baystate”) are tax-exempt organizations. The charitable mission of these organizations includes promoting quality research that contributes to the advancement of scientific and medical knowledge. In furtherance of its mission and to promote research of the highest quality, Baystate has achieved full accreditation from the Association for the Accreditation of Human Research Protection Programs (“AAHRPP”).

Baystate supports participation in research sponsored by unaffiliated entities when the research is related to its mission and consistent with its tax-exempt status and the requirements of AAHRPP accreditation. A clinical trial agreement with an unaffiliated entity cannot violate pertinent standards.

All clinical trial agreements must demonstrate Baystate’s adherence to applicable laws, regulations, and standards. Certain terms are especially important.

I. STATEMENT OF PURPOSE

The agreement should contain a statement to the effect that the research contemplated by the agreement is in the public interest and is related to Baystate’s charitable mission of promoting quality research that contributes to the advancement of scientific and medical knowledge.

II. EXCULPATORY CLAUSES

A clinical trial agreement cannot contain any language that would eliminate or limit any legal right of a subject.

III. BAYSTATE REAL PROPERTY

The tax exempt status of certain Baystate property may be threatened if the property is preferentially provided for the advancement of private interests. The agreement must not grant the sponsor preferential rights over the use of Baystate property.

IV. PUBLICATION RIGHTS

The agreement should insure that the results of the clinical trials will be in the public domain and that the research is intended to further scientific knowledge.

Generally, Baystate retains the right to publish at its discretion the results of the clinical trials in scientific journals. The sponsor cannot be granted approval rights over such publications, but can be granted reasonable time to review publications to identify such information and to delay publication so that it can apply for patent protection for inventions. The sponsor also can be permitted to require the removal of confidential information (as the term is defined in the agreement) that, if published, could impair the sponsor’s ability to secure patent protection for inventions.

If the sponsored study is a multi-center study, Baystate may agree to delay independent publication or disclosure of information relating to Baystate specific study activities until a multi-center publication is published unless the sponsor grants permission for earlier publication. However, if no multi-center publication is published within a certain time period (generally, 12 to 18 months) following completion or termination of the study at all study sites, Baystate then may publish the results of its own study activities, including study data collected.

IV. CONFIDENTIALITY AND INTELLECTUAL PROPERTY

Confidentiality. Baystate will agree to reasonable conditions to protect the confidentiality of a sponsor's information that is clearly labeled "Confidential Information of [Sponsor Name]."

Intellectual Property The agreement may grant the study sponsor exclusive rights to all intellectual property created during the study that relate directly to the drug, device, or other subject of the study. Rights in other intellectual property created during the course of the study should be owned by the party whose employee or other representative created that intellectual property. The agreement should not affect the respective rights of Baystate or the sponsor in intellectual property existing at the time of the agreement.

VI. DATA OWNERSHIP AND USE

The agreement may provide that case reports, records, and data (but not patient records) generated during the course of a sponsored study are owned by the sponsor and protected by confidentiality terms. Baystate should retain a license to use data collected at Baystate to advance Baystate's mission through research, in the continuing care of study subjects, and as the basis for publications of the results of the research activity.

VII. INDEMNIFICATION AND INSURANCE

Indemnification

Baystate cannot indemnify an unaffiliated, commercial entity without risk to its tax-exempt status.

When conducting a clinical trial, Baystate and its investigators are required to follow the sponsor's instructions and are utilizing the sponsor's drug or device. Therefore, sponsors must provide indemnification for costs related to any third-party claims of injury or death arising out of claims related to the drug or device or the requirements of the protocol, except for claims arising from the negligent or willful misconduct of Baystate or the investigator,

Insurance

The Sponsor must agree to maintain coverage sufficient to meet its obligations of indemnification and subject injury at minimum levels of \$1 million per occurrence and \$3 million in the aggregate and provide evidence of insurance at Baystate's request.

If a sponsor is not a party to the clinical trial agreement, Baystate may require a separate letter of agreement from the sponsor agreeing to the indemnification and insurance obligations.

VIII. SUBJECT INJURY

Subject injury must be addressed unless IRB determines all the elements of the protocol do not present any risk of injury. The obligation with respect to subject injury is separate and distinct from the obligation to indemnify.

When a clinical trial results in injury to a subject either from the drug or device or the requirements of the protocol, the sponsor must pay the costs associated with the treatment of the injury. An exception for the negligent or willful misconduct of Baystate or the investigator is acceptable.

