

Index

Altman DG	319
Alzheimer's Disease Anti-inflammatory Prevention Trial	319
Bradley H	320
committee	
masked treatment effects monitoring committee	235
Coronary Drug Project	319
Craigie WA	320
Davidoff F	319
Definitions	
acknowledgment	140
adaptive treatment assignment	68
adjudication	271
adverse event	210
advisory-review	131
advisory-review and treatment effects monitoring committee	131
advisory-review committee	131
advocacy representation construct	116
ancillary paper	282
ancillary publication	279, 287
aristocracy representation construct	116
assent	205
associate center	193
audit trail	68
bin number drug system	68, 218, 222
blackout	228
block	68
blocked randomization	68
center representation construct	116
central institutional review board	193
centralized data system	98
certification	165
class of trial	30
commercial institutional review board	193
commissioned manuscript	287
complete factorial	36
complete randomization	68
concealment	68
conflict of interest	162
consent	205
consent renewal	205
contiguous time window	83
conventional author citation	282
corporate author citation	282
data audit	103
data edit	103
data harvest	107
deconsent	205
deidentified data	57
dependent double data entry	107

Index

design variable	33, 261
direct funding	14
discipline representation construct	116
disclosed masked monitoring	253
disjoint time window	83
distributed data system	98
double placebo	222
dropout	83
enrollment override	76
envelope treatment assignment	68
executive committee	110, 123
fabrication	304
factorial treatment design	36
falsification	304
final dataset	261
firewall	235
fixed treatment assignment	68
followup visit schedule	83
fraud	304
full masking	218, 222
full study credit roster	140
haphazard treatment assignment	69
identified data	57
identifier data	93
imposed masked monitoring	253
incomplete factorial	36
independent double data entry	107
indirect funding	14
institutional review board	193
interim analysis	261
interim data analysis	267
interim dataset	261
investigator-proposed manuscript	287
key committee	110
local institutional review board	193
lost to followup	83
mask	218, 222
masked treatment assignment	69
masked treatment effects monitoring	235
masked treatment effects monitoring committee	235
masked treatment effects monitoring report	235
masking level	218, 222
med Id number drug system	69, 218, 222
missed visit	83
modified conventional author citation	282
modified corporate author citation	282
open treatment assignment	69
outcome measure	33
overlapping time window	83
parent center	193

Index

partial masking	218, 222
partial study credit roster	140
per assignment analysis	271
per protocol analysis	271
PI representation construct	116
plagiarism	304
primary outcome	261
primary outcome measure	33
primary paper	282
primary publication	279, 287
primary treatment group comparison	30
protocol amendment	193
protocol violation	76
random treatment assignment	69
reconsent	205
reportable event	210
representation construct	116
request for application	4
request for proposal	4
research group	110, 134
resource center	110
restricted randomization	69
safety report	211
satellite center	193
scientific misconduct	304
secondary outcome measure	33
secondary publication	279, 287
separation	218, 222
serious adverse drug experience	211
shielding	228
steering committee	110, 116
stratification	69
stratification variable	69
study center	110
study credit roster	140
study curriculum vitae	291
study directory	140
study name	50
study officers	110, 114
subgroup comparison	33
support center	110
surrogate outcome measure	33
time window	83
treatment assignment ratio	69
treatment design	36
treatment effects monitoring committee	131
treatment group	30
treatment modality	36
treatment structure	36
umbrella name	50

Index

unexpected adverse drug experience	211
voluntary masked monitoring	253
Department of Health and Human Services	319
Department of Health and Human Services (DHHS)	319
effect	
masked treatment effects monitoring	235
masked treatment effects monitoring committee	235
masked treatment effects monitoring report	235
Egger M	319
Elbourne D	319
Glaucoma Laser Trial	319
Gøtzsche PC	319
Hypertension Prevention Trial	319
Lang T	319
Macular Photocoagulation Study	319
mask/masking	
masked treatment effects monitoring	235
masked treatment effects monitoring committee	235
masked treatment effects monitoring report	235
Meinert CL	319
Moher D	319
monitor/monitoring	
masked treatment effects monitoring	235
masked treatment effects monitoring committee	235
masked treatment effects monitoring report	235
Multiple Risk Factor Intervention Trial	320
Murray JAH	320
National Emphysema Treatment Trial	320
Onion CT	320
Schulz KF	319
treatment effect	
masked treatment effects monitoring	235
masked treatment effects monitoring committee	235
masked treatment effects monitoring report	235
University Group Diabetes Program	320
