



## Key Contractual Terms and Conditions – Research Grants

If your research grant is approved, your institution 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). Pfizer does not have the resources to negotiate grant agreements, so please ensure that your institution is able and willing to abide by these terms before proceeding with your application.

**All clinical** research grant contracts will contain the following key terms:

- 1) **Submission of Required Documents.** Pfizer will not provide any Funding until Pfizer has received documentation of IRB/IEC approval, any necessary regulatory approval, exemption or waiver of approvals and the Final Protocol.
- 2) **Compliance with Applicable Requirements.** Grant Recipient will conduct the Study and undertake Study-related activities in accordance with Applicable Requirements and ensure compliance with Applicable Requirements by all Staff involved in the Study. “**Applicable Requirements**” means: (i) the terms of this Agreement; (ii) the Protocol; (iii) the terms of any institutional review board (“**IRB**”) or independent ethics committee (“**IEC**”) approvals and any regulatory authority approvals, if required for this type of Study; (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 Study in any region or regulatory jurisdiction in which the Study is conducted (“**Applicable Law**”); (v) 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 (vi) applicable guidelines of the International Council on Harmonisation.

*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 study/project or to jurisdiction where study/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.*

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

*Pfizer’s online grant system will automatically request updates twice per year. This cannot be changed to a different frequency. Monthly patient enrolment reports may also be requested depending on the study type.*

- 4) **Use of Funding.** Grant Recipient will use the Funding solely for purposes of the Study. 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 Study. If a third party is providing funding

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for the Study, Grant Recipient will use the Funding only for those Study 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.

*If new equipment is required for the delivery of the study, it can be rented for the duration of the study using Pfizer funding.*

- 5) **Confidentiality.** Any information or materials provided to Pfizer by Grant Recipient related to the Study 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 Study or the Funding. Grant Recipient acknowledges that Pfizer may conduct ongoing or future research substantially similar or identical to the Study. Until after release of a Publication by Grant Recipient, Pfizer will not use the Study Report or Protocol for any purpose other than internal review.

*All information related to a grant is submitted through Pfizer's online grant system. Because the system is accessible to 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 Study 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.*

- 6) **Use of Study Data and Study Results.** Grant Recipient will obtain Study Data from all Participating Sites and will arrange for the analysis of the overall Study Results. Grant Recipient is free to publish the Study Results, subject to the provisions of this Agreement, and owns and is free to use the Study Results for any other lawful purpose. Grant Recipient owns and is free to use the Study 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 Study Data for the commercial benefit of any third party.

*While Study Data is owned by the grantee, in exchange for our support of the Study, we ask that the Study 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 Study Data, it would need to self-fund the study.*

- 7) **Global Trade Control Laws.** The parties and their affiliates and Staff involved in activities under this Agreement, will perform the activities under this Agreement in full compliance with all applicable Global Trade Control Laws.

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*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.*

- 8) **Termination by Pfizer.** Pfizer may terminate this Agreement (A) upon 30 days prior written notice to Grant Recipient if: (i) the Protocol is materially modified in a way unacceptable to Pfizer, (ii) Study conduct is not completed within six months after the expected Study Completion Date, (iii) the Study 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 Protocol or needed to complete the Study by the Study Completion Date; or (B) immediately upon written notice to Grant Recipient if Investigator becomes unavailable or withdraws from the Study and Pfizer and Grant Recipient are unable to agree upon a successor within 30 days after Pfizer is notified.

*When Pfizer agrees to support a Study, 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 study 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 Study will not be timely, Pfizer may terminate the grant.*

**Research Involving a Pfizer Product** - Contracts for research grants involving the study of a Pfizer asset will also contain the following provisions (whether or not Pfizer is supplying the asset, except as noted):

1. **Notifications to Pfizer.** Institution will notify Pfizer promptly upon becoming aware during the conduct of the Study of any of the following information or circumstances relating to the Pfizer Product (as defined below), even if complete information is not yet available:
  - 1.1. imposition by an applicable competent regulatory authority in any area of the world in which the Pfizer Product is marketed of any prohibition or restriction of the Pfizer Product's use; or
  - 1.2. any new information that might influence the evaluation of the risks and benefits of the Pfizer Product, which may include both positive and negative results from clinical trials or other studies in relation to all indications and populations, whether or not use of the Pfizer Product for that indication or in that population is approved under the relevant marketing authorization.

*This provision was developed in response to legislation by the European Medicines Agency (EMA) that has a worldwide impact on Pfizer ISR studies. Under this provision, if an ISR PI becomes aware, during the conduct of the study, of certain types of new safety-related information relating to the Pfizer product – even if the information is not related to that particular study or if Pfizer does not provide the product – the PI must inform Pfizer. Note that this provision does not impose on the PI any affirmative duty to investigate or take steps to keep abreast of new studies or other information about the Pfizer product.*

2. **[Included only if Pfizer is providing the Pfizer Product as part of the grant support] Ownership and Permitted Use.** Except for, and limited to, the use specified in the Protocol, Pfizer grants Institution no express or implied intellectual property rights in the Pfizer Product or in any

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methods of making or using the Pfizer Product. Institution will use the Pfizer Product only as specified in the Protocol.

