**DEFINED TERMS USED FOR PROTOCOL**

**FOR**

**COVID-19 VACCINE FACILITY NO-FAULT COMPENSATION SCHEME[1]**

Note: The definitions of words in singular shall apply to such words when used in the plural, and vice versa. Reference to the male pronoun throughout this Protocol should be read as reference to the male or female pronoun, as the context requires.

**"Administrator"** means ESIS, Inc., the claims Administrator appointed to manage and administer the Scheme, including, but not limited to, the receipt and registration of Claims, distributing acknowledgements of receipt of Claims, setting financial reserves for Receivable Claims, review of Claims, Supporting Evidence and other documents to assess receivability, assessing Receivable Claims, and approve or deny, as the case may be, Payment for compensation, in accordance with the terms of the Scheme's Protocol.

"**Applicable Law**" means all civil codes, statutes, legislation, regulations, rules, by-laws, instruments, rules of common law, judgments, decrees or orders of any governmental, administrative, supervisory, regulatory or determinative authority, agency, court or other organisation of any jurisdiction, in each case adopted, enacted, implemented, promulgated, issued, entered or deemed applicable by or under the authority of any governmental body having jurisdiction over a specified person or any of such person's properties or assets from time to time.

"**Appeals Panel**" – a three-member panel:

i. That is comprised of 2 duly licensed physicians and 1 duly licensed nurse, who shall be appointed by the Administrator from a roster of 6 such physicians and nurses; and

ii. That will review all Notices of Appeal of Denied Receivable Claims filed by Claimants and determine – in accordance with the terms of the Scheme's Protocol — whether the Review Panel's denial of the relevant Receivable Claim should be upheld or reversed.

"**Claim**" – a written claim for compensation completed by a Claimant, using the Claim Form approved by and provided by the Administrator, as set forth in Schedule 2 of the Scheme's Protocol, which must be accompanied by all Supporting Evidence.

"**Claimant**" – any individual, who meets all of the following requirements:

i. is a Patient who was administered a Vaccine (or in the event the Patient has died, is a child, or is disabled or otherwise lacks the legal capacity to submit a Claim for himself or herself, is an individual who is a duly authorised heir (in the case of death), parent, legal guardian or other legal representative of the Patient); and

ii. is, or is duly authorised to represent, a Patient who has sustained an Injury which, in the opinion of a Registered Healthcare Professional, is deemed to have resulted from a Vaccine or its administration; and

[1] Version dated 24 March 2022.

iii. the Vaccine was administered before its Scope of Coverage Endpoint (as indicated in Schedule 1 of the Scheme's Protocol); and

iv. has submitted a Claim for compensation, using the prescribed form in Schedule 2 of the Scheme's Protocol, together with all Supporting Evidence, using the prescribed form in Schedule 3 of the Scheme's Protocol to the Administrator, following the procedures described in the Scheme's Protocol, and provided that this Claim is submitted: (a) in full observance of the waiting period of 30 days referred to in Section 1(c) and in Schedules 2 and 3 of the Scheme's Protocol; (b) before the end of the Reporting Period; and (c) otherwise within the time limits set forth in Section 4 of the Scheme's Protocol; and

v. has not received any prior payment from any other public source, including from any governmental or publically funded no-fault compensation scheme, as compensation for the Injury; and

vi. is not eligible to receive compensation from any other source for the Injury, or if eligible for such compensation, discloses the nature and full extent of such eligibility; and

vii. has no pending lawsuits or claims for compensation for the Injury; and

viii. agrees not to seek or make any claims for compensation from any other public source, including from any governmental or publically funded no-fault compensation scheme, for the Injury for as long as the Claim, and/or Receivable Claim, as applicable, is pending with the Scheme; and

ix. is not and does not represent a Patient in respect of whom the Administrator is by any applicable sanctions regime, including any UN Security Council sanctions regime, precluded from accepting a Claim and/or paying compensation under the Scheme.

"**Hospital**" means a public or private institution which: (1) is licensed or otherwise formally recognised as a hospital, clinic or other healthcare facility by the government of the relevant country where it is located; (2) provides 24-hour medical, surgical and/or nursing care or treatment under the supervision of licensed physicians, surgeons, nurses and/or other healthcare professionals; and (3) has the capacity to provide room and board to patients resident overnight.

"**Hospitalisation**" means the admission of the Patient to a Hospital for more than 24 consecutive hours of resident overnight medical, surgical and/or nursing care.

"**Impairment**" means a significant deviation, loss, or loss of use of any body structure or body function in an individual with a health condition, disorder, or disease.

The evaluation of an Impairment as provided in the Scheme's Protocol will be based upon the most recently published edition of the *American Medical Association's Guides to the Evaluation of Permanent Impairment* (AMA's Guides). Impairment percentages or ratings contained in the AMA's Guides have been developed by medical specialists and are consensus-derived estimates that reflect the severity of the medical condition and the degree to which the Impairment decreases an individual's ability to perform common activities of daily living.

