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| **INSTITUTIONAL MEMBERSHIP APPLICATION CHECKLIST** |

**Your complete application package must include the following documents:**

[ ]  Completed Membership Application

[ ]  Federalwide Assurance (FWA) Number and Expiration Date

[ ]  Curriculum Vitae (CV) (for Principal Investigator only)

**Submit this completed checklist and the requested documentation to:**

AMC Operations and Data Management Center
Attn: AMC Regulatory Coordinator
The Emmes Company, LLC
401 N. Washington Street, Suite 700
Rockville, MD 20850

**If approved for AMC Membership, you must then provide the following documents prior to activating any studies:**

[ ]  Laboratory Certifications (CLIA, CAP, or equivalent certificate)

[ ]  Curriculum Vitae (CV) (required for all investigators)

[ ]  Site Staff Information Form (required for all participating staff)

[ ]  Signed Adherence Statement (original copy required for Principal Investigator)

**Additional documentation for site contracting will be requested by the AMC financial office following approval from the Executive Committee. The documents required in order to execute a site contract with the AMC will include but are not limited to: Signed AMC Statement of Financial, Equity, and Intellectual Property Interests (for all investigators).**

**Email application requests and questions can be sent to:** **amcpm@emmes.com**

**SITE DEFINITION**

AMC Sites are defined as those clinical sites that wish to participate in the scientific deliberations of the AMC and register participants to AMC studies. Sites should consist of a single institution or institutions under the administrative authority of a single institution.

PIs and other designated investigators at AMC Sites may perform the following functions for the AMC:

***Sites must attain a minimum of 4 accrual credits per grant year to AMC studies.***One full credit is awarded for each subject enrolled in Kaposi sarcoma, hematologic malignancies, and solid tumor treatment trials, half (1/2) credit for most HPV and lab studies. Payment for enrolled subjects will be based on a per capita basis and prorated based on key milestones in the protocol, e.g., entry on the trial, completion of half of the study visits, completion of end of study visit, etc. Accrual payment will vary depending on the intensity of the study as determined by the appropriate Executive Committee subcommittee. Cost reimbursement for procedures not covered by insurance will be made on a per protocol basis.

PIs and other designated investigators at AMC sites may perform the following functions for the AMC:

* Serve as Working Group Chairs or Vice-chairs.
* Serve as Protocol Chairs/Co-Chair or protocol development team members.
* Participate as a member of AMC Working Groups
* Serve as an elected member of the Concept Review Committee.
* PI must attend at least one group meeting per year.

Acceptance into the group is determined by vote of the Executive Committee (EC) and will be based on the qualifications and demonstrated capabilities of the site’s PI and the site’s experience and infrastructure for conducting clinical trials, particularly in the area of cancers in HIV, and also based on the needs of the group as determined by the EC. Acceptance into the group is also contingent upon the availability of funding for the additional site. All newly accepted sites will be required to familiarize themselves with the policies and procedures of the AMC and meet all performance guidelines for their site status as specified by the Site Evaluation Subcommittee.

**MEMBERSHIP APPLICATION**

Complete this application in *proposal* format where applicable to be reviewed by the AMC Executive Committee. We prefer concise and convincing replies over length. Responses that address the questions by presenting tabular information are encouraged. Do not refer the reviewer to documentation not included in this application.

**Institution Information**

City:       State:       Zip + 4:

1. Legal name of Institution:

*(Confirm the legal name with an institutional official)*

1. Legal Address of Institution:
2. Are there any additional street addresses where you would intend to conduct research and enroll participants for AMC studies:

*(Please note for CTEP requirements that* ***all*** *addresses must be listed, even if all locations are located within the same campus, institution, block, etc.)*

[ ]  Yes **🡪** If “Yes” please provide all street addresses. For each address listed, please name one investigator that can be responsible for overseeing activities at this location. Any Investigator listed for oversight must have a CV submitted as part of the Membership Application Packet:

[ ]  No

1. Name of Academic Affiliation, if any:
2. Name of Proposed Principal Investigator:
3. Is the Proposed Principal Investigator registered with CTEP?

*(Check one)*

[ ]  Yes **🡪** If “Yes” please provide current CTEP Investigator ID:

[ ]  No **🡪** If “No”, please complete the required steps necessary in order to complete an Investigator (IVR) or non-physician Investigator (NPIVR) registration. Information on completing CTEP registration requirements can be located at the following link: <https://ctep.cancer.gov/investigatorResources/default.htm>

1. CTEP Institution Code:
2. Name of Lead Clinical Research Coordinator or Research Manager:
3. Does your Institution currently partner with a local Community Advisory Board (CAB)?

