Amgen has expressed an interest in your recent submission to Amgen's Investigator Sponsored Studies (ISS) Program. To facilitate your decision to move forward with the submission of a complete protocol for Amgen's consideration, please review Amgen's required key contractual positions with your institution's legal group responsible for contracts. This will ensure timely contracting process should the protocol receive final approval for support from Amgen. Please note that Amgen will not agree to negotiate these contractual requirements so alignment with your legal team prior to applying for an Amgen support is essential.

## AMGEN'S KEY CONTRACTUAL REQUIREMENTS FOR ISS SUPPORT

- Audit Rights. Although Amgen does not conduct audits on a routine basis in the context of investigator sponsored studies, Amgen requires a contractual reservation of the right to audit sponsor activities, at no cost to Amgen, for example, related to regulatory concerns in connection with the study or concerns regarding sponsor's compliance with the agreement (e.g., with respect to drug handling).
- Biological Samples. When study drug is provided, the use of biological materials obtained in the course of the study (except those for routine medical care) must be limited to tests, analyses, or procedures identified in the protocol as approved by Amgen and the informed consent as approved by the Institutional Review Board or Independent Ethics Committee. Protocols cannot contain a general reference to "future research" or "biobanking", as Amgen's approval of a protocol is based on detailed study information and objectives. Biological materials are expected to be destroyed at end of study, except and solely as required for record keeping purposes in compliance with the agreement.
- Compliance with Applicable Laws. The study must be conducted in compliance with all applicable laws, regulations, guidance, and the protocol as approved by Amgen. Additionally, site is expected to follow Amgen instructions such as those regarding safety reporting or, when provided, handling of study drug (e.g., storage and handling, expiration of drug notices, drug destruction).
- Confidentiality. Standard confidentiality and use terms requiring the sponsor to maintain the confidentiality of any information received from or on behalf of Amgen and restrict access to such information to only those persons controlled by sponsor and have a need to know.
- Debarment. To ensure the integrity of the study for which Amgen's support is requested, Amgen requires sponsors to represent and warrant that they are not debarred, disqualified, or excluded from any reimbursement program in the US or in other countries, and to notify Amgen if such status changes during the course of the agreement.
- Indemnification by Sponsor. Amgen expects the sponsor to indemnify and defend Amgen against any third party claims that may be brought against Amgen in connection with the study.
- Indemnification by Amgen. When Amgen provides study drug, Amgen provides limited indemnification for third party claims brought against the sponsor resulting from Amgen's failure to manufacture the study drug in accordance with applicable regulations.
- Liability Insurance. The sponsor is to maintain comprehensive insurance coverage for any damages caused as a result of the study (including subject deaths or injuries), and provide proof of such coverage upon request.
- Participating Sites. If the sponsor decides to use other sites for the conduct of the study, Amgen will not enter into separate agreements with these participating sites. If a multi-site study, sponsor will be required to represent that it has entered into separate written agreement with participating site(s) on terms substantively similar to the terms agreed to between the sponsor and Amgen. The sponsor will be responsible for the overall conduct of the participating sites and their compliance with any requirements in the Amgen – sponsor agreement that apply.

- Proprietary Rights. The sponsor will own all data and inventions resulting from the study. In consideration for Amgen's support, Amgen shall automatically (i.e., a present grant) be granted the right to freely use any data, results, conclusions resulting from the study. Amgen also requires a royalty free, non-exclusive license with a right to sublicense to any inventions and discoveries resulting from the study for all purposes (including commercial), as well as an option for an exclusive license to any such inventions. In the event of any unauthorized uses of Amgen provided study drug or confidential information, Amgen will own any resulting data or inventions.

  In the event the sponsor is receiving support from other industry partners, additional terms may apply depending on the circumstances.

- Publications. Amgen is committed to the highest standards for publications, which includes the publication of results regardless of outcome. Based on this commitment, Amgen expects the sponsor to exercise best efforts to publish the results of the study and provide Amgen pre-publication / presentation review. Amgen will not exercise editorial control over the proposed publication, but will require removal of confidential information if applicable. Timelines for the review are 45 days for manuscripts; 15 days to review any poster, presentation, or other written or oral material; and 5 days to review any abstract derived from the study. Amgen may request sponsors to withhold any publication or presentation an additional period upon request. The sponsor is expected to keep study results confidential until publication and must acknowledge Amgen's support in all publications. Sponsor to grant Amgen, subject to publisher's rights, a license to distribute copies of any publication / presentation within Amgen and to licensees, licensors, affiliates, and authorized representatives and to prepare derivative works of any publication.

- Safety Reporting Requirements. The sponsor must comply with Amgen's safety reporting requirements that will be described in an exhibit. While the sponsor controls the protocol, Amgen remains the subject matter expert for safety on its product and has legal obligations to receive and report on uses of its product. The exhibit will take precedence over the protocol regarding safety reporting.

- Subject Injury. Amgen provides no compensation or support for subject injury in an investigator sponsored study. The sponsor is to inform subjects that Amgen will not provide any compensation for subject injuries.

- Termination. Amgen reserves the right to terminate the agreement, and Amgen will not continue to supply study drug (when provided by Amgen) after termination.