2.1. *Unauthorized Research.* If Institution uses, or permits others to use, the Pfizer Product for any research not specified in the Protocol, Pfizer will be the exclusive owner of the results of that research (“**Unauthorized Research Results**”), including any inventions or discoveries that arise out of it, whether patentable or not (“**Unauthorized Inventions**”). Institution will assign to Pfizer all interest in such Unauthorized Research Results and Unauthorized Inventions and cooperate with Pfizer to ensure execution and delivery of all documentation that Pfizer reasonably deems necessary to perfect Pfizer’s rights therein.

*This provision discusses the ramifications of a material breach of the Agreement. It specifies what is generally considered the minimum remedy that the aggrieved party would receive were a breach like this to be litigated. Simply being able to prove a breach does not mean Pfizer would be granted all IP rights by a court, however. This contractual obligation assures us of the minimum remedies we require.*

3. **Study Data.** Pfizer reserves the right to request the Study Data at a later time if a regulatory agency requests such information from Pfizer. In such case and in accordance with the Study subjects’ informed consent or IRB/IEC waiver and Applicable Law, Institution will promptly provide such Study Data to Pfizer.

*This provision is necessary to address those rare situations where a regulatory body requests information from Pfizer. It does not entitle Pfizer to access or own Study Data for commercial or research reasons.*

4. **Product-Related Inventions.** Institution will grant to Pfizer a non-exclusive, sub-licensable, transferable, perpetual, irrevocable, worldwide, royalty-free, fully paid-up license for all purposes to each Product-Related Invention [any invention which arises from or is supported by the Study Data or analysis thereof that: (i) encompasses treatment with, or the delivery, manufacture, form, formulation or use of, the Pfizer Product (including use in combination with other products or agents); or (ii) is or relates to a biomarker useful in selecting patients for treatment with the Pfizer Product] owned by Institution (including for avoidance of doubt any patent rights filed on such Invention). Such non-exclusive license will include the rights to: (i) sublicense to a Pfizer affiliate, contractor or collaborator working for the benefit of Pfizer or in connection with a product or service of Pfizer or a Pfizer affiliate, collaborator or contractor; and (ii) sublicense or assign to a successor-in-interest some or all rights in a Pfizer product to which the Product-Related Invention is relevant. Institution hereby grants to Pfizer the first right to negotiate an exclusive, sub-licensable, transferable, perpetual, irrevocable, worldwide license for all purposes, with full rights to sublicense and assign, to each Product-Related Invention owned in whole or in part by Institution, under terms to be negotiated in good faith between the Parties. Institution will promptly inform Pfizer in writing upon generation of any Product-Related Invention.

*Pfizer considers royalty-free non-exclusive rights for all purposes, with rights to sub-license and the option to negotiate for exclusive rights to any Product-Related Invention that arises out of conduct*

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*of the study to be a condition to Pfizer's support (whether or not Pfizer supplies the Product). Pfizer does not, and most sites we grant ISRs to do not, view this a State Aid for EU organizations.*

5. **Safety Reporting.** Pfizer will not monitor the Study. Institution is solely responsible for any safety reporting obligations associated with the Study required by Applicable Law and will report certain safety information to Pfizer in accordance with Attachment A.

## **Attachment A REPORTING SERIOUS ADVERSE EVENTS**

### **Definitions**

**“Adverse Event”** or **“AE”** means an untoward medical occurrence in a Study subject receiving the Pfizer Product, or an individual otherwise exposed to the Pfizer Product, without regard to whether there is a causal relationship between the Pfizer Product and the medical occurrence.

**“Serious Adverse Event”** or **“SAE”** means any Adverse Event, without regard to causality, that is life-threatening (*i.e.*, causes an immediate risk of death) or that results in any of the following outcomes: death; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity (*i.e.*, substantial disruption of the ability to conduct normal life functions); or a congenital anomaly or birth defect. Any other medical event that, in the medical judgment of Principal Investigator, may jeopardize the health of the subject or may require medical or surgical intervention to prevent one of the outcomes listed above, also is considered an SAE. A planned medical or surgical procedure is not, in itself, an SAE.

**“Device Incident”** is any malfunction or deterioration in the characteristics and/or performance of a medical device made available on the market, including use error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect.

**“Serious Device Incident”** means any incident that directly or indirectly led, might have led or might lead to any of the following: death of a patient, user or other person, temporary or permanent serious deterioration of the patient's, user's or other person's state of health, serious public health threat. A serious deterioration in health would include: a life-threatening illness or injury, a permanent impairment of a body function or permanent damage to a body structure or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

**“Reportable Event”** means any SAE, Device Incident or Serious Device Incident, whether individually or collectively.

If the Pfizer Product is, or contains, a medical device, all references to SAEs herein should be read to include the term “Reportable Event.”

**Reporting Requirements.** Additional information about the requirements herein and detailed information about reporting SAEs to Pfizer (including applicable reporting forms and completion guide) has been provided to the Principal Investigator and is available on Pfizer's online grant system.

