Common IRB Acronyms

AAHRPP	Association for the Accreditation of Human Research Protection Programs
AE	Adverse Event
CBER	Center for Biologics Evaluation and Research
CFR	Code of Federal Regulations
CDER	Center for Drug Evaluation and Research
CDHR	Center for Devices and Radiological Health
CFA	**Criteria for Approval**
CIRB	Central Institutional Review Board
CITI	Collaborative Institutional Training Initiative
CLIA	Clinical Laboratory Improvement Amendments
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COI	Conflict of Interest
CR	**Continuing Review**
CRF	Case Report Form
CRO	Clinical Research Organization
CTA	Clinical Trial Agreement
DHHS	Department of Health and Human Services
DSMB/C	Data Safety Monitoring Board/Committee
DUA	Data Use Agreement
FDA	Food and Drug Administration
FWA	Federal Wide Assurance
GCP	Good Clinical Practice
HDE	Humanitarian Device Exemption
HIPAA	Health Insurance Portability and Accountability Act
HUD	Humanitarian Use Device
HRPP	Human Research Protection Program
IB	Investigator Brochure
IBC	Institutional Biosafety Committee
IFU	Information for Use
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IND	Investigational New Drug
IO	Institutional Official
IRB	Institutional Review Board
LDS	Limited Data Set
MOD / MODs Required	**Modifications Required in order to secure approval**
NCI	National Cancer Institute
NIH	National Institution of Health
IVD	In Vitro Diagnostic

Common IRB Acronyms

NDA	New Drug Application
NIH	National Institute of Health
NSR	Non-Significant Risk (device)
OHRP	Office of Human Research Protections
OSP	Office of Sponsored Programs
PHI	Protected Health Information
PI	Principal Investigator
PMA	Pre-market Approval
PRIM&R	Public Responsibility in Medicine and Research
QI	Quality Improvement
RNI	**Reportable New Information**
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
SIV	Site Initiation Visit
SOC	Standard of Care
SOP	Standard Operating Procedure
SR	Significant Risk (device)
UAP	**Unanticipated Problem**
UADE	Unanticipated Adverse Device Effect
510K	Pre-market Notification