CONFIDENTIAL – CONTAINS TRADE SECRETS

Attachment A-1: Company Contact Information

Company Name:
Company Address:
Company PI name:
Company PI Email:
Additional Company Contact Name:
Additional Company Contact Email:

CONFIDENTIAL – CONTAINS TRADE SECRETS

Attachment A-1: Human Subjects

Activities involving HUMAN SUBJECTS

	Study				**Research Entity**				**Study Site** *(If more than one study site per study, list one per excel row.)*			**Exemption**		**IRB**				
	Proposed CARB-X Stage	Type of Human subjects Research	Anticipated Study Start Date [1] (e.g., Apr 2018 or Q2 2018)	Study Name	Type of Entity	Entity Name	Entity Address	Entity FWA [2]	Name	Address	FWA [3]	Exempt? *(i.e., Not Human Subjects Research designation)*	If Yes, Exemption #	IRB Name [4] *(of record)*	Enter FWA of the IRB *(if different than Research Entity)*	IRB Approval Status	IRB Approval Date *(leave blank if pending)*	If more than one IRB must approve the research, describe all.
Study 1																		
Study 2																		
Study 3																		
Study 4																		
Study 5																		
Study 6																		
Study 7																		
Study 8																		
Study 9																		

[1] *Study Start Date is subject to satisfactory completion of all compliance requirements.*

[2] *Enter FWA # of the research entity conducting or responsible for the research.*

[3] *Enter FWA # of each site performing the study, if different from the research entity or more than one study site is being used.*

[4] *Enter information about the IRB of record. If more than one IRB approval is required, please complete Column S.*

Attachment A-1: Animal Subjects

Activities involving ANIMAL SUBJECTS

Protocol/Study						IACUC Approval		Performance Site				Inter-Institutional Assurance (IIA)	
	Protocol Name *(indicate the Protocol the study/studies fall under)*	Study Name(s) (Add more rows if required)	Study Species	Proposed CARB-X Stage	Anticipated Study Start Date(s)[1] (e.g., Apr 2018 or Q2 2018)	Status of IACUC Approval Letter[2]	IACUC Approval Date *(Leave blank if pending)*	Type of Entity	Entity Name	Entity Address	Animal Welfare Assurance #[3] *(Domestic or Foreign)*	Inter-Institutional Assurance #[4] *(Mark "To be requested" until obtained through CARB-X/BU process)*	OLAW Approval Date *(Leave blank if pending)*
Protocol 1													
Protocol 2													
Protocol 3													
Protocol 4													
Protocol 5													

[1] *Study Start Date is subject to satisfactory completion of all compliance requirements.*
[2] *An IACUC (or IACUC equivalent) approval letter is required for each protocol. Preliminary or conditional approvals are insufficient.*
[3] *Enter the OLAW Assurance # for the performance site.*
[4] *An Inter-Institutional Assurance (IIA) is required for sites/product developers that do not/cannot have their own Assurance and must rely on a CRO or other third party performance site that has an Assurance. The IIA is CARB-X project specific; it can be requested by CARB-X/BU Administration upon a positive JOC funding decision.*

Stage	Status	Type of Entity	IACUC Approval		Type of Study
Base	To Be Requested	CRO	Pending	Yes	Clinical Trial
Option	Pending	In-house	Final	No	Biospecimens
	Obtained	Government agency/entity			Other
		Other			