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Institution will ensure that this additional, detailed, information is provided to all Study Staff engaged in the reporting of SAEs.

1. Timing and Scope. Within 24 hours of Institution's first awareness of an SAE, or immediately if the SAE is fatal or life-threatening, Institution will notify Pfizer by fax, email or E2B (as concurred with Pfizer) of any SAE for which reporting hereunder is required. SAEs that are subject to these reporting requirements are those that occur in: (i) Study subjects who are assigned or, in the case of a blinded Study, possibly assigned to receive the Pfizer Product; or (ii) individuals otherwise exposed to the Pfizer Product.

Institution will notify Pfizer of any such SAE within the timeframes set forth herein even if complete information is not yet available. Institution will ensure that all Study Staff notify Institution of any SAE immediately upon becoming aware.

2. Reporting Format. Each Study site will report SAEs using one of the following: (i) a reporting form approved by the local regulatory authority, (ii) a CIOMS form, (iii) a Pfizer provided *Investigator Sponsored Research or Clinical Research Collaboration Interventional Serious Adverse Event Report Form* or (iv) any other form prospectively approved by Pfizer. The *Reportable Event Fax Cover Sheet* provided by Pfizer also must be included with each SAE submitted.
3. Specific SAEs. Exposure to the Pfizer Product during pregnancy or lactation, drug overdose, medication error, occupational/environmental exposure to the Pfizer Product and lack of efficacy of the Pfizer Product are reportable to Pfizer.
  - 3.1. Exposure during pregnancy and lactation are reported independently from any associated SAE. Medication errors and overdoses are reportable only if associated with an SAE. Occupational/environmental exposure is reported independently from any associated AE/SAE.
  - 3.2. Lack of Efficacy is reportable only if associated with an SAE (except for certain scenarios which are outlined in the Pfizer provided training materials: vaccines, contraceptive and anti-infectives products).
4. Hy's Law: If the Pfizer Product is not approved in the US for the indication being studied, (irrespective of being authorized/approved elsewhere), cases of potential drug-induced liver injury as assessed by laboratory test values ("**Hy's Law Cases**") are SAEs reportable to Pfizer. If a Study subject develops abnormal values in aspartate transaminase ("**AST**") or alanine transaminase ("**ALT**") or both, concurrent with abnormal elevations in total bilirubin and there is no other known cause of liver injury, that event would be classified as a Hy's Law Case.
5. Crizotinib: If Study subjects will receive crizotinib, any AE of potential sight threatening event ("**PSTE**") or severe visual loss ("**SVL**") must be reported as an SAE in subjects treated with crizotinib, even if the study drug is not (or is not otherwise related to) crizotinib.
  - 5.1. SVL is defined as Grade 3 or Grade 4 eye disorders based on Common Terminology Criteria for Adverse Events ("**CTCAE**") published by the National Cancer Institute. According to CTCAE, Grade 3 eye disorders include symptomatic retinopathy with marked decrease in

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visual acuity (worse than 20/40) or disabling (limited self-care activities of daily living). Grade 4 eye disorders include blindness (20/200 or worse) in the affected eye.

- 5.2. PSTE includes all identified Grade 2 eye disorders listed above (except visual field defect) and the following Grade 2 eye disorders: retinal detachment, retinal edema, maculopathy, iritis, uveitis, and abnormal visual field tests.
6. Exclusions. Specifically excluded from the reporting requirements for SAEs is: (i) any SAE identified in the Protocol as anticipated to occur in the Study population at some frequency independent of drug exposure, unless a Principal Investigator suspects a causal relationship between the SAE and the Pfizer Product; and (ii) if the Pfizer Product is an oncology drug, any SAE judged by a Principal Investigator to represent progression of the malignancy under study, unless it results in death within the SAE reporting period.
7. Reporting Period. SAEs that are subject to these reporting requirements are those that: (i) occur from the first dose of the Pfizer Product or the Study subject's enrollment in the Study (whichever is later) through 28 calendar days after the last administration of the Pfizer Product or the subject's last Study visit (whichever is earlier), or longer if so specified in the Protocol; or (ii) occur any time after the 28-days period (i.e., any time after the completion of the active study collection/reporting period), if Institution or Principal Investigator suspects a causal relationship between the Pfizer Product and the SAE.
8. Follow-Up Information. Institution will assist Pfizer in investigating any SAE and will provide any follow-up information reasonably requested by Pfizer.
9. Regulatory Reporting. Reporting an SAE to Pfizer does not relieve Institution of responsibility for reporting such SAE to appropriate regulatory authorities, if required.
10. IMP and SRSD. Principal Investigator will identify the Pfizer Investigational Medicinal Product(s) and respective Single Reference Safety Documents to be used for expectedness assessment for the Study and will provide this information via Pfizer's online grants system prior to Study start.
11. Pfizer-Provided Safety Information. Pfizer distributes ISR line listings to Institutions bi-annually, or more frequently based on the risk assessment of the ongoing interventional clinical studies.

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