Funding Agreement
(CEPI Identification: _____)

Agreement Summary

AWARDEE INFORMATION	
Name:	
Mailing Address:	
Project Lead:	
Management Contact:	
Bank Account Details:	Account Name: Account Number: Sort Code: IBAN: Swift Code: Bank:

CEPI INFORMATION	
Mailing Address:	Marcus Thranesgate 2, PO Box 123 Torshov, N-0412 Oslo, Norway
Project Lead:	
Management Contact:	

AGREEMENT INFORMATION	
Project Name	
CEPI Program Name	
Effective Date	Date of last signature below
Termination Date	
This Agreement includes and incorporates by reference:	The agreement (referred to as the "Agreement") means this Agreement Summary together with the following: - Terms and Conditions ("T&Cs") *(Annex A)* - Glossary of Defined Terms for the T&Cs *(Schedule A)* - Effects of Termination for the T&Cs *(Schedule B)* - Team Charter *(Annex B)* - Integrated Product Development Plan ("IPDP") *(Annex C)* - IPDP Reporting Templates *(Annex D)*

	- Project Budget *(Annex E)* - Payment Request Form and Financial Report Templates *(Annex F)* - CEPI Policies and Procedures *(Annex G)*

THIS AGREEMENT is between _____ ("Awardee" or "You") and the Coalition for Epidemic Preparedness Innovations ("CEPI") and is effective as of the date of the last signature, below. Each party to this Agreement may be referred to individually as a "Party" and together as the "Parties." This Agreement sets out the terms and conditions governing the performance of the Project, funding of the Project and how the results of the Project will be used to further CEPI's mission. As a condition of this funding award, the Parties enter into this Agreement by having their authorized representatives sign below.

Signed for and on behalf of **COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS** by:

Signature:……

Name:……..

Title:……

Date:……

Signed for and on behalf of **[AWARDEE]** by:

Signature:……

Name:……..

Title:……

Date:……

CfP3i Award Terms and Conditions

1. These Terms and Conditions

[This Clause 1 describes the "Terms and Conditions" or "T&Cs", including an attached "Glossary" of key defined terms. This template may be modified by CEPI and is not binding until it becomes part of a fully executed "Agreement" that also includes an Agreement Summary and the other annexes described below.][1]

1.1 These "Terms and Conditions" (or "T&Cs") describe the contractual relationship between CEPI and Awardee for a particular Project under CEPI's CfP3i Programme. They describe each Party's rights and obligations, and provide instructions on the conduct of funded activities and the intended use of the results from funded activities. The Parties commit to participate in the Project with good intent and in good faith.

1.2 A glossary of defined terms used in these T&Cs is set out in Schedule A. A table setting out the effects of termination may be found in Schedule B to the T&Cs.

2. Project Organization and Management

[This Clause 2 describes the Project and the annexes to this Agreement in addition to these T&Cs. It also describes an Awardee's responsibilities for project management.]

2.1 **The IPDP and Work Packages**. The Awardee's Project activities, which are intended to further develop a Chikungunya Vaccine and/or Rift Valley Fever Vaccine, are set out in the Integrated Product Development Plan (IPDP), which may be found in Annex C. The IPDP also sets out the associated Project deliverables, milestones and timelines.

2.2 **Project Organization**. The Project will be organized and managed as described in the Team Charter in Annex B. The Awardee will be expected to provide monthly and quarterly reporting of its activities under the Project (referred to as "IPDP Reports"), templates for these reports may be found in Annex D. The Project Budget is described in Annex E. The Payment Request Form and a template for quarterly Financial Reports may be found in Annex F.

2.3 **Joint Monitoring and Advisory Group**. The Team Charter establishes a Joint Monitoring and Advisory Group (or "JMAG") to facilitate communications and interactions between the Parties, as well as review Project activities in terms of timelines and budget.

2.4 **The Awardee will**:

a. undertake the activities and comply with the obligations described in the Team Charter;

b. participate in the designated activities and meetings of the JMAG;

[1] *Italicized comments in brackets at the beginning of each Clause of this template describe the purposes of each Clause and will facilitate review by potential awardees. These comments will be removed before the agreement is signed.*

c. keep accurate, complete and reliable records of activities performed and results arising as a result of the activities set out in the IPDP ("IPDP Records");

d. maintain the IPDP Records for seven (7) years after the termination or expiry of the Project, or for any longer period as required by law, the CEPI Clinical Trials Policy or Awardee's own policies;

e. monitor progress of the Project and make IPDP Reports to the JMAG as described in the IPDP;

f. propose amendments to the IPDP and Project Budget to the JMAG, as may be required; however, such amendments may require CEPI approval beyond the JMAG level; and

g. notify CEPI if the Project Lead designated in the IPDP becomes unavailable and designate a replacement reasonably satisfactory to CEPI within thirty (30) days.

3. Sub-Awardee Participation in the Project

[This Clause 3 explains how Sub-Awardees will be designated and approved to work with Awardee on the Project. CEPI expects that all compliance, management and warranty obligations on Awardee will flow down to each Sub-Awardee. This Clause also explains Awardee's responsibilities for Sub-Awardees. Upon Awardee's request, CEPI will pre-identify potential collaborators in LMICs.]

3.1 **Sub-Awardees and Affiliates**. Awardee's activities under the Project may be undertaken by Affiliates and contracted third parties (collectively, "Sub-Awardees") as reflected in the IPDP and Project Budget. Awardee will be responsible for the acts and omissions of its Sub-Awardees.

3.2 **CEPI Approval of Additional Sub-Awardees**. Any proposed Sub-Awardee not expressly referred to in the IPDP or Project Budget must be approved by CEPI in writing before a sub-award has been made.

3.3 **Sub-Awardee Obligations**. A Sub-Awardee must agree to comply with all of the relevant obligations applicable to Awardee, whether explicitly identified as such or as is reasonable from the nature of the obligation. Each sub-agreement with a Sub-Awardee must:

a. be consistent with the Work Package structure as well as the associated milestones and budgets;

b. require the same record keeping obligations and provide CEPI the same access (either directly or indirectly through Awardee) to IPDP and Financial Records (as are applicable to Awardee);

c. require compliance with the same laws, policies and procedures as are applicable under these T&Cs;

d. be consistent with the obligations in the sections related to Dissemination and Publication of Project Data (Clause 11); Dissemination of Project Materials (Clause 12); Intellectual Property (Clause 13); Equitable Access (Clause 14); Sharing of Commercial Benefits (Clause 15); Preparation for Outbreaks (Clause 16); the Public Health License (Clause 17); and Term and Termination (Clause 20); and

e. prohibit the Sub-Awardee from subcontracting its obligations.

3.4 **The Awardee will**:

a. sign an agreement with each Sub-Awardee, prior to their conducting any activities under the Project, that is consistent with Awardee's relevant obligations to CEPI under the IPDP;

b. cooperate with CEPI to preferentially use Sub-Awardees operating in Low and Middle Income Countries where Outbreaks are likely to occur in order to build infrastructure and develop experienced personnel in the relevant territory; and

c. promptly provide a copy of each Sub-Awardee agreement to CEPI.

4. Project Funding and Work Packages

[This Clause 4 explains how the Project will be funded and describes Awardee's responsibilities for financial record keeping. It also explains CEPI's rights to terminate or modify funding under certain circumstances, in part related to decisions CEPI may have to make about the priorities for funding among its various activities. Any c*o-funding by Awardee is described in the Project Budget.]*

4.1 **Work Packages**. The IPDP will be organized into discrete phases, corresponding with the Project Budget. The associated activities, budgets, deliverables and timelines for each phase are set out in work packages (each a "Work Package").

