

Republic of the Philippines

DEPARTMENT OF THE INTERIOR AND LOCAL GOVERNMENT

DILG NAPOLCOM CENTER, EDSA cor. QUEZON AVENUE, QUEZON CITY http://www.dilg.gov.ph

OFFICIAL RELEASED TO DATE: 01-26-2021 TIME: 6:00PM

MEMORANDUM CIRCULAR No. 2021-011

FOR: ALL INVOLVED PROVINCIAL GOVERNORS,

CITY AND MUNICIPAL MAYORS, PUNONG BARANGAYS, DILG REGIONAL DIRECTORS,

AND OTHERS CONCERNED

SUBJECT : GUIDELINES FOR LGU AND DILG FIELD

SUPPORT FOR THE COVID-19 VACCINE

CLINICAL TRIALS

DATE : 26 JAN 2021

1. Background

- 1.1 At the onset of the COVID-19 pandemic, the President has placed the entire Philippines under a State of Public Health Emergency and later a State of Calamity in order to mobilize all the necessary instrumentalities of government to fight the disease.
- 1.2 As part of the ongoing efforts to curtail and eventually halt the spread of COVID-19, the Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF-EID) approved the recommendation of the Department of Science and Technology (DOST) for the participation of the Philippines in the clinical trials for COVID-19 vaccines.
- 1.3 To advance such endeavor, the DOST and this Department have entered into a Memorandum of Agreement (MOA) to provide for the framework for mutual cooperation and collaboration between the parties on the zoning and implementation of said vaccine clinical trials.
- 1.4 This Memorandum Circular serves as the guidelines for local government units (LGUs) and DILG regional/field offices in

participation and coordination in the COVID-19 vaccine clinical trials.

2. Legal Bases

- 2.1 Presidential Proclamation No. 922, dated March 8, 2020, "Declaring a State of Public Health Emergency throughout the Philippines";
- 2.2 Presidential Proclamation No. 929, dated March 16, 2020, "Declaring a State of Calamity throughout the Philippines due to Corona Virus Disease 2019":
- 2.3 Presidential Proclamation No. 1021, dated September 16, 2020, "Extending the Period of the State of Calamity throughout the Philippines due to Corona Virus Disease 2019 declared under Proclamation No. 929, s. 2020";
- 2.4 Memorandum from the Executive Secretary, dated March 18, 2020, "Additional Guidelines for the Community Quarantine over the Entire Luzon and Management of the Coronavirus Disease 2019 (COVID-19) Situation";
- 2.5 IATF-EID Resolution No. 39, dated May 22, 2020, where the recommendation of DOST on the participation of the Philippines in the clinical trials for COVID-19 vaccines are approved by said IATF, and where the Sub-Technical Working Group on Vaccine Development was formed and chaired by DOST to coordinate with other government agencies on matters related to said vaccine clinical trials;
- 2.6 IATF-EID Resolution No. 47, dated June 19, 2020, where the recommendation of the Sub-TWG on Vaccine Development for the Philippines to participate in the World Health Organization (WHO) Solidarity Trial (ST) for a COVID-19 vaccine was adopted;
- 2.7 IATF-EID Resolution No. 65, dated August 20, 2020, where the Sub-TWG for Vaccine Development was directed to issue zoning guidelines on vaccine clinical trials;
- 2.8 IATF-EID Resolution No. 68, dated September 3, 2020, where the recommendations of the Sub-TWG on Vaccine

Development on the zoning guidelines to implement the COVID-19 vaccine clinical trials and the execution of a MOA between DOST and DILG for said zoning and implementation were adopted;

2.9 Memorandum of Agreement between DOST and DILG on the Zoning and Implementation of the COVID-19 vaccine trials in selected/identified LGUs and hospital sites (Annex 1)

3. Policy Content and Guidelines

- 3.1 Per the DOST-DILG Memorandum of Agreement on the Zoning and Implementation of the COVID-19 Vaccine Clinical Trials, the term 'PROJECT' refers to the said clinical trials.
- 3.2 Concerning LGUs, the following are the zoning guidelines for the conduct of the COVID-19 Vaccine Clinical Trials:
 - 3.2.1 The WHO Solidarity Trial shall be prioritized in the assignment of trial zones. This notwithstanding, independent trials should nonetheless be considered in such a way that they will not be deprived of trial sites.
 - Vaccine Recipients under the WHO Solidarity Trial will 3.2.2 be recruited from the top 5-10 barangays reporting high COVID-19 cases, based on the attack rates per 1000 population per barangay. The data will come from the DOH Epidemiology Bureau (EB). Trial sites will be at the barangay level, and randomization will be by households. The household census will be obtained from the barangay/s to identify residents to ensure follow up. Transient residents will be discouraged unless they can show proof that they will be staying in the area or the trial site for the next two (2) years. clinical trials bv private vaccine Independent companies may also be assigned trial zones such that they are equally and rationally distributed.
 - 3.2.3 Independent clinical trials by private vaccine companies will also be assigned