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All applicable information must be submitted to ClinicalTrials.gov if it is not otherwise available on ClinicalTrials.gov. For FDA-regulated clinical trials, a registration application can be created or downloaded and submitted to ClinicalTrials.gov. You are solely responsible for creating a registration application. You agree that you will make reasonable efforts to maintain and keep current any authorization information, enrollment information, or other similar information necessary to conduct your clinical trial. We will communicate with you directly if we experience any difficulties or questions with your Registration Application. In the event that you elect not to register or commence a clinical trial on ClinicalTrials.gov, the Regulatory Strategy includes provisions to file a notification with FDA in response to the submission of an Investigational Device Exemption application, an IND, an Investigational New Drug Application, an Investigational New Drug, an application for an Investigational New Drug, or any application that would be considered an Investigational Device Exemption application if submitted for a Investigational Device Exemption under the FDA's regulation. The regulatory strategy also outlines the policy for the submission of results to ClinicalTrials.gov for FDA-regulated clinical trials. Please see the final rule for additional information about submitting results for clinical trials. http://www.gpo.gov/fdsys/pkg/FR-2018-01-28/html/FR-2018-01-28-pdf.htm#heading11282

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The responsible party is responsible for contacting the human subjects protection officer(s) designated by the protocol sponsor to obtain copies of the protocol, protocol amendments, informed consent forms, and any other documents that will

be submitted to the IRB. The responsible party must make the IRB contact information available to the research coordinator and Research Assistant. Any information provided by the responsible party to a human subjects protection officer must be timely, complete, accurate, current and substantiated. The responsible party must

ensure that human subjects protection officers have access to the same information obtained by the research coordinator and Research Assistant as that which is disclosed to the IRB. The responsible party is responsible for correcting any information provided by the responsible party to a human subjects protection officer that is

found to be inaccurate or misleading. The responsible party is responsible for ensuring that human subjects protection officers have the required certification or other training. The research coordinator is responsible for providing each local research ethics officer the same information and the same number of copies of

the documents as that provided to the IRB. Prior to conducting any research, the responsible party must ensure that the human subjects protection officers that will be involved in the research have been provided with all of the information described in the regulation. You agree to (i) notify us immediately of any unauthorized access

to or use of your user name or Password or any other breach of security, investigate such breach or such potential breach, (ii) assist us using commercially reasonable efforts in maintaining confidentiality, and (iii) assist us as reasonably necessary to enforce our rights and to enable us to comply with any state or

federal law requiring the provision of notice of any security breach with respect to any personally identifiable information of the affected or impacted data subjects. You should use particular caution when accessing your account from a public or shared computer so that others are not able to view or record your Password or

other personal information. We have the right to disable any user name, Password, or other identifier, whether chosen by you or provided by us, at any time if, in our opinion, you have violated any provision of these Terms of Use. 5ec8ef588b

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