4.2 **Work Package Payments**. Payments for each Work Package will be made in US dollars ($) to Awardee's bank account identified on the Agreement Summary. CEPI will make payments in advance covering the planned activities for the subsequent six (6) month period, and beginning on the Effective Date of the Award.

4.3 **Subsequent Tranches**. CEPI will pay the initial tranche of funding after receipt of a payment request by Awardee following signature of this Agreement. All subsequent tranches for each Work Package will be paid by CEPI within twenty (20) Business Days after receipt of all of the following: (i) a payment request by Awardee; and (ii) the required IPDP Report (Annex D) and Financial Reports (Annex F), adjusted appropriately for any underspend from any previous payments.

4.4 **Payment when there is a Breach**. CEPI is not obliged to pay any tranches of funding for any Work Package for so long as Awardee is in breach of a material obligation under this Agreement.

4.5 **Delayed Payments.** CEPI may delay or condition a payment if:

a. Awardee has not achieved a milestone by the agreed time, unless such delay has been approved by the JMAG;

b. CEPI has been notified that Awardee or any of its Sub-awardees are no longer in compliance with the Warranties under Clause 18 at the time the tranche is requested; or

c. Awardee has not completed the payment request form or submitted satisfactory IPDP Reports and/or Financial Reports.

4.6 **No Obligation to Fund Additional Work Packages**. CEPI may decide not to proceed with any additional or sequential Work Package if it is not in the best interest of CEPI's mission. If CEPI decides not to fund additional Work Packages, it will notify Awardee as soon as such a decision is made and will cooperate with Awardee in an appropriate Project wind down.

4.7 **Retained Payment**. CEPI will retain ten per cent (10%) of the final payment tranche until Awardee submits the final IPDP Report and Financial Report.

4.8 **The Awardee will**:

a. use award payments only in accordance with the IPDP, agreed Work Package and Project Budget;

b. provide a Financial Report to CEPI regarding its expenditures pursuant to the Project Budget, using the template provided in Annex F; and

c. reimburse CEPI for any funding underspend.

5. Financial Management and Oversight

[This Clause 5 explains financial management and oversight practices. As an ethical organization and as the recipient of funds from several governments, CEPI follows good management practices including transparent and well-controlled procurement and prudent anti-corruption principles and observes international sanctions. Accordingly, for example, CEPI will reimburse only travel expenses in line with CEPI's travel policy.]

5.1 **Financial Practices**. Awardee's financial management of the Project will be governed by controls, good management practices, procedures and standards at least as rigorous as its local Generally Accepted Accounting Principles (GAAP), or International Financial Reporting Standards (IFRS) if adopted by the Awardee, as confirmed in Awardee's annual audited financial statement.

5.2 **Financial Oversight**. CEPI, or its designee, will have on-site access to Awardee's Financial Records at least annually, including at such times as CEPI may request provided CEPI has given not less than five (5) Business Days' notice, in order that CEPI may monitor Awardee's expenditure of Project funds.

5.3 **The Awardee will**:

a. keep accurate, complete and reliable records of revenues and expenditures under the Project Budget ("Financial Records") against an individual project code;

b. retain all Financial Records for seven (7) years after termination or expiry of the Project or for any longer period as required by law or Awardee's own policies and allow CEPI access to such records as set out in Clause 5.2 for such retention period;

c. provide sixty (60) days written notice to CEPI before destroying Financial Records;

d. provide up-to-date audited financial statements, as requested by CEPI, and relevant extracts from the auditors' report for such financial statement as well as the management letter to the auditors;

e. if requested by CEPI, Awardee will procure Awardee's external auditors to conduct a Project audit (on and off site) and provide CEPI with audited statements regarding the Project Budget (in accordance with ISA800) at CEPI's reasonable cost and expense;

f. procure a Project audit as identified above from Sub-Awardees at CEPI's request; and

g. provide information required by the European Communities Court of Auditors and Anti-Fraud Office.

6. Compliance with Applicable Laws and CEPI Policies and Procedures

[This Clause 6 describes various compliance obligations applicable to Awardee, including "CEPI Policies and Procedures" and other policies that flow down from CEPI's own funders. Compliance with CEPI's Clinical Studies and Animal Studies policies are also addressed in Clauses 7 and 8 respectively, and CEPI's Open Access policy is addressed in Clause 11.6.]

6.1 **Compliance Requirements**. Relevant national and supranational laws and governmental regulations will apply to Awardee's Project-related activities. In addition, Awardee must also comply with the CEPI Policies and Procedures, which include specified procurement requirements. This Agreement incorporates requirements from CEPI's own funders, and CEPI will cooperate with Awardee to ensure that it is able to fulfill its obligations as found in the CEPI Policies and Procedures and this Agreement.

6.2 **Amendment of CEPI Policies and Procedures**. CEPI may notify Awardee from time-to-time that the CEPI Policies and Procedures have been amended. Such amended CEPI Policies and Procedures will become effective with respect to Awardee and Sub-Awardees sixty (60) days after notification from CEPI absent notification of objection by the Awardee.

6.3 **The Awardee will**:

a. comply with applicable laws and regulations;

b. subject to Clause 22.6, comply with CEPI Policies and Procedures;

c. provide access to information to the EC Court of Auditors and Anti-Fraud Office as required;

d. to the extent that the Project involves relevant activities, comply with Good Laboratory Practices ("GLP"), Good Clinical Practices ("GCP") and Good Manufacturing Practices ("GMP") as defined either in the CEPI Policies and Procedures or otherwise under applicable law or best practice; and

e. notify CEPI promptly to discuss any amended CEPI Policies and Procedures that raise concerns about Awardee's ability to perform its obligations under this Agreement.

7. Clinical Studies

[Some Projects may involve clinical studies, and this Clause 7 describes relevant compliance obligations in addition to the conditions given under Clause 6. Some of the "consent" requirements described here are necessary for enabling some of the data and sample access procedures described in Clauses 11 and 12.]

7.1 **Clinical Studies**. If any Work Package includes research involving human subjects, such activities must comply with applicable laws, relevant regulatory agencies and CEPI's Clinical Trials Policy.

7.2 **Clinical Data**. The data arising in the conduct of a clinical trial will be collected in a way that ensures that each subject, prior to enrolment and in accordance with all applicable laws and regulations, including the EU's General Data Protection Regulation (GDPR), provides informed consent to allow:

a. direct access to her or his medical records;

b. the processing of data relating to her or him and to the movement of that data to other countries, including countries outside of the European Economic Area;

c. the transfer of such data to Awardee;

d. the transfer of anonymised data to CEPI;

e. the collection and use of clinical study data (duly anonymised and, at CEPI's request, blinded) for the purposes indicated in Clause 11;

f. the collection and use of biological samples and the use of data (duly anonymised and, at CEPI's request, blinded) derived from such samples by CEPI or its designated Assessors for the purposes indicated in Clause 12; and

g. the use of such data for the purpose of obtaining approval from applicable regulatory agencies.

7.3 **Priority for Clinical Studies**. Awardee acknowledges that the pool of subjects available in areas of Outbreak to participate in a clinical study to test products such as the Product may be limited. Accordingly, if CEPI determines that a product other than the Awardee's Product has substantially greater potential and should be used for a particular clinical study, the Awardee agrees that it shall abide by such decision and will not proceed with a clinical study of the Product unless agreed with CEPI.

7.4 **The Awardee will**:

a. be the sponsor of any clinical study (unless CEPI and Awardee otherwise agree in writing);

b. be responsible for obtaining and maintaining all regulatory approvals (including ethical committee approvals) necessary or reasonably useful for the conduct of the clinical trial and appropriate clinical trial insurance cover;

c. publish details of any clinical study in a publicly accessible clinical study register, where patient privacy is upheld, as required under law and, as applicable, prior to the commencement of patient recruitment for such clinical study;

d. ensure that any informed consent form permits the use of Project Results described in these T&Cs and in the IPDP;

e. establish a Trial Steering Committee (TSC) and Data Safety Monitoring Board (DSMB);

f. notify the JMAG and TSC in writing immediately following any Safety Issues or similar events;

g. verify that the clinical study data are complete and include all completed case report forms and all other clinical study documentation required to be in the possession of a clinical trial sponsor by applicable law; and

h. permit a CEPI representative or nominee (except for any matters that should remain blinded to CEPI in the interests of the integrity of the clinical study) to:

i. attend meetings of the TSC and the DSMB for the clinical study as an observer (either in person or by electronic means); and

ii. receive all papers that a member of the TSC or DSMB would be entitled to receive.

8. Animal Studies

[Some Projects may involve animal studies. This Clause 8 describes relevant compliance obligations in addition to those mentioned in Clause 6.]

8.1 **Animal Studies**. If any Work Package includes studies using animals, such activities must comply with applicable laws as well as CEPI's Animals in Research Policy.

8.2 **The Awardee will**:

a. obtain and maintain all regulatory approvals (including ethical committee approvals) necessary or reasonably useful for the conduct of research involving animals; and

b. inform JMAG of any anticipated deviations from the original design of animal studies described in the IPDP and obtain JMAG approval before implementing those changes.

9. Standards and Assays

[Some Projects may involve the sourcing of samples or other materials and the development of assays and biological standards, and this Clause 9 describes relevant obligations. Additional provisions for such Project activities will be included. This clause may not be relevant to all Project awards.]

9.1 **Standards Development**. If any Work Package relates to the development of biological reference materials, Awardee will provide relevant materials and data and shall grant rights to their use for International Standards development, to an independent standards development agency, such as the National Institute for Biological Standards and Control (NIBSC) in the United Kingdom, as CEPI may direct.

9.2 **Assay Development**. A Work Package may include the development of assays (including immunogenicity and potency/release assays) intended for use by CEPI's awardees in the CfP3 Programme, as will be described in the IPDP.

9.3 **The Awardee will**:

a. as described in the IPDP, participate in collaborative interlaboratory studies for evaluation of a candidate reference material. Such studies ultimately will be included in reports to the WHO Expert Committee on Biological Standardization; and

b. provide written Standard Operating Procedures ("SOPs") for any assays developed and qualified with CEPI funding or with the use of samples or biological material facilitated by CEPI. Transfer assay capacity and technology to a designated third party laboratory if required by CEPI for the assay to be validated for Phase 3 clinical trials.

10. Project Results and their Ownership

[This Clause 10 confirms that Awardee owns its Project Results. Several Clauses that follow explain how Project Results will be published and shared.]

10.1 **Project Results**. The Project Results, meaning the outcomes and results of the Project, may comprise biological samples, data, intellectual property, materials, any Product and Investigational Product, publications, reference standards, technology and other results and shall include all Project IP, Project Data and Project Materials.

10.2 **Ownership of Project Results**. Awardee will own the Project Results.

10.3 **The Awardee will**:

a. record Project Results accurately, completely and reliably in Awardee's IPDP Records; and

b. identify Project Results in the IPDP Reports provided to the JMAG.

11. Dissemination and Publication of Project Data

[This Clause 11 describes how Project Data, including clinical study data, should be disseminated. CEPI's Scientific Integrity Policy and Clinical Trials Policy are pertinent.]

11.1 **Reporting of Project Data**. Awardee shall provide CEPI with access to all data and information, including all clinical study data, produced or arising as a result of the Project ("Project Data"), and will report Project Data regularly to the JMAG.

11.2 **Sharing of Project Data with the Research Community**. Awardee will share Project Data as described in the IPDP relevant to topics of interest to the research community, such as disease-specific assays, animal models, correlates of protection or diagnostics and epidemic preparedness mechanisms, subject to reasonable protection for Awardee's rights under this Agreement.

11.3 **Publication of Project Data**. CEPI encourages the timely publication of Project Data and other Project Results in scientific literature.

11.4 **Clinical Study Data**. CEPI's Clinical Trials Policy requires that clinical data and results (including negative results) must be disclosed publicly in as close to real time as possible. Accordingly, such data must be shared through an easily discoverable public route (website or system) that includes a metadata description, where patient privacy is upheld, and the system follows a request-for-information approach (where requests are fulfilled subject to an independent review and approval step). Clinical study data will be submitted for publication within twelve (12) months after each final study report or report submitted to CEPI. The Clinical Trial ID or registry identifier code/number shall be included in all publications of clinical trials.

11.5 **Outbreak-Related Publications**. Additionally, Project Data will be shared in accordance with WHO's 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks and WHO's 2016 Guidance on Good Participatory Practices in Trials of Interventions Against Emerging Pathogens.

11.6 **Open Access**. CEPI requires "Open Access" for Project Data. This means that a copy of the final manuscript of all research publications, journal articles, scholarly monologues and book chapters published under this Clause 11 must be deposited into PubMed Central (or Europe PubMed Central) or otherwise made freely available upon acceptance for publication or immediately after the publisher's official date of final publication. Moreover, all peer-reviewed published research that is funded, in whole or in part, by CEPI shall be published in accordance with the principles of "Plan S" - Accelerating the transition to full and immediate Open Access to scientific publications, a UK and European data sharing initiative for research funded by public grants.

11.7 **The Awardee will**:

a. notify the JMAG on an ongoing basis as Project Data is produced and disseminated;

b. disseminate Project Data consistent with the requirements set out above; and

c. cooperate in regard to data analysis, to the extent relevant under a given Work Package, by CEPI's Assessors by:

i. providing data or other information generated under this Agreement to CEPI's designated Assessor as CEPI shall request, including data regarding CMC, formulation or the results of any of its pre-clinical or clinical trials (duly anonymized and, upon CEPI's request, blinded);

ii. providing CEPI's designated Assessor with other data (duly anonymised and, upon CEPI's request, blinded) as CEPI may reasonably request in order to conduct comparative assessments; and

iii. providing CEPI's designated Assessor with clinical study data (duly de-identified and, at CEPI's request, blinded) for the purposes of signal detection or meta-analyses of safety data (including across candidate vaccines).

12. Dissemination of Project Materials

[This Clause 12 describes how Project Materials, including biological samples, should be disseminated.]

12.1 **Dissemination and Sharing of Project Materials**. Awardee will share biological samples, vaccines (including Product), animal models and other tangible materials produced under the Project (together "Project Materials") as described in the IPDP and this Agreement.

12.2 **Comparative Evaluation of Samples**. CEPI may engage one or more independent third party laboratories or collaborators ("Assessors") to perform additional testing on Project Materials, at CEPI's expense, in order to provide CEPI with directly comparable evaluations of similar materials produced under CEPI's portfolio of awarded projects. CEPI may, in its sole discretion and at its own expense, also engage certain independent third party entities to transport the samples from Awardee to the Assessor, address import/export issues, or provide any documentation CEPI may determine is required for such samples. The results of the testing, analysis, meta-analysis or other assessments will be subject to the confidentiality obligations under this Agreement. CEPI will provide to the Awardee the results of such data analysis relevant to Awardee's activities under the Project.

12.3 **The Awardee will**:

a. notify the JMAG on an ongoing basis as Project Materials are produced under the IPDP;

b. disseminate and share Project Materials consistent with the requirements set out above; and

c. cooperate with CEPI's Assessor, to the extent relevant under a given Work Package, by:

i. providing CEPI's designated Assessor a reasonable number of doses of a candidate vaccine, as specified in the IPDP, representative of the final Product, for animal immunogenicity studies;

ii. providing CEPI's designated Assessors with an agreed number of samples from clinical studies under the Project for use in future research carried out by or on behalf of CEPI including agreed volumes of biological samples (for example, serum, and peripheral blood mononuclear cells (PBMCs)) from human subjects vaccinated with the Project vaccines in Phase 1 clinical trials at specified timepoints agreed with CEPI for immunology testing; and

iii. ensuring that any samples to be transferred or exported by or on behalf of Awardee from a clinical trial site or sample storage site are transferred and/or exported pursuant to the terms and conditions of a suitable to-be-agreed-upon material transfer agreement to be entered into between Awardee and the Assessor in addition to any other applicable laws and regulations.

13. Intellectual Property

[This Clause 13 describes the treatment of IP rights that arise under the Project or that are owned by third parties and may affect the Project. Generally, CEPI's interest in IP is knowing what IP has been developed with CEPI funding and having rights under that IP sufficient to utilize the Public Health License described in Clause 17.]

13.1 **Protection for Project IP**. Awardee has the right, but not the obligation, to seek protection, at its own cost, for the discoveries, inventions, know-how, patents, trademarks and other forms of intellectual property that arise under the Project ("Project IP").

13.2 **Third Party Patents**. The Parties will notify each other promptly regarding any third party intellectual property they become aware of that raises concerns about Awardee's ability to perform its obligations under this Agreement or the potential use by CEPI of the Public Health License described in Clause 17. The Parties will cooperate in good faith to resolve any such matters.

13.3 **The Awardee will**:

a. notify the JMAG as Project IP is created, discovered or made; any applications for any rights to Project IP are submitted or are otherwise prosecuted; any application regarding the registration of any Project IP is granted, including the granting of any patent or trade mark, as part of its regular IPDP reports; and

b. ensure that it has enforceable policies or written agreements with all of its employees, agents and subcontractors which assign to the Awardee ownership of all Project IP.

14. Equitable Access

[This Clause 14 is based on CEPI's expectation that most of the vaccines it helps to develop will not be profit-making, particularly in low to middle income countries ("LMICs") in affected areas where purchasing power is limited. It is CEPI's policy that access to these vaccines will be provided at a cost to LMICs that is fair both to the populations who need them and to CEPI's awardees who develop products.]

14.1 **Equitable Access**. CEPI is committed to achieving equitable access to the outputs of all CEPI-supported programmes including access to all Project Results, pursuant to CEPI's "Equitable Access" Policy. Equitable Access to epidemic vaccines in the context of an Outbreak means that appropriate vaccines are first available to populations when and where they are needed to end an Outbreak or curtail an epidemic, regardless of ability to pay. CEPI is also committed to supporting Equitable Access so that the economics are sustainable to the manufacturer.

14.2 **The Awardee will**: to the extent that Awardee commercializes Product which utilizes or otherwise benefits from, whether directly or indirectly, any Project Result, the distribution of that product in LMICs will be consistent with CEPI's Equitable Access Policy and Cost Guidance Policy, as well as with The Bill & Melinda Gates Foundation's approach to determining appropriate product costs.

15. Sharing of Commercial Benefits

[This Clause 15 explains that, although CEPI's awards are intended to result in vaccines for Outbreaks most likely to occur at scale in LMICs, there may be other markets in which Project Results will have commercial value, for example, in the production of traveler vaccines or other products appropriate for non-Outbreak purposes. CEPI is obligated to its own funders to seek a share of non-Outbreak commercial benefits as a contribution to support CEPI's programme activities. CEPI is willing to discuss reasonable commercial benefit sharing at a time in the future when commercial benefits are predictable or to include a specific approach in this Agreement.]

15.1 **Sharing of Commercial Benefits**. CEPI has committed to its own funders to obtain a share of Awardee's Commercial Benefits as a contribution to support CEPI's programme activities.

15.2 **CEPI's Commitment**. CEPI will work with Awardee to ensure that the risks, costs and benefits of Product development and commercialization are accounted for fairly, proportionately and reasonably when calculating an appropriate share of any Commercial Benefits. Mechanisms for benefit sharing may include: sharing of profits, other than those arising from activities directly related to the curtailment of an Outbreak, as a way to support CEPI's future awards; a specific commitment in relation to Equitable Access; a commitment to participate in future award programmes; the allocation of certain percentages of Product doses for distribution after the end of the Project as determined by CEPI; the provision of in-kind services in support of CEPI's mission; or in other appropriate ways agreed with CEPI.

15.3 **The Awardee will**:

a. share Commercial Benefits with CEPI through an appropriate mechanism agreed by the Parties;

b. notify CEPI as commercial activities which benefit from the Project Results are undertaken along with, if relevant, an indication of how Commercial Benefits might be shared; and

c. provide CEPI with the information reasonably required to assess the formulation and calculation of an appropriate mechanism for sharing of Commercial Benefits.

16. Preparation for Outbreaks

[This Clause 16 explains that Awardee may be requested to undertake additional Product-related work at CEPI's expense, consistent with the provisions of Equitable Access. If Awardee is unable or unavailable to do so, CEPI would prefer that Awardee designate a trusted collaborator to complete this work. The definition of "Outbreak" reflects the WHO definition and may be triggered by WHO or declarations by governments in an affected area.]

16.1 **Outbreak**. CEPI will notify Awardee in writing in the event of an Outbreak ("Outbreak Notice") or if there is an Increased Outbreak Preparation Need. In consultation with relevant public health authorities, CEPI may request that Awardee discuss in good faith whether and how the Project Results could be utilized in response to the Outbreak Notice. Once an Outbreak Notice has been provided, CEPI shall have the right to direct how any Product manufactured pursuant to Clause 16.3 may be used and to whom it may be provided.

16.2 **Additional Product Development**. Pursuant to an Outbreak Notice, CEPI may request that Awardee undertake additional Product development at CEPI's expense or other activities, including the pursuit of regulatory approvals and licensure. An additional Work Package covering these activities will be negotiated expeditiously and in good faith by the Parties.

16.3 **Investigational Product Stockpiles**. Following the successful completion of a Phase 2 clinical study supported under the Project, CEPI may request that Awardee undertake, at CEPI's expense, the manufacturing of a stockpile of Investigational Product. Such Product may be used for further clinical trials in Outbreak conditions to advance vaccine development, or pursuant to an emergency use authorization, in each case in emergency situations based on national or international guidance (such as WHO). An additional Work Package covering this activity will be negotiated expeditiously and in good faith by the Parties.

16.4 **Trusted Collaborator**. At the time that Awardee submits a Phase 2 study report to CEPI (or at any earlier time), Awardee will propose a third party, for example, a Sub-Awardee, as a preferred alternative to itself ("Trusted Collaborator"), that is capable of performing the work and would be prepared to undertake activities pursuant to Clauses 16.2 or 16.3 in the event that Awardee declines CEPI's request to do so, or if Awardee and CEPI do not reach agreement on a new Work Package. Alternatively, CEPI may propose a Trusted Collaborator to Awardee. Neither Party may unreasonably decline to accept the designation of a proposed Trusted Collaborator.

16.5 **Technology Transfer**. As described in the IPDP, or otherwise upon designation of a Trusted Collaborator pursuant to Clause 16.4, Awardee will promptly and diligently provide all necessary guidance, information, materials and assistance reasonably required by the Trusted Collaborator to accomplish the activities that may be requested by CEPI under Clauses 16.2 or 16.3 ("Technology Transfer") at CEPI's reasonable cost.

16.6 **The Awardee will**: cooperate with CEPI in developing a response to an Outbreak or Increased Outbreak Preparation Need` which may include opportunities for Awardee and its Sub-Awardees to receive additional Work Packages and funding from CEPI.

17. Public Health License

[This Clause 17 explains that If Awardee is unable or unavailable to do additional Outbreak-related work, and does not agree with CEPI in the designation of a Trusted Collaborator, then CEPI may utilize Project Results and Products to prepare stockpiles of Investigational Products and otherwise to respond to an Outbreak. This is referred to as the "Public Health License." CEPI would need to have freedom to operate under a Public Health License. So, a grant of rights under Awardee's "Enabling Rights" is also required to capture concepts sometimes described, for example, as background IP, improvements or sideground rights.]

17.1 **Grant of a Public Health License**. Awardee hereby grants the Public Health License to CEPI, on the condition that CEPI may only exercise the rights granted under the Public Health License in the following circumstances:

a. Awardee's activities supported by CEPI under the Project have meaningfully advanced the Product;

b. the Awardee has not notified CEPI that it wishes to terminate the Agreement pursuant to Clause 20.2; and

c. one or more of the triggers set out in Clause 17.2 has occurred.

17.2 **Public Health License Triggers**. Consistent with Clause 17.1, CEPI's right to exercise the Public Health License will be triggered when:

a. Awardee declines to participate in activities requested by CEPI under one or both of Clauses 16.2 or 16.3,

b. CEPI determines, in good faith, that Awardee will not be able to perform the activities under Clauses 16.2 or 16.3 if requested by CEPI;

c. thirty (30) days have passed since an Outbreak Notice and the Parties have not signed an agreement for the activities contemplated under Clauses 16.2 or 16.3, despite CEPI's request; or

d. the Agreement is terminated by CEPI pursuant to Clause 20.2, 20.3a) or 20.3c).

17.3 **Agreement with Trusted Collaborator**. In the event that the Public Health License becomes exercisable in accordance with Clause 17.1, CEPI may endeavor to reach agreement with a Trusted Collaborator to perform such activities as CEPI may deem necessary. If those negotiations do not result, or CEPI deems that such negotiations are unlikely to result, in an agreement, then CEPI may grant rights under its Public Health License to a third party unilaterally designated as a Trusted Collaborator by CEPI, without reference to the Awardee.

17.4 **The Awardee will**:

a. identify Enabling Rights to CEPI as of the Effective Date and provide updates to the JMAG regarding the Enabling Rights during the course of the Project;

b. provide an updated list of Enabling Rights to CEPI in the event that the Public Health License becomes exercisable; and

c. make no encumbrances regarding ownership or access to Project Results or Enabling Rights that may be inconsistent with the Public Health License without the express written permission of CEPI, such permission not to be unreasonably withheld.

18. Warranties

[This Clause 18 describes the warranties and undertakings that CEPI requires of an awardee.]

18.1 **Warranties**. As of the Effective Date, Awardee warrants that the following statements ("Warranties") are true and correct:

a. it has the full power and authority to enter into and assume its obligations under this Agreement;

b. it is in material compliance with all statutes, regulations, directives and requirements of any governmental entity that relate to its activities and obligations;

c. to the best of its knowledge and belief, it does not infringe, misappropriate or violate the intellectual property, privacy or publicity rights of any third party that are relevant to the Project;

d. it has not granted rights to any third party in respect of Project Results (other than in accordance with the terms of this Agreement);

e. to the best of its knowledge and belief, no person has any right or claim to any payment or other compensation in respect of the use or exploitation of the Project Results, except as set out in pre-existing or contemplated licence agreements with third parties, copies of which have been provided to CEPI prior to the Effective Date;

f. to the best of its knowledge and belief, none of Awardee and its Sub-awardees, nor any officer or employee of the foregoing has been debarred or is subject to debarment by a regulatory authority or funding agency anywhere;

g. all financial statements and budgets submitted to CEPI as of the Effective Date are true, complete and accurate; and

h. to the best of its knowledge and belief, all encumbrances have been disclosed that could affect CEPI's use of the Public Health License.

18.2 **The Awardee will:** undertake during the Term of this Agreement that all of the statements warrantied above will remain true and correct, and shall notify CEPI promptly in the event that this changes.

19. Indemnification and Insurance

[This Clause 19 describes the insurance and provides mutual indemnification provisions.]

19.1 **Indemnification for Third Party Claims**. Awardee will indemnify and defend CEPI, its Affiliates, third party contractors and employees from and against any and all claims, damages, and liabilities asserted by third parties (including claims for negligence) which arise directly or indirectly from: (i) Awardee's, or its Sub-Awardee's activities under this Agreement, or (ii) the use of the Product, Project Results or Enabling Rights (including for the avoidance of doubt, the use of the Product in development activities and clinical studies), save to the extent such claim, damage or liability is caused by CEPI's negligence or intentional misconduct.

19.2 **Conduct of Responses to Third Party Claims**. Each Party shall use its reasonable endeavours to inform the other Party promptly of any circumstances that are likely to give rise to a third party claim which may be covered by Clause 19.1 together with copies of all relevant papers and official documents. CEPI shall not take any material action in respect of any third party claim without the consent of Awardee, including settlement of any such third party claim, provided such consent is not unreasonably conditioned, withheld or delayed. The Awardee will keep CEPI fully informed of the progress of all relevant third party claims for which are covered by Clause 19.1 and shall fully consult CEPI on the nature of any defence to be advanced in advance.

19.3 **Exclusions**. Neither Party shall be liable to the other Party for any loss of profits or economic loss; or indirect, incidental or consequential damages, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of any breach of or failure to perform any of the provisions of this Agreement.

19.4 **Liability Cap**. CEPI's maximum liability in aggregate to Awardee arising out of this Agreement shall not exceed the aggregate of the total Work Package budget unless CEPI has exercised the Public Health Licence in which event CEPI's maximum liability to Awardee arising out of this Agreement shall not exceed the lesser of: (i) the aggregate of the total Work Package budget or (ii) CEPI's total insurance cover for any clinical trials or provision of pharmaceutical Product under the Public Health Licence.

19.5 **Exclusions from Liability Cap**. Notwithstanding the foregoing, nothing in this Agreement shall limit the liability of either Party in respect of:

a. personal injury or death arising out of that Party's negligence or intentional misconduct; or

b. fraud or fraudulent misrepresentation.

19.6 **Clinical Studies by CEPI under the Public Health License**. In the event that the Public Health License becomes exercisable and CEPI intends to exercise such rights, CEPI will procure insurance protection consistent with the requirements for Awardee below.

19.7 **The Awardee will**:

a. satisfy the indemnification obligations arising under this Clause 19;

b. obtain and continuously maintain insurance on a claims-arising basis with an insurance company of a credit rating of A or better to cover reasonably foreseeable claims that may arise in connection with its activities under the Project;

c. if Awardee is the sponsor of a clinical trial pursuant to this Agreement, it will obtain and will ensure that any Sub-awardee that is the sponsor of a clinical trial will obtain, clinical trial insurance on a claims-arising basis pursuant to the guidelines of the Association of the British Pharmaceutical Industry or relevant local guidelines for the country in which the clinical study is conducted. Such insurance is to be effective from the commencement date of the clinical study until at least six (6) years after the completion of the clinical study or such longer period as is required by the relevant ethical committee or an applicable statutory period of limitation; and

d. if requested by CEPI, Awardee will:

i. ensure that the insurer records CEPI's interest on each such insurance policy;

ii. provide CEPI with a copy of each such certificate of insurance and annually on renewal;

iii. notify CEPI of any claims made under these policies relating to the subject matter of this Agreement during the Term and for at least the duration of any applicable statutory period of limitation afterwards; and

iv. comply with the terms of these insurance policies for the Term and for at least the duration of any applicable statutory period of limitation afterwards.

20. Term and Termination

[This Clause 20 describes the termination provisions and effects of termination of this Agreement.]

20.1 **Term**. This Agreement shall commence on the Effective Date identified in the Agreement Summary and will continue in full force and effect until the activities set out in the IPDP and all agreed Work Packages have been completed, or as otherwise terminated pursuant to this Clause 20 (the "Term").

20.2 **Termination for Default**. If either Party (the "Defaulting Party"):

a. breaches a material obligation in this Agreement and either fails to cure that breach within a cure period of thirty (30) Business Days (or longer time agreed in writing) after notice from the other Party (the "Terminating Party") or if that breach is not capable of cure; or

b. makes any arrangement with its creditors, resolves to or undergoes any insolvency proceeding anywhere in the world (except for the purpose of solvent amalgamation or reconstruction);

then the Terminating Party may terminate this Agreement by giving written notice of termination to the Defaulting Party effective immediately or at the end of any cure period if later.

20.3 **Additional CEPI Termination Rights**. In addition, CEPI shall be entitled to terminate this Agreement with immediate effect by providing written notice to Awardee in the following circumstances:

a. if CEPI reasonably determines that Awardee is unable, or will become unable, to discharge its obligations under this Agreement, for example if key personnel or technology resources required for successful completion of the Project become unavailable to Awardee, and Awardee does not promptly and reasonably alleviate CEPI's concerns;

b. there are safety, regulatory or ethical issues with continuing the Project, as reasonably determined by CEPI; or

c. Awardee does not satisfy the criteria in Clause 4.5 required for CEPI to pay funding tranches under a Work Package and fails to satisfy those criteria in full within a cure period of thirty (30) Business Days (or longer time agreed in writing) after notice from CEPI.

20.4 **Effects of Termination**. In all termination events:

a. CEPI will not be required to make any further payments to Awardee under this Agreement or any Work Package other than to reimburse Awardee for any non-cancellable expenses incurred in accordance with the Work Package in accordance with Schedule B;

b. Awardee will return any CEPI funds which are unspent at the date of termination within twenty (20) Business Days of the date of termination;

c. each Party shall return or destroy, as requested by the other Party, the Confidential Information of the other Party except each Party may keep one (1) copy of such Confidential Information for monitoring compliance and shall not be required to delete copies of Confidential Information stored on automatic electronic backup systems;

d. if there is an on-going clinical study, unless agreed otherwise by the Parties in writing, Awardee will ensure that no additional trial subjects are enrolled and the Parties will work together to plan and implement a wind-down of the study in an orderly fashion, with due regard for patient safety and the rights of any participating subjects; and

e. the Parties will give effect to the relevant termination or expiration obligations described in Schedule B to these T&Cs.

20.5 **Survival of Rights and Identified Clauses**. Termination of this Agreement shall be without prejudice to the rights and duties of either Party accrued prior to termination. The following sections will continue to be enforceable notwithstanding termination or expiration: Clauses 2.4c), 2.4d), 4.8, 5.3, 11.7, 14.2, 15 - 17 and 19 – 22, as well as any other provision, which by its nature, is intended to survive termination.

20.6 **The Awardee will**:

a. perform all acts necessary to comply with the relevant effects of termination described above; and

b. honour the rights and duties that survive termination.

21. Resolving Differences

[This Clause 21 describes the procedures for resolving disputes.]

21.1 **Escalation process**. Any question, difference or dispute which may arise concerning the construction, meaning or effect of this Agreement, or concerning the rights or liabilities of the Parties hereunder, or any other matter arising out of or in connection with this Agreement shall first be submitted to the Chief Executive Officer of CEPI and to the Chief Executive Officer of the Awardee (the "Senior Officers") for resolution (each of whom may call on others to advise them as they see fit). The Senior Officers shall discuss the matter arising in good faith and in a timely manner and endeavour to reach a mutually agreeable solution. If the Parties are unable to resolve such dispute through such negotiations within sixty (60) days of such dispute being escalated to the Senior Officers, then in respect of any dispute, controversy or claim the Parties irrevocably submit to arbitration in accordance with Clause 21.2.

21.2 **Arbitration**. Any disputes to be resolved by binding arbitration pursuant to Clause 21.1 (including any question regarding its existence, validity or termination or this Agreement), shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which Rules are deemed to be incorporated by reference into this Clause. The number of arbitrators shall be one. The seat, or legal place, of arbitration shall be London, England. The language to be used in the arbitral proceedings shall be English. Notwithstanding the foregoing, any Party may seek specific performance, interim or final injunctive relief or any other relief of similar nature or effect in any court of competent jurisdiction.

21.3 **Public Health License**. If CEPI invokes its rights under a Public Health License, then the Parties will pursue an expedited resolution of any differences under Clause 21.1 within fourteen (14) days. However, because of the exigent circumstances when there is an Outbreak or Increased Outbreak Preparation Need, Awardee agrees that CEPI may proceed under a Public Health License and the ultimate resolution of any dispute will be limited to recovery of monetary damages by Awardee rather than any injunctive relief.

21.4 **The Awardee will**: cooperate in good faith with CEPI to resolve differences and disputes pursuant to this Clause 21.

22. General Provisions

[This Clause 22 provides general and miscellaneous provisions.]

22.1 **Defined Terms**. The terms defined in these T&Cs shall have the meaning explicitly ascribed to them or as otherwise is clear in the context of their use.

22.2 **Announcements**. The Parties will agree in writing upon the form of all press releases and public announcements concerning this Agreement except that:

a. either may disclose a description of the Project, as well as the names of participating organizations and investigators;

b. CEPI may publish the summarized progress and outcomes of the Project, a summary of the terms and conditions of this Agreement, the name of Awardee and the Project Lead, and the amount of the CEPI funding; and

c. as required by law or any competent regulatory authority.

22.3 **Assignment**. Neither Party will, without the prior written consent of the other Party assign, transfer, convey or declare a trust over this Agreement or make any other disposition (whether in whole or in part) of any of its rights and obligations to any third party, including by novation except that:

a. CEPI may transfer its rights and obligations under this Agreement to an organisation of equivalent charitable mission, if CEPI determines (in good faith) that CEPI will not be in a position to fulfil its obligations or exercise its rights in the future.

b. Awardee may transfer its rights and obligations under this Agreement as part of a sale of the entire business required for the satisfaction of Awardee's obligations under this Agreement either:

i. to an Affiliate of Awardee, provided that if the assignee ceases to be an Affiliate of Awardee at any time the other provisions of this Clause 22.3 will apply, and CEPI will have the right to terminate this Agreement at any time unless and until the noviation agreement referred to in Clause 22.3(b)(ii) has entered into; or

ii. to a third party provided that (a) the assignee has, in CEPI's reasonable opinion, sufficient capital, expertise and commitment to carry on that business as a going concern and to meet Awardee's obligations under this Agreement at least at the same level as Awardee prior to such transfer, and (b) the assignee, Awardee and CEPI enter into a novation agreement in a form reasonably acceptable to CEPI at the time of the assignment or other conveyance in the event of the transfer of all or a substantial part of Awardee's activities related to the Project.