*(Check one)*

[ ]  Yes**🡪** If “Yes”, please provide the name of your site’s CAB representative and complete a site staff information form for the purpose of collecting contact information:

Briefly describe your site’s interactions and relationship with the CAB:

[ ]  No**🡪** If “No”, please be advised that a component of AMC member site evaluation includes affiliation and communication with a CAB and that your site will need to establish a relationship with a local CAB if approved as an AMC member institution.

**IRB Information**

1. Specify IRB Name and Location:

IRB registration number:

Expiration date:

1. Does your institution have a current Federalwide Assurance (FWA)?

*(Check one)*

[ ]  Yes**🡪** If “Yes”, provide your current Assurance number and its expiration date.

Assurance number:

Expiration date:

[ ]  No**🡪** If “No”, please obtain a Federalwide Assurance from OHRP prior to submitting this application. *This form can be found on the OHRP website at:* [*http://www.hhs.gov/ohrp/assurances/assurances\_index.html*](http://www.hhs.gov/ohrp/assurances/assurances_index.html)

*Applications will be delayed until this information is provided. It is an NIH requirement.*

**Radiation Oncology Information**

1. Will patients entered at this facility have access to Radiation Therapy?
*(Check one)*

[ ]  Yes**🡪** If “Yes”, list below the name and street address of each RT facility that will be used:

[ ]  No

**Membership Proposal**

1. Describe the support resources available to assure timely compliance with AMC administrative and data requirements, e.g., oncology nurses, clinical research associates, administrative support for IRB requirements:

1. Describe your pharmacy resources and how you plan to handle investigational drugs that are part of AMC research.

1. Describe your IRB review structure (i.e., central versus local, timing of review, etc.)

1. Document adequate patient resources available for entry into clinical trials. List your annual caseload of AIDS-related malignancies by disease and cite the source of the data (tumor registry, etc.). Please include data for the past 5 years if available.

1. Indicate anticipated accrual by types of studies (by disease). Specify any disease areas of AMC research in which you do NOT foresee participation.

1. Discuss any preclinical or other special resources which could benefit the AMC’s current scientific directions.

1. Describe your current cancer research programs and your HIV research programs. Describe your accruals to clinical trials for the past three years and cite accessibility rates of patients entered onto studies. Any audit reports or monitoring reviews by outside reviewers could be attached as an appendix.

1. Describe any prior or current cancer research cooperative group experience of your institution.

1. Provide any other information that you feel is important to the review of this application.

**Application submitted by/on:**

|  |  |  |
| --- | --- | --- |
|  |  | Click or tap to enter a date. |
| Signature of Proposed PI |  | Date |

**Return Completed Application to:**

AMC Operations and Data Management Center
Attn: AMC Regulatory Coordinator
The Emmes Company, LLC
401 N. Washington Street, Suite 700
Rockville, MD 20850

**ADHERENCE STATEMENT**(Version 2.0 • September 24, 2019)

The AMC is comprised of individuals whose ethical standards build the foundation for the research conducted. The highest standards of integrity are expected among all members of the Group. The AMC Data Safety and Monitoring Plan follows the NCI Data Safety Monitoring Guidelines for Clinical Trials (available on the agency’s web page [[www.nci.nih.gov](http://www.nci.nih.gov)]). To gain the utmost quality of scientific research, the AMC and its members are committed to the prevention and detection of research misconduct in clinical trials. All data are audited internally for data inconsistencies and are periodically audited by AMC monitors during external site visits. Furthermore, all members are obliged to communicate concerns about research misconduct to the Group. The primary purpose of monitoring a clinical trial is to ensure the safety and well-being of the specific patients entered on the trial. All members of the AMC are dedicated to this purpose. Submission of falsified data by member sites will not be tolerated and will be reported according to Federal guidelines.

The AMC Operations and Data Management Center (ODMC) oversees the development of all clinical protocols, including protocol activation and the production of all protocol documents, and is responsible for the data management and database activities involved in all AMC clinical protocols. Their duty is to ensure that the Group, consisting of all AMC institutions, investigators, and operations personnel are in compliance with the Office for Human Research Protections (OHRP) regulations, FDA regulatory requirements, and GCP guidelines. For the AMC to be successful in its mission, the participating sites must be committed to the consortium and must perform at an effective level in accordance to these regulations and guidelines.

By completing the registration materials to become an AMC site, you are agreeing to:

* Abide by the AMC Data and Safety Monitoring policy.
* Adhere to FDA regulatory requirements and GCP guidelines.
* Supply a copy of the Investigator’s most recent curriculum vitae to the AMC ODMC, stating whether you are board certified.
* Provide new information regarding personnel at the AMC institution to the AMC ODMC in a timely manner, including laboratory certifications, licensure of site personnel, and changes occurring to the status/role of any personnel involved in an AMC-sponsored clinical trial (via the Site Staff Information Form).
* To notify the AMC ODMC of lapses in required certifications and/or scientific misconduct.

