Key Contractual Terms and Conditions – Quality Improvement (QI)

If your QI grant is approved, your organisation will be required to enter into an agreement with Pfizer in order that support can be provided. The core terms of the agreement are detailed below for your information (though note that this is not the complete contract template). Note that Pfizer does not have the resource to extensively negotiate every grant contract, so please ensure that your institution is able and willing to abide by these terms before proceeding with your application.

All QI contracts will contain the following key terms:

Compliance with Applicable Requirements. Grant Recipient will conduct the Project and undertake Project-related activities in accordance with Applicable Requirements and ensure compliance with Applicable Requirements by all Staff involved in the Project. "**Applicable Requirements**" means: (i) the terms of this Agreement; (ii) the Project Plan; (iii) the terms of any institutional review board ("**IRB**") or independent ethics committee ("**IEC**") approvals and any regulatory authority approvals, if applicable; (iv) all applicable laws, rules, regulations guidelines or requirements of any supranational, federal, national, state or local court, agency, authority, department, regulatory body or other governmental instrument that may be in effect during the performance of the Project in any region or regulatory jurisdiction in which the Project is conducted ("**Applicable Law**"); (vi) all applicable good practice quality guidelines and regulations encompassing internationally recognized standards such as Good Clinical Practice, Good Laboratory Practice, and Good Review Practice; and (vii) applicable guidelines of the International Council on Harmonisation ("**ICH**").

Details: This definition (and others) have been qualified with "applicable." As such, we will not agree to limit these terms further. These are studies/projects undertaken by Grant Recipient and Grant Recipient is responsible for ascertaining which laws or guidelines apply. If a law or guidelines does not apply (since it does not apply to the Project/project or to jurisdiction where Project/project is being conducted) it would not play a role in the grant agreement. Limiting this language to a specific jurisdiction is therefore not necessary.

Status Updates. Grant Recipient will provide Pfizer with an online update of Project status at least twice a year. Each update will include publication plans, adjustments in the estimated Project Completion date, and any other information reasonably requested by Pfizer.

Details: Pfizer's online grant system will automatically request updates twice per year. This cannot be changed to a different frequency.

Use of Funding. Grant Recipient will use the Funding solely for purposes of the Project. The Funding may not be used to pay physicians or other health care providers or health care institutions for referring potential subjects (if any) for enrolment in the Project. If a third party is providing funding for the Project, Grant Recipient will use the Funding only for those Project activities that are not

covered by such third-party funding. No portion of the Funding may be used to purchase capital equipment such as computers, iPhones, tablets, appliances, machinery, camera equipment, sensors, etc.

Details: If new equipment is required for the delivery of the Project, it can be rented for the duration of the Project using Pfizer funding.

Grant Recipient may not use the Funding to: (i) pay travel, lodging, registration fees, or personal expenses for Project participants; or (ii) purchase and distribute items to Faculty or Project participants that possess a discernible value on the open market (e.g., textbooks).
The Funding may be used for food and/or beverages for Faculty or Project participants, unless Pfizer Inc. is a party to this Agreement. If Pfizer Inc. is the Pfizer entity that is party to this Agreement and is providing the Funding, no portion of the Funding may be used for food and/or beverages for Project participants, per Pfizer Inc. policy. Note that the rationale for this is that Pfizer Inc. is subject to different policy requirements relating to provision of support for food and beverage than some other Pfizer entities around the globe.

Confidentiality. Any information or materials provided to Pfizer by Grant Recipient related to the Project or the Funding are non-confidential and will not contain any markings claiming confidentiality. Grant Recipient acknowledges that Pfizer will not treat such materials as confidential or assume any obligation to keep them confidential. Grant Recipient's rights with respect to such information or materials will be only those obtained under patent laws and/or under a separate written agreement between Grant Recipient and Pfizer. Grant Recipient has not, and will not, submit any confidential information to Pfizer in connection with the Project or the Funding. Grant Recipient acknowledges that Pfizer may conduct ongoing or future research substantially similar or identical to the Project. Until after release of a Publication by Grant Recipient, Pfizer will not use the Project Report or Project Plan for any purpose other than internal review.

