INDEPENDENT INVESTIGATIONAL REVIEW BOARD INC.

EPA PROTOCOL CHECKLIST

#:_____

	YES	NO	NA	Notes
Title and Protocol number version date	_____	_____	_____	
Index/Page #'s	_____	_____	_____	
Sponsor contact info	_____	_____	_____	
Study population • Inclusion/Exclusion criteria • Number of subjects • Number of SItes	_____	_____	_____	
Nature and Purpose of study including • **Balance of risks and benefits of research** • **Alternate means of obtaining comparable information**	_____	_____	_____	
Study Design	_____	_____	_____	
Duration of the study	_____	_____	_____	
All Field Procedures including • **Potential Risk to Human Subjects, measures to minimize risk** • **Nature and magnitude of expected benefits and to whom they accrue**	_____	_____	_____	
Restrictions	_____	_____	_____	
Birth Control/Pregnancy testing	_____	_____	_____	
Withdrawal/voluntary/(involuntary by Sponsor/PI/**EPA**)	_____	_____	_____	
Study monitoring/Audit/Compliance with Regulatory Authorities	_____	_____	_____	
Confidentiality/Disclosure of data/not identified in publications • (EPA)/absolute confidentiality not guaranteed	_____	_____	_____	
Supplies/shipping/storage	_____	_____	_____	
Assignment of subject numbers	_____	_____	_____	
Recording of data/Case report forms	_____	_____	_____	
Deviations from protocol	_____	_____	_____	
Adverse Events	_____	_____	_____	
Study records/Source documents	_____	_____	_____	
Termination of study	_____	_____	_____	

Consenting of subjects i.e. description of circumstances and methods proposed for presenting information to potential Subjects

Notes: