IND SUBMISSIONS TIMETABLE

SUBMISSION	TIMING
Amendment – New Protocol	After IRB approval
Amendment – Changed Protocol	At time of change, usually after IRB approval
Amendment – New Principal Investigator	Within 30 days of being added
IND Safety Report (unexpected AE that is serious and associated with the use of the drug or lab tests that suggest significant risk)	Within 15 calendar days of receiving notification Contact MIAP when you receive notification
IND Safety Report (unexpected fatal or life threatening experience associated with the use of the drug)	Within 7 calendar days of receiving notification Contact MIAP when you receive notification
Annual Report	At time of withdrawal
Discontinuation of Investigation	Within 5 working days of discontinuance

IDE SUBMISSIONS TIMETABLE

SUBMISSION	TIMING
Supplement – New Protocol	Before implementing the protocol, usually after IRB approval
Supplement – Changed Protocol	At time of change, major changes or changes affecting safety must have prior FDA approval
Supplement – New Principal Investigator	At time of change, must have prior FDA approval
Supplement – Information	At time of occurrence
Unanticipated Adverse Device Effects (serious adverse event that is unexpected and caused by or associated with the device)	Within 10 working days of receiving notification
Recalls and Device Disposition	Within 30 days
Investigator List/Progress/Annual Report	At regular intervals (at least yearly)
Withdrawal of IRB Approval	Within 5 working days of receipt of notice

Completion or Termination of Investigation – Final Report	Within 30 days