By signing below, you are stating that you have read the AMC Data and Safety Monitoring Policy and agree to adhere to the policies outlined by the AMC to become one of its members.

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|  |  | Click or tap to enter a date. |
| Signature of Principal Investigator |  | Date |
|  |  |  |
|       |  |  |
| Printed Name of Principal Investigator |  |  |

**AMC DATA SAFETY MONITORING PLAN**(Version 6.0 • March 21, 2017)

All AMC protocols that collect safety data follow the *National Cancer Institute (NCI), Cancer Therapy Evaluation Program (CTEP) Guidelines: Adverse Event Reporting Requirements* [(http://ctep.cancer.gov/guidelines/i](http://ctep.cancer.gov/guidelines/index.html%29)n[dex.html).](http://ctep.cancer.gov/guidelines/index.html%29) All adverse events that meet the NCI’s expedited reporting requirements are reported to the Investigational Drug Branch (IDB) of the NCI via the CTEP Adverse Event Reporting System (CTEP-AERS) web application. All expedited adverse event reports are also required to be submitted to the local Institutional Review Board (IRB) of the reporting institution. If NCI holds the IND or no IND is required for a study, the AMC site reports serious adverse events directly to the AMC Operations and Data Management Center (ODMC) via CTEP-AERS; expedited reporting via AdvantageEDC/Advantage eClinical may be permitted for select commercial agent studies per protocol requirements. In some instances, the AMC sites may report serious adverse events directly to a commercial sponsor holding the IND, who will then report the event to the AMC ODMC. Most AMC protocols require sites to report all serious adverse events via CTEP-AERS and the AMC ODMC to forward a copy of the report to the sponsor. The AMC ODMC also distributes all IND safety reports to all investigators upon receipt, and makes these reports available on the password-protected section of the AMC Operations web site. Unless an AMC protocol specifies an alternate plan for the review and submission of serious adverse events, all serious adverse events received by the AMC ODMC will be reviewed by the AMC Medical Monitor at the AMC ODMC. For protocols for which the IDB does not have an assigned drug monitor to review serious adverse event reports, in the event of disagreement between the reporting physician and the AMC Medical Monitor regarding the attribution of the event to the investigational agent(s) (i.e., determination of whether the relationship is unrelated, unlikely, possible, probable, or definite), the AMC Medical Monitor will provide the final determination of the relationship.

The AMC ODMC provides listings of all reported adverse events and serious adverse events to the Protocol Chair and Co-chair(s) for review on a regular basis. The AMC ODMC compiles these events in a tabular format and posts them on the password-protected section of the AMC web site where these reports are updated nightly. The AMC web site is accessible to all AMC investigators, co-investigators, and their staff. Email notification that this information is available on the web site will be sent to all site PIs. It is the responsibility of each site to provide this information to their respective IRBs, if required by their IRB. For blinded studies, the serious adverse events are reviewed and tabulated without treatment assignment. The AMC Medical Monitor will review listings of all reported adverse events on a quarterly basis for safety concerns.

Accrual summaries for each AMC trial are updated nightly on the password-protected section of the AMC web site. The progress of each AMC trial is reviewed regularly by the Protocol Chair and also by the appropriate disease-oriented Working Group during scheduled conference calls. For phase I dose escalation trials, dose escalation (or dose de-escalation) is based on the rules in the protocol and the Protocol Chair, AMC Medical Monitor, and Group Statistician determine whether these criteria have been met. For phase II trials, stopping the trial for toxicity or efficacy, or suspending enrollment pending observation of responses in a multi-stage phase II trial, is based on meeting criteria stated in the protocol, and the Protocol Chair, AMC Medical Monitor, and Group Statistician determine whether these criteria have been met.

For phase III trials and other select studies requiring additional oversight, the AMC has formed an independent Data and Safety Monitoring Board (DSMB). Voting members of the DSMB are physicians, a statistician, and a patient advocate. All voting members are from outside the AMC. Nonvoting members are the AMC Group Statistician, the protocol statistician, an AMC Operations Center staff member, two representatives (normally a clinician or statistician) from the Office of HIV AIDS Malignancy (OHAM) or from the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, of the National Cancer Institute (NCI). The DSMB reviews AMC phase III studies in accordance with the National Cancer Institute’s Policy for Data and Safety Monitoring. Confidential reports of all phase III trials are prepared by the AMC Group Statistician with support from the AMC ODMC. A written report containing the current status of each trial monitored, and when appropriate, any toxicity and outcome data, are sent to DSMB members by the AMC ODMC within the timelines specified by the DSMB Charter. This report addresses specific toxicity concerns as well as concerns about the conduct of the trial. The report may contain recommendations for consideration by the DSMB concerning whether to close the trial, report the results, or continue accrual or follow-up.

