GLOSSARY OF COMMON TERMS

BRANY-Biomedical Research Alliance of NY: is an outsourcing agent for Montefiore and Einstein for some of our clinical trials portfolio. The Montefiore - Einstein IRB automatically accepts BRANY IRB determinations. Some additional services rendered by BRANY include contracting and budgeting, along with regulatory administration and study invoicing for services. BRANY is also available to provide monitoring services for investigator-initiated studies. Investigators at Montefiore and Einstein are able to use BRANY and their services conjointly or selectively. BRANY should be used for industry sponsored clinical research. They work with research administrator and study team to set up and activate study.

BRANY SMART: Outside portal for managing BRANY studies, including enrollment, study calendars and payments.

EPIC- (EHR): Electronic Health Record System- EPIC is a digital version of a patients paper chart. Contains the medical and treatment histories of patients.

IC- Informed Consent: The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for under the HHS regulations at 45 CFR part 46. This requirement is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report.

Ethical Principles of Informed Consent: The principle of respect for persons requires that people be given the opportunity to choose what will or will not happen to them. Freely given informed consent must be obtained from every capable, potential adult subject before any research procedures begin, unless the IRB has waived some or all of the consent requirements.

IRB- Institutional Review Board: is a committee, operating under Federal regulations, State laws, and institutional policy, that reviews research involving human subjects to ensure the ethical and equitable treatment of those subjects.

iRIS- IRB software used for both Montefiore and Einstein IRB submissions. Researchers are able to electronically submit their protocols and related materials for review.

NCT: A unique identification code given to each clinical study registered on ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419). This identifier is also known as the NCT Number.

OCT-Office of Clinical Trials: Office that reviews and works with Research administrator to manage an investigator initiated clinical trial

OGS- Office of Grant Support: Processes contracts and funding submissions with your research administrator. All requests should first go through your research administrator. RA will work with the OGS to ensure contracts and funding requests are submitted in a timely manner.

OSRP-Office of sponsored research projects: Processes contracts that are directly tied to Montefiore. All requests should FIRST go to your research administrator. RA will work with the OSRP to ensure your contract is processed correctly.

PI-Principal Investigator: A researcher involved in a clinical study. Related terms include Site Principal Investigator, Site Sub-Investigator, Study Chair, Study Director, and Study Principal

Investigator. A medical professional, under whose direction an investigational study takes place. A principal investigator is responsible for the overall conduct of the research.

Protocol: A detailed plan that sets forth the objectives, study design, and methodology for a research project. A clinical study protocol must be approved by an IRB before any human intervention is allowed.

Protocol Amendment: Changes or clarifications made in writing to the original protocol.

PT-Patient: Volunteer subject involved in research study

RA-Research Administrator: Your designated research contact for all research related and extramural funding tasks. **Should be the first point of contact** when initiating any research related work. This includes grants submissions, all external assistance submissions, investigator initiated protocols, new clinical research discussions, Data use agreements, and confidentiality agreements that are research related, new hires for research purposes.

RC-Regulatory Coordinator: The Regulatory Coordinator is typically responsible for drafting or editing the protocol document and submitting new protocols, protocol amendments, continuing reviews and safety reports to the appropriate IRB for review. They are responsible for maintaining regulatory binders in accordance with sponsor specifications and general industry standards. They often are the keepers of the delegation of authority log for key personnel involved in the study. In VELOS the RC has the ability to update the study summary. (Note: RC and Study Coordinator can be the same individual).

SC-Study Coordinator: See attached Appendix A

Sponsor: Individual, company, institution or organization taking responsibility for initiation, management and financing of study.

VELOS: Clinical Research Management System to streamline, integrate and manage all clinical trial and research activities. The Velos system will standardize operations and management of research related activities and ultimately reduce workload by linking many disparate systems currently utilized for research management. The goals of this system will be to improve quality of data, ensure regulatory compliance, and streamline administrative and financial management of the studies, sponsors, and patients by providing comprehensive protocol management, patient recruitment, coordination and calendaring, regulatory reporting, adverse event management and reporting, quality assurance reporting, and consolidated invoicing and financial management