Details: All information related to a grant is submitted through Pfizer's online grant system. Because the system is accessible to everyone in Pfizer's Independent Medical Grants group, Pfizer colleagues and contractors with a role in relation to grants, we cannot guarantee confidentiality of anything submitted. Pfizer's online system makes clear at the application stage (on the landing page) that nothing submitted to Pfizer will be treated as confidential. Finally, other than the Project Report and Protocol (which we agree to use only for internal purposes) there is no information that Pfizer wants, or needs, in the context of a grant.

Use of Project Results and Project Data. Grant Recipient is free to publish the Project Results, subject to the provisions of this Agreement, and owns and is free to use the Project Results for any other lawful purpose. Grant Recipient owns and is free to use the Project Data for its own research,

educational, and patient care purposes. In consideration of the Funding, Grant Recipient will not use, or permit others to use, the Project Data for the commercial benefit of any third party.

Details: While Project Data is owned by the grantee, in exchange for our support of the Project, we ask that the Project Data is not commercialized. The language is designed to allow an organization to engage in research they are interested in pursuing, but only for the sake of pure research. Pfizer does not fund studies the results of which could then be commercialized and/or sold/licensed to Pfizer's competitors. If a grantee organization wants full rights to the Project Data, it would need to self-fund the Project.

Global Trade Control Laws. The parties and their agents and employees involved in activities under this Agreement, will perform the activities under this Agreement in full compliance with all applicable Global Trade Control Laws.

Details: It is Pfizer policy to comply with all applicable Global Trade Control Laws and to require anyone with whom it contracts to also comply in order to mitigate risks in this area of law.

Reconciliation. At Project Completion or termination of this Agreement, Grant Recipient will provide a detailed accounting of the costs and expenses for the Project compared to the budget and Pfizer payments. Grant Recipient agrees to refund any unused, undisbursed or misallocated funds. Upon request from Pfizer based on a good-faith belief that all or some portion of the Funding was not used in accordance with the terms of this Agreement, Grant Recipient will provide Pfizer access to all records related to the Funding to allow Pfizer to verify that the Funding was used in accordance with the terms of this Agreement.

Details: Pfizer has, in the past, received complaints alleging that grant money has been spent improperly, hence the inclusion of this language.

Termination by Pfizer. Pfizer may terminate this Agreement (A) upon 30 days prior written notice to Grant Recipient if: (i) the Project Plan is materially modified in a way unacceptable to Pfizer, (ii) the Project is not completed within six months after the expected Project Completion Date, (iii) the Project does not start within six months of the Effective Date, or (iv) if applicable, the Subject enrolment rate is significantly slower than outlined in the Project Plan or needed to complete the Project by the Project Completion Date; or (B) immediately upon written notice to Grant Recipient if Project Lead becomes unavailable or withdraws from the Project and Pfizer and Grant Recipient are unable to agree upon a successor within 30 days after Pfizer is notified.

Details: When Pfizer agrees to support a Project, it's based on the Protocol we are sent and approve. If that Protocol is materially changed, Pfizer may decide not to continue support for any number of reasons.

Similarly, Pfizer approves a Project on the assumption that it will be completed in a timely manner in order for the research to remain relevant. If it is clear that the Project will not be timely, Pfizer may terminate the grant.

Medical Education Standards. Grant Recipient will ensure the Project conforms to all applicable medical education standards and guidelines, such as the Accreditation Council for Continuing Medical Education "Standards for Commercial Support," and the European Accreditation Council for Continuing Medical Education. Grant Recipient will adhere to the IACPDA Consensus Statement (https://academy4cpd-accreditation.org/) even if the Project is not an accredited or certified continuing medical education program.

Details: This section is only relevant to QI projects that involve an medical education component. Since this section is qualified with "if" this section does not need to be deleted if it does not apply.