22.4 **Confidential Information**. "Confidential Information" means any and all non-public information disclosed on or after the Effective Date of this Agreement by one Party to the other Party whether orally or in writing or in any other form. Each Party undertakes that both during the term of this Agreement and for a period of three (3) years after its termination or expiry, it shall keep confidential and not disclose to any person other than its employees, Sub-Awardees and, in the case of CEPI, its funders, who have a need to know, any Confidential Information of the other Party disclosed to or obtained by it in connection with this Agreement. Each Party shall take commercially reasonable security precautions to protect against unauthorized disclosure of such Confidential Information. Each Party shall ensure that all employees, Sub-Awardees, CEPI funders and third parties to which Confidential Information of the other Party is disclosed are: (i) informed of the confidentiality provisions of this Agreement; and (ii) bound by confidentiality and non-use obligations at least as stringent as these. Confidential information will not include:

a. the Project Results;

b. information that is or was already known to the receiving Party at the time of disclosure, as shown by written records, without any obligation to keep it confidential;

c. information that is independently developed by employees of the receiving Party who have not had access to the Confidential Information of the disclosing Party as evidenced by contemporaneous written records;

d. information that at the time of being disclosed or obtained by the receiving Party or at any time thereafter, is published or otherwise generally available to the public other than due to default by the receiving Party of its obligations hereunder; and

e. information to the limited extent that is required to be disclosed by a competent Court or regulatory authority or otherwise by applicable law (including any requirements for disclosure under the Freedom of Information Act 2000); provided, that where it is free to do so, the receiving Party shall give notice of such disclosure to the disclosing Party as soon as reasonably practicable.

22.5 **Entire Agreement**. This Agreement, including its Agreement Summary and Annexes, including CEPI Policies and Procedures, constitutes the entire agreement and understanding between the Parties relating to its subject matter and together they supersede and replace all prior arrangements, whether written or oral, between the Parties relating to the subject matter of this Agreement.

22.6 **Conflicts Between Components**. If there is any conflict between the provisions of this Agreement, any Work Package or the CEPI Policies and Procedures, then the provisions of this Agreement will prevail, followed by the provisions of the Work Package and finally the terms of the CEPI Policies and Procedures.

22.7 **Force Majeure**. Neither Party shall be deemed to have defaulted under or to be in breach of this Agreement for failure or delay in fulfilling material obligations when such failure or delay is directly caused by an event outside of their reasonable control, including but not limited to acts of war, insurrections, acts of terrorism, acts of God or acts, omissions or delays in acting or failure to act by any of CEPI's funders (collectively a "Force Majeure Event"). Each Party shall inform the other promptly and in writing of any Force Majeure Event and the Parties will discuss the situation, and acting in good faith, agree on the appropriate course of action under the circumstances. Notwithstanding the foregoing, in the case of an Outbreak or Increased Outbreak Preparation Need, the Parties will be expected to continue to carry out their obligations pursuant to applicable Work Packages with all due health and safety precautions.

22.8 **Further Assurances**. Each Party will perform such acts and execute such documents as reasonably may be required for securing to or vesting in the other Party the rights agreed to be granted to it pursuant to this Agreement.

22.9 **No Rights for Third Parties**. A person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 or otherwise to enforce or to enjoy the benefit of any term of this Agreement.

22.10 **Notices**. Any notice to be given pursuant to this Agreement shall be in writing in the English language and shall be delivered by overnight courier, by registered, recorded delivery or certified mail (postage prepaid) to the address of the recipient Party provided in the Agreement Summary or such other address as a Party may from time to time designate by written notice. Any notice given pursuant to this clause shall be deemed to have been received on the day of receipt, provided receipt occurs on a Business Day of the recipient Party or otherwise on the next following Business Day of the recipient. The Parties agree that email and fax are not valid methods of giving notice under this Agreement.

22.11 **No Waiver**. Neither Party shall be deemed to have waived any of its rights or remedies under this Agreement unless the waiver is expressly made in writing and signed by a duly authorized representative of that Party.

22.12 **Awardee Efforts**. Awardee will use all reasonable endeavors in achieving the milestones and objectives of the Project in the applicable timeframe.

22.13 **Relationship of the Parties**. Neither Party shall by reason of this Agreement be empowered to act as agent for the other Party or to pledge the credit of the other Party. Neither Party will be held liable for or incur liability in respect of the acts or defaults of the other Party.

22.14 **Variation**. No variation, amendment, modification or supplement to this Agreement will be valid unless and until it is made in writing and signed by a duly authorised representative of each Party.

22.15 **Choice of Law**. This Agreement and any Dispute arising out of this Agreement or its formation will be governed by and construed in accordance with the laws of England and Wales without giving effect to any choice of law or conflict of law provisions or rules that would cause the application of the laws of any other jurisdiction.

Schedule A: Glossary of Defined Terms

"**Affiliate**" means any business entity controlled by, controlling or under common control with a Party.

"**Agreement Summary**" means the cover page to this Agreement signed by the Parties.

"**Assessor**" has the meaning set out in Clause 12.2.

"**Business Day**" means a day on which banks are normally open for business and which is not a Saturday or Sunday, or a bank or public holiday in Norway and [Awardee's home country].

"**CEPI Policies and Procedures**" means the policies and procedures published on CEPI's website or provided separately to Awardee, as updated from time to time pursuant to Clause 6.

"**CfP3i Programme**" means the first phase of CEPI's award programme under its Third Call for Proposals to develop vaccines against Rift Valley Fever and Chikungunya.

"**Chikungunya Investigational Vaccine**" means a candidate vaccine that induces a specific immune response against at least one Chikungunya antigen in the prophylaxis of infection or therapeutic use against Chikungunya virus.

"**Commercial Benefits**" means any economically quantifiable benefits that arise from the commercial exploitation of the Project Results other than in preparation for or in response to an Outbreak or Increased Outbreak Preparation Need. Examples of Commercial Benefits include the commercial licensing of Project IP, receipt of government-granted incentives such as Priority Review Vouchers and revenue from the commercialization of combination, derivative or follow-on products (including antibody products, assays and vaccines) or application of production technology.

"**Confidential Information**" has the meaning set out in Clause 22.4.

"**Data Safety and Monitoring Board**" or "**DSMB**" means an independent group that reviews and evaluates clinical study data for participant safety and makes recommendations to concerning the continuation, modification, or termination of a study.

"**Effective Date**" means the date on the Agreement Summary of the Agreement.

"**Enabling Rights**" means any and all rights owned or controlled by the Awardee at the Effective Date, together with those which arise on or after the Effective Date, which in each case, relate to the development, manufacture, supply or marketing of the Product, including improvements to the Project Results and Product existing at the date that CEPI is first entitled to utilize the Public Health License pursuant to Clause 17, whether or not arising under the Project. Enabling Rights do not include any rights that Awardee is contractually precluded from granting to CEPI.

"Equitable Access" means that vaccines and other products developed, in whole or in part, with CEPI's financial support must be first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay, while at a price that is sustainable to the manufacturer, as further detiled in CEPI's "Equitable Access" Policy.

"**Financial Records**" has the meaning set out in Clause 5.3.

"**Financial Report**" means Awardee's report to CEPI of its expenditures under the Project Budget on the Financial Report Template in Annex F and Awardee's report of its activities under the IPDP.

