

AMGEN'S CONTRACTUAL REQUIREMENTS FOR ISS SUPPORT

PLEASE REVIEW AMGEN'S CONTRACTUAL REQUIREMENTS WITH YOUR CONTRACTING OR LEGAL TEAM. COMPLETION OF THE ACKNOWLEDGEMENT FORM IS A REQUIREMENT OF THE ISS PROPOSAL SUBMISSION PROCESS

This document describes certain non-negotiable provisions that will be included in a definitive agreement should Amgen agree to support your request. The definitive agreement will additionally contain typical provisions associated with investigator sponsored studies (e.g., confidentiality, debarment, insurance, termination, payment reconciliation, audit rights).¹

- **No Sponsorship.** Sponsor² will not represent to anyone, including subjects that Amgen is the “sponsor” of the study.
- **Study Data.** Study data (including data derived from the study, study results) are the property of sponsor and shall be disclosed to Amgen. Amgen shall have the right to use the data in its sole discretion in compliance with applicable laws. Upon Amgen's request, sponsor will furnish the data in a coded format that protects the confidentiality of subjects.
- **Proprietary Rights.** The sponsor will own inventions resulting from the study. Sponsor shall provide a present grant of a royalty free, non-exclusive license with a right to sublicense any inventions and discoveries resulting from the study for all purposes (including commercial), and an option for an exclusive license to any such inventions.
- **Unauthorized Use of Study Drug or Amgen Confidential Information.** Amgen shall own any resulting data and inventions resulting from any unauthorized uses of Amgen provided study drug or confidential information.
- **Biological Samples.** When study drug is provided, the use of biological materials shall be consistent with that identified in the Amgen-approved protocol. Amgen will not agree to unspecified future research or any form of biobanking of biological samples containing Amgen study drug. Biological materials are to be destroyed at end of study.
- **No Injury Compensation.** Amgen will not provide any compensation for any research-related injuries; sponsor shall not state or imply in an informed consent form that Amgen will provide any such compensation.
- **Study Drug Provision.** When study drug is provided, such provision shall cease upon termination (e.g., end of study or earlier termination). The sponsor does not have authority to bind Amgen to or in any way represent to study participants post-study drug access.
- **Publications.** Publication of study results is encouraged. To protect Amgen confidential information and without exercising editorial control, Amgen requires advanced review (5 to 45 days) of any publication (e.g., manuscripts, abstracts, oral presentations, study registrations (e.g., CT.gov)). Review periods are extendable to protect Amgen's patent rights.
- **Safety Reporting.** Sponsor will be responsible for safety reporting requirements both to regulatory authorities and to Amgen. The safety reporting requirements will be specific to the protocol and included in the agreement.

¹ Note: If sponsor is receiving support (financial or product) from another company for the ISS, sponsor shall disclose this information during the application process. Regardless of any contractual obligations with such other company(ies), alignment with Amgen's contractual positions is required.

² “Sponsor” used to include to institution, investigator, regulatory sponsor, all of whom will be identified accordingly in the definitive agreement.

- Termination. Amgen expects the study to be activated in a timely manner. Delays in activation or failure to enroll sufficient patients within reasonable timelines may result in termination of Amgen's support.
- Compliance Instructions Regarding Study Drug. When study drug is provided, the sponsor shall comply with all storage, handling, access and destruction requirements.
- Indemnification by Sponsor. Sponsor will indemnify and defend Amgen against any third-party claims that may be brought in connection with the study.
- Indemnification by Amgen. When Amgen provides study drug, Amgen will indemnify sponsor against third party claims brought solely because of Amgen's failure to manufacture the study drug in accordance with applicable regulations. For studies with only financial support from Amgen, no indemnification is provided.
- Participating Sites. If the sponsor conducts the study at other institutions, sponsor shall be responsible to contractually engage such sites. Sponsor will represent it has entered into such agreements on terms substantively similar to the terms agreed to between the sponsor and Amgen.