The Impairment rating is a percentage that represents the extent of a whole person impairment of an individual, based on the organ or body function affected by an Injury (as defined in the Scheme's Protocol).

"**Injury**" – serious bodily injury or illness suffered or sustained by a Patient that:

i. requires Hospitalisation or prolongs an existing Hospitalisation; and

ii. results in permanent total or partial Impairment; or

iii. is a congenital birth injury or illness in an unborn or new-born child of a woman who received a Vaccine and results in permanent total or partial Impairment; or

iv. results in death.

"**Most Probable Cause**" – the most likely cause (based on the balance of probabilities) that a Vaccine or its administration resulted in a claimed Injury.

"**Notary Official**" – a notary public or other public official legally authorised to provide notarisation, and/or legalisation services within the country in which the Claimant resides.

"**Notice of Appeal of Denied Receivable Claim**" – an appeal filed by a Claimant, following the denial of his Receivable Claim by the Review Panel, in accordance with the procedure described in Section 8 of the Scheme's Protocol and using the form in Schedule 5 of the Scheme's Protocol.

"**Notice of Appeal of Rejected Claim (denial of receivability)"** – an appeal filed by a Claimant, following the denial of receivability of his or her Claim by the Administrator, in accordance with the procedure described in Section 7 of the Scheme's Protocol and using the form in Schedule 4 of the Scheme's Protocol.

"**Participating Country**" means any country participating in the Scheme as listed in Schedule 9 of the Scheme's Protocol (as may be updated from time to time).

"**Patient**" – means a beneficiary of a Vaccine (i) procured and/or delivered by UNICEF on a Participating Country's behalf; (ii) donated to a Participating Country through UNICEF; or (iii) formally included into the Scheme (but otherwise procured and/or delivered but not by or through UNICEF) who claims or in respect of whom it is claimed that he or she has suffered or sustained a Serious Adverse Event which is associated with a Vaccine or its administration, and which, in turn, has resulted in an Injury.

"**Payment**" – the no-fault, lump-sum payment which in respect of a Receivable Claim (i) has been approved by the Review Panel or the Appeals Panel, as applicable, (ii) is calculated utilising the mechanism detailed in Section 9 of the Scheme's Protocol, and (iii) is to be paid (subject to and in accordance with the conditions set forth in the Scheme's Protocol and its Schedules) to a Claimant in full and final settlement and compensation of all claims arising from or relating to the Injury.

"**Payment Method Election Form**" – the written form to be provided by the Administrator, in which the Claimant will elect the means through which the Claimant will receive the Payment, out of the list of possible Payment means set forth in Section 9(d) of the Scheme's Protocol.

"**Personal Data**" means any data that contains one or more unique identifiers from which the identity of the person can be determined or accessed directly or indirectly such as (but not limited to) their full name, national identification number, social insurance or social security number, passport number, driver's license, or other government-issued identification number, credit card, debit card or financial

account information, date of birth, mother's maiden name, medical information or health insurance information, biometric records, digital signature files, account login information (such as a combination of user ID or email address when combined with password or other information that would give access to an account), and any other data that is protected by Privacy Laws.

"**Privacy Laws**" means any and all applicable international, federal, state, provincial or other local laws, rules, regulations, or regulatory guidance and codes (to the extent binding) relating to data privacy, information security, personally identifiable information, identity theft, data breach notification, trans-border data flow or data protection, as amended from time to time.

"**Receiveable Claim**" - any duly completed Claim for compensation (i) that is accompanied by all Supporting Evidence, (ii) that is filed/submitted by a Claimant prior to the end of the Reporting Period with the Administrator, and (iii) that is found by the Administrator and/or by the Administrator's Vice President of Risk Consulting to be receivable as provided in Section 4 or Section 7 of the Scheme's Protocol.

"**Registered Healthcare Professional**" – any healthcare professional, including physicians, surgeons, nurses, midwives, nurse practitioners, physicians' assistants, psychiatrists, psychiatrists, physical therapists, occupational therapists, dentists and pharmacists, who is duly licensed or legally authorised to practice the profession in the country in which the Patient resides and received the Vaccine, or in the case of birth defects, where the Patient's mother resides and received the Vaccine.

"**Reporting Period**" means on a per Vaccine basis, the period during which a Claimant may file a Claim for compensation under the Scheme in respect of such Vaccine. The **maximum** Reporting Period for each Vaccine extends from:

a. the date on which such Vaccine was first put into circulation by the manufacturer following regulatory approval or an emergency use authorisation of such Vaccine by any regulator (as indicated in Schedule 1 of the Scheme's Protocol); and

b. terminates on the date which is **36 calendar months** immediately after the Scope of Coverage Endpoint for such Vaccine (as indicated in Schedule 1 of the Scheme's Protocol), provided always that the Vaccine was administered **before** this Vaccine's Scope of Coverage Endpoint (as defined in Section 2 of the Scheme's Protocol and indicated in Schedule 1 of the Scheme's Protocol). See the illustrative diagram of the Reporting Period in Schedule 6 of the Scheme's Protocol.

For each Patient, the Reporting Period depends on the date the Vaccine was administered to the Patient. To calculate the Reporting Period that applies to the Patient, the Patient (or the person who is a duly authorised to represent the Patient as provided in limb (ii) of the definition of Claimant in the Scheme's Protocol) needs to:

1. determine (through Schedule 1 of the Scheme's Protocol) what is the date of the Scope of Coverage End Point that applies to the Vaccine that was administered to Patient; and

2. calculate the number of months and days from the vaccination date (i.e. date that the Vaccine was administered to the Patient) until the date of the Vaccine's Scope of Coverage End Point, and add another 36 months. This establishes the Reporting Period that applies to the Patient.

"**Review Panel**" – a panel appointed by the Administrator comprised of 5 duly licensed nurses, selected from a roster of 11 such nurses, who will review all Receivable Claims submitted by Claimants and

determine – in accordance with the terms of the Scheme's Protocol – whether Payment for compensation should be approved or denied.

**"Scheme"** means the Covid-19 Vaccine Facility No-Fault Compensation Scheme, established to provide fair compensation to eligible vaccine recipients who suffer a Serious Adverse Event related to a COVID-19 vaccination that has been either:

i. procured and/or delivered by UNICEF on a Participating Country's behalf;

ii. donated to a Participating Country through UNICEF; or

iii. formally included into the Scheme (but otherwise procured and/or delivered but not by or through UNICEF),

as detailed in this Protocol and its Schedules.

"**Scientific Advisory Committee**" – an advisory panel of experts appointed by the Administrator, comprised of at least 3 duly qualified public health experts with relevant expertise and experience (which experts may include licensed physicians, epidemiologists and/or statisticians) that will conduct a review of the evolving literature on COVID-19 Vaccine safety and will provide the Administrator, Review Panel and Appeals Panel with updated information on the safety of the Vaccines and with relevant expert scientific advice to guide the process of the determination of Receivable Claims, including, but not limited to, advice on which, if any, types of injuries that manifest after vaccination are likely to have been caused by a Vaccine and the characteristics of those injuries.

"**Scope of Coverage Endpoint**" – for each Vaccine, the date which is 24 months following the date on which a Vaccine was first put into circulation by the manufacturer following regulatory approval or an emergency use authorisation of such Vaccine by any regulator.

"**Serious Adverse Event**" means a serious untoward medical occurrence that (i) is sustained or suffered by a Patient following the administration of a Vaccine, and (ii) results in an Injury, as evidenced by the supporting evidence, using the form in Schedule 3 of the Scheme's Protocol, required to evaluate a Claim and that shall include:

i. detailed medical documentation from a Registered Healthcare Professional describing the Injury and medical treatment required as a result of the Injury, together with details of any Hospitalisation or prolonged Hospitalisation, including but not limited to admission and discharge records;

ii. a description of the nature, extent, functional impact and prognosis of the Injury, as assessed by the Registered Healthcare Professional.

iii. a statement from the Registered Healthcare Professional that the Injury was, in the Registered Healthcare Professional's opinion, the result of the Vaccine or its administration;

iv. certification from a Registered Healthcare Professional of when, where and which Vaccine was administered;

v. in the case of death, a death certificate and any other documentation available from a Registered Healthcare Professional of the cause and manner of death; and

vi. any further evidence that the Administrator may deem necessary to adjudicate the Claim and/or Receivable Claim, as applicable, guided, as appropriate, by the Scientific Advisory Committee, the Review Panel, and/or the Appeals Panel.

"**UNICEF**" means the United Nations Children's Fund, an international inter-governmental organisation established by the General Assembly of the United Nations by resolution No. 57(1) of 11 December 1946 as a subsidiary organ of the United Nations.

"**Vaccine**" – a COVID-19 vaccine received in any Participating Country that is either: (i) procured and/or delivered by UNICEF on a Participating Country's behalf; (ii) donated to a Participating Country through UNICEF; or (iii) formally included into the Scheme (but otherwise procured and/or delivered but not by or through UNICEF), that:

i. either (A) has licensure or authorisation from a stringent ("functional") regulatory authority or (B) has received WHO prequalification, following licensure or authorisation from a stringent ("functional") regulatory authority, or (C) has been issued authorisation for emergency use based on licensure or authorisation by a stringent ("functional") regulatory authority; and

ii. is included in Schedule 1 of the Scheme's Protocol, as updated from time to time; and

iii. has received all required approvals and authorisations for importation, distribution and use in the relevant country; and

iv. has not reached its Scope of Coverage Endpoint.