The results of each DSMB meeting are summarized in a formal report sent by the DSMB Chair to the Group Chair and AMC ODMC. The DSMB report contains recommendations on whether to close each study reviewed, whether to report the results, and whether to continue accrual or follow-up. A primary recommendation (e.g., continue with no change; recommended or required modification; stop) must be included in the document. The Group Chair is then responsible for notifying the Protocol Chair and relevant Disease-oriented Working Group Chair before the recommendations of the DSMB are carried out. In the unlikely event that the Protocol Chair does not concur with the DSMB, then the NCI Division Director or designee must be informed of the reason for the disagreement. The Study Chair, relevant Disease-oriented Working Group Chair, Group Chair, DSMB Chair, and NCI Division Director or designee will be responsible for reaching a mutually acceptable decision about the study. CTEP approval of a formal amendment will be required prior to any implementation of a change to the study.

Following a DSMB meeting, a summary of the serious adverse events reported to the DSMB is posted to the AMC web site. It is each site’s responsibility for conveying this information to its IRB.

# Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events (AE)

For trials monitored by the NCI’s Clinical Data Update System (CDUS), adverse event information is transmitted electronically to NCI on a quarterly basis. For trials monitored by NCI’s Clinical Trials Monitoring Service (CTMS), adverse event information is transmitted electronically to NCI every two weeks.

The Protocol Chair, AMC Group Chair, and the AMC ODMC share responsibility in assuring that participating investigators comply with the protocol requirements for adverse event reporting. All AMC investigators certify compliance with NCI and FDA requirements for adverse event reporting by signing the AMC Adherence Statement for site membership, the protocol signature page for each protocol active at the site, and Form FDA-1572 for CTEP investigator registration and IND studies sponsored by AMC investigators. Investigators are responsible for identifying and reporting all adverse events to the AMC ODMC, CTEP-AERS, and/or sponsors according to the protocol requirements, and assuring compliance with reporting to the local IRB. Protocol compliance with adverse event reporting requirements is assessed by the AMC ODMC during routine site audits by reviewing the site’s source documentation.

The data entry system used for AMC studies, AdvantageEDC/Advantage eClinical (a web-based data entry and enrollment system), is programmed to notify the site investigator, protocol chair, AMC Medical Monitor, and AMC ODMC via email in the event that a site reports an adverse event that meets expedited reporting criteria to NCI and/or FDA. If the site does not follow with an expedited report, the AMC ODMC contacts sites to request compliance with reporting requirements. Additionally, the protocol chair, AMC ODMC, and the AMC Medical Monitor review reported adverse events on a routine basis to identify adverse events reported by sites that require expedited reporting. The Protocol Chair, AMC Group Chair, and IND sponsors have general oversight for assuring that routine and expedited adverse reporting requirements are met by the responsible parties.

# Plans for Assuring that any Action Resulting in a Temporary or Permanent Suspension of an NCI- Funded Clinical Trial is Reported to the NCI Grant Program Director Responsible for the Grant

In the event that termination of the trial or major modification to the protocol is under consideration, the Protocol Chair will convene the AMC Data Coordinator and Disease-oriented Working Group Chair by conference call to discuss the options. For phase I and II trials, the Protocol Chair also has the option of asking the DSMB to review the study. The AMC ODMC will inform the CTEP Protocol Information Office (PIO) when studies are temporarily or permanently closed. The Cancer Treatment and Evaluation Program (CTEP) of the National Cancer Institute (NCI) must approve all protocol amendments prior to distributing to the AMC sites.

# Plans for Assuring Data Accuracy and Protocol Compliance

All study data for AMC clinical trials are entered directly by AMC clinical site staff into AdvantageEDC/Advantage eClinical. During data entry, the system performs validation checks on many fields and performs consistency checks between select fields. Range checks are placed on each field to eliminate entry of out-of-range values. Edit check programs are run on the database on a set schedule to identify and resolve inconsistencies between forms or data collected at different points in time. AMC ODMC staff routinely interacts with site staff to resolve any data problems.

In accordance with NCI guidelines, the AMC ODMC conducts audits at the AMC sites to evaluate compliance with regulatory issues, and to review data for specific cases by checking source documents. These reports are sent to the site Principal Investigator and to the NCI. In the event that major violations are identified, sites are asked to provide a written corrective and preventative action plan. If needed, a repeat site audit is conducted. In the event that a site does not correct deficiencies in a pre-determined time frame, the AMC Executive Committee has the option of taking action against the site. Possible actions include, but are not limited to, suspending enrollment of new patients to AMC trials until deficiencies are corrected; recommending a decrease in funding to the site; and requiring specific training for site investigators or staff members.