Helpful Acronyms

510(k) – Premarket Notification Submission
AE – Adverse Event
AAHRPP – Association for the Accreditation of Human Research Protection Programs
BA – Bioavailability
BE – Bioequivalence
BIMO – Bioresearch Monitoring
BSPH – Bloomberg School of Public Health
CBER – Center for Biologics Evaluation and Research
COI – Committee on Outside Interests
CDER – Center for Drug Evaluation and Research
CDRH – Center for Devices and Radiological Health
CFR – Code of Federal Regulations
CRF – Case Report Form
CRO – Contract Research Organization
CRO (JHM only) - Clinical Research Office (Oncology)
CRRC – Clinical Radiation Research Committee
CSO – Consumer Safety Officer (FDA)
DHHS – Department of Health and Human Services
DQ – Disqualification
EI – Establishment Inspection (FDA)
EIR – Establishment Inspection Report (FDA)
eIRB – Electronic IRB
FDA – Food and Drug Administration
Form FDA 482 – “Notice of Inspection”
Form FDA 483 – “Inspectional Observations”
Form FDA 1572 – Statement of Investigator
GCP – Good Clinical Practice
GCRC – General Clinical Research Center
HDE – Humanitarian Device Exemption
HIPAA – Health Insurance Portability and Accountability Act
HUD – Humanitarian Use Device
IC – Informed Consent
ICF – Informed Consent Form
ICH – International Conference on Harmonization
IDE – Investigational Device Exemption
IND – Investigational New Drug (Application)
IRB – Institutional Review Board
IVD – In Vitro Diagnostic
JHBMC – Johns Hopkins Bayview Medical Center

KKI – Kennedy Krieger Institute
NAI – No Action Indicated (FDA inspection classification)
NCI – National Cancer Institute
NDA – New Drug Application
NIDPOE – Notice of Initiation of Disqualification Proceeding and Opportunity to Explain
NIH – National Institutes of Health
NSR – Non-significant risk
OAI – Official Action Indicated (FDA inspection classification)
OHRP – Office of Human Research Protections (HHS)
OHSR – Office of Human Subjects Research
ORA (FDA) – Office of Regulatory Affairs
ORA (JHM) – Office of Research Administration
ORI – Office of Research Integrity
PHI – Protected Health Information
PI – Principal Investigator
PMA – Premarket Application
P&T – Pharmacy and Therapeutics Committee
QA – Quality Assurance
QC – Quality Control
R&D – Research and Development
RDRC – Radioactive Drug Research Committee
SAE – Serious Adverse Event
SC – Study Coordinator
SOM – School of Medicine
SON – School of Nursing
SMO – Site Management Organization
SOP – Standard Operating Procedure
SR – Significant Risk
VAI – Voluntary Action Indicated (FDA inspection classification)
WIRB – Western Institutional Review Board
WL – Warning Letter