

Institutional Review Board – Standard Operating Procedures
ABBREVIATION INDEX

*Abbreviations of terms utilized throughout the Standard Operating Procedure Manual

ABBREVIATION	DEFINITION
ADR	Adverse Drug Reaction
CIOMS	Council for International Organizations of Medical Sciences
CRF	Case Report Form
CRO	Contract Research Organization or Clinical Research Organization
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
D/M/Y	Date/Month/Year
DOH	Department of Health
DSMB	Data and Safety Monitoring Board
DSMC	Data and Safety Monitoring Committee
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigator’s Brochure
ICF	Informed Consent Form
ICH-GCP	International Conference on the Harmonization of Good Clinical Practice
IDE	Investigational Device Exemption
IRB	Institutional Review Board
ISER	Initial Submission Expedited
ISFB	Initial Submission Full Board
MMC	Makati Medical Center
MMC IRB	Makati Medical Center Institutional Review Board
NSR	Non Significant Risk
OIC	Officer-in-Charge
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
RM	Research Monitor
RSER	Resubmission Expedited
RSFR	Resubmission Full Board
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SR	Significant Risk
SUSAR	Suspected, Unexpected Serious Adverse Reaction
TOR	Terms of Reference
WHO	World Health Organization