It is not acceptable to (1) require Baystate to bill a third party for any costs associated with subject injury, or (2) make payment contingent upon the strict adherence to the protocol by the subject, the investigator, or Baystate.

The research consent form must inform the potential subject accurately about the sponsor's obligation to pay in the event of injury in text that is at the 8th grade level or lower. It is not acceptable to insert higher level terminology from the clinical trial agreement into the research consent form.

IX. SUBJECT COMPENSATION

Baystate follows the ethical principles contained in the NIH Guidance on Remuneration of Subjects. Therefore, the amount of compensation must bear some relationship to the time and effort that a subject expends in order to participate in the protocol. If compensation is given in installments, each payment should relate to the time and effort needed to participate to that milestone.

X. SPONSOR DATA MONITORING AND REPORTING

Baystate is fully accredited by AAHRPP and is required to comply fully with all AAHRPP accreditation standards. Three such standards are relevant to a Sponsor's duty to report certain findings to Baystate:

AAHRPP Standard I.8.B In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the Organization has a written agreement with the Sponsor that the Sponsor promptly reports to the Organization findings that could affect the safety of participants or influence the conduct of the study.

AAHRPP Standard I.8.C When the Sponsor has the responsibility to conduct data and safety monitoring, the Organization has a written agreement with the Sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the Organization.

AAHRPP Standard I.8.E When participant safety could be directly affected by study results after the study has ended, the Organization has a written agreement with the Sponsor that the Researcher or Organization will be notified of the results in order to consider informing participants.

Every clinical trial agreement must meet these standards. Baystate cannot enter into any clinical trial agreement that does not include Sponsor obligations to meet these standards. .

If a Sponsor is not a party to the clinical trial agreement, Baystate may require a separate letter of agreement from the sponsor accepting these obligations.

XI. PAYMENTS TO BAYSTATE OR INVESTIGATORS

Payment arrangements must avoid components that could influence or appear to influence how patients are enrolled. Payment terms must adhere to these principles:

1. Payments must be based on the costs of providing all components necessary to conduct the research, including personnel, and reflect fair market value.
2. Per-subject payments are generally acceptable if the payment is based on actual costs and is the same throughout the life of the trial, or if payments are made to fixed milestones.
3. A per-subject payment schedule that increases after a certain number of subjects are enrolled is not acceptable unless associated with actual increases in costs.
4. Payment that is provided only if a specified number of subjects are enrolled is not acceptable.
5. Bonus payments tied to the rate, timing, or number of subjects enrolled are not acceptable.
6. Any type of incentive, monetary or non-monetary, to refer or enroll subjects, so-called "finder's fees," are strictly prohibited.

XII. START-UP COSTS

Generally, Baystate will require payment of one or more one-time fees to cover administrative and processing costs necessary to begin a trial, such as IRB, Pharmacy Start Up, and Laboratory Start Up Fees.

XIII. DATA SECURITY

Baystate is required under federal and state laws and regulations to guard the confidentiality and privacy of identifiable patient information and to take steps in the event certain patient information is disclosed or breached in a manner that violates one or more of these laws or regulations. Baystate therefore has an interest in ensuring that identifiable patient information be protected when disclosed to a third party. When such information is disclosed to a Sponsor, Baystate must have assurances that the Sponsor will safeguard the security of PHI, report any security incident or breach promptly, and mitigate the adverse effects of any improper use or disclosure of confidential patient information.

XIV. SIGNATURE ON BEHALF OF BAYSTATE

It is Baystate policy that a clinical trial agreement may be signed on its behalf only after the IRB has approved or otherwise acted upon the underlying protocol, a review has been conducted to ensure that the terms of the clinical trial agreement are consistent with IRB requirements, and, where necessary, the agreement terms have been modified to conform to IRB requirements.

Baystate policy dictates that only the Senior Vice President for Academic Affairs or the Director of Sponsored Programs Administration is authorized to sign a clinical trial agreement on behalf of Baystate.

XV. DISCLAIMERS AND LIMITATIONS OF LIABILITY

Terms that disclaim or limit a Sponsor's liability are not acceptable.

References

- NIH Guidelines on Remuneration of Subjects (available at <http://ohsr.od.nih.gov/info/sheet20.html>)
- Standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) (available at AAHRPP.org)