"**Financial Report Template**" means the form of report in Annex F to be used by Awardee for its reports to the JMAG.

"**Increased Outbreak Preparation Need**" means when, having considered all reasonably accessible and relevant information including epidemiological data, travel and migration patterns and the likely availability of other products or product candidates, CEPI determines, in its sole discretion, that there is a heightened need for a Product.

"**Integrated Product Development Plan**" or "**IPDP**" means the document in Annex C that describes the research and development activities and associated deliverables, milestones and timelines under the Project as may be amended from time-to-time.

"**International Standard**" means a biological standard accepted by WHO for use as an International Reference Preparation.

"**Investigational Product**" means a Product that has not received a marketing approval.

"**IPDP Records**" has the meaning set out in Clause 2.4.

"**IPDP Reports**" has the meaning set out in Clause 2.2.

"**IPDP Report Template**" means the form of report in Annex D to be used by Awardee for its reports to the JMAG.

"**Joint Monitoring and Advisory Group**" or "**JMAG**" has the meaning set out in Clause 2.3.

"**Low and Middle Income Countries**" or "**LMICs**" are those countries defined by the Organisation for Economic Co-operation and Development.

"**Outbreak**" means a Public Health Emergency of International Concern declared by WHO or a public health emergency on a national or regional scale declared by one or more national governments, in each case as a result of a material increase in the number of cases of people infected with CHIK or RVF including any regional out-break, an epidemic or a pandemic.

"**Outbreak Notice**" has the meaning set out in Clause 16.1.

"**Product**" means a Chikungunya Investigational Vaccine and/or the Rift Valley Fever Investigational Vaccine as the case may be under the Project and includes any form or dosage of pharmaceutical composition or preparation for use in humans that is developed in whole or in part as part of the Project, including any Investigational Product.

"**Project**" means Awardee's activities as described under the IPDP or as otherwise funded by CEPI.

"**Project Budget**" means the documents in Annex D that describes CEPI's funding award, payment schedules, and any co-funding or in-kind contributions by Awardee.

"**Project Data**" has the meaning set out in Clause 11.1.

"**Project IP**" has the meaning set out in Clause 13.1.

"**Project Lead**" means the principal investigator named by Awardee in the IPDP or otherwise agreed by the Parties.

"**Project Materials**" has the meaning set out in Clause 12.1.

"**Project Results**" has the meaning set out in Clause 10.1.

"**Public Health License**" means a non-exclusive, fully paid-up, sublicensable and worldwide license under the Project Results and Enabling Rights to develop, manufacture, market and/or supply the Product worldwide; in each case for use in preparation for or response to an Outbreak or Increased Outbreak Preparation Need. For the purposes of this definition, the term 'Product' shall mean the Chikungunya Investigational Vaccine and/or the Rift Valley Fever Investigational Vaccine (as applicable) in any form or dosage of pharmaceutical composition or preparation for use in humans.

"**Retained Amount**" means the ten per cent (10%) of the final payment tranche retained by CEPI under Clause 4.8.

"**Rift Valley Fever Investigational Vaccine**" means a candidate vaccine that induces a specific immune response against at least one Rift Valley Fever antigen in the prophylaxis of infection or therapeutic use against Rift Valley Fever virus.

"**Safety Issues**" means any material concerns regarding safety or efficacy of any Product studied under the Project, including serious adverse events or serious adverse reaction, safety-related signals, product recalls or relevant recommendations from the Data Safety Monitoring Board to place a hold on or to end a clinical study.

"**Sub-Awardee**" has the meaning set out in Clause 3.1.

"**Team Charter**" means the description of how the Project will be organized and managed as described in Annex B.

"**Technology Transfer**" has the meaning set out in Clause 16.5.

"**Term**" has the meaning set out in Clause 20.1.

"**Terms and Conditions**" or "**T&Cs**" shall have the meaning set out in Clause 1.1.

"**Trial Steering Committee**" or "**TSC**" means a group of independent experts who are not involved in the clinical study that will approve the clinical study protocol and monitor the progress of the clinical trial, including any changes to the protocol.

"**Trusted Collaborator**" has the meaning set out in Clause 16.

"**Warranties**" has the meaning set out in Clause 18.

"**WHO**" means the World Health Organization.

"**Work Package**" has the meaning set out in Clause 4.1.

Schedule B: Effects of Termination

OBLIGATIONS ON TERMINATION BY AWARDEE PURSUANT TO CLAUSE 20.2 *(Termination for Default)*
CEPI shall reimburse Awardee for all reasonably incurred non-cancellable expenses relating to the Project which were authorised by CEPI and which arise after the termination date, solely to the extent they are not otherwise covered by CEPI funding.

OBLIGATIONS ON EXPIRATION OR TERMINATION PURSUANT TO CLAUSE Error! Reference source not found.**)** *(Termination due to Safety, Regulatory or Ethical Issues)*
Awardee shall provide CEPI with a list of all sub-license, contract manufacturing agreements and other third party agreements and arrangement to which Awardee is a party which relate to the development and marketing of the Product (the "**Contracts**"), within thirty (30) days of the Termination Date.
CEPI shall reimburse Awardee for all reasonably incurred non-cancellable expenses relating to the Project which were authorised by CEPI and which arise after the termination date, solely to the extent they are not otherwise covered by CEPI funding.

OBLIGATIONS ON TERMINATION BY CEPI PURSUANT TO CLAUSES 20.2, 20.3a) OR 20.3c) *(Termination For Default; CEPI's Reasonable Determination that Awardee will be Unable to Perform; or Failure to Satisfy Clause 4.5, respectively)*
Solely at CEPI's discretion, CEPI may reimburse Awardee for some or all or Awardee's reasonably incurred non-cancellable expenses relating to the Project which were authorised by CEPI and which arise after the termination date.
Awardee shall promptly make all Project Data publically available in such manner as CEPI may direct, save to the extent that to do so would result in the public disclosure of Enabling Technology which would not otherwise be publically disclosed.
CEPI shall have the right to require the Awardee, at CEPI's discretion, to either: (i) perform Technology Transfer to a Trusted Collaborator (including any Trusted Collaborator appointed pursuant to Clause 17.3) on an expedited basis at the Awardee's cost, or (ii) if Technology Transfer has already occurred at the date of termination and certain costs in relation to such Technology Transfer were borne by CEPI, reimburse CEPI for such costs.
CEPI shall have the right to exercise the Public Health License, pursuant to Clause 17.2d).
Awardee shall use all reasonable endeavours to promptly transfer to CEPI (or its nominee), at Awardee's cost, any regulatory approvals and applications for regulatory approvals relating to the Product.

Awardee shall ship to CEPI (or its nominee) all Project Materials within thirty (30) days of CEPI requesting such Materials.
Awardee shall provide CEPI with a list of all sub-license, contract manufacturing agreements and other agreements and arrangement to which Awardee is a party which relate to the development and marketing of the Product (the "**Contracts**"), within thirty (30) days of the Termination Date. CEPI may request copies of any Contracts, which Awardee will promptly provide.
CEPI shall have the right to require Awardee to: (i) assign the benefit (subject to the assumption of the burden) of one or more Contracts to CEPI or its nominee and, where consent of a third party is required, seek to obtain such consent; (ii) novate one or more Contracts to CEPI or its nominee; or (iii) terminate one or more Contracts in accordance with its terms at Awardee's cost.
Where termination is due to any financial irregularity or fraudulent or illegal activity by Awardee, Awardee shall repay to CEPI the amount of funds related to such financial irregularity or fraudulent or illegal activity within twenty (20) Business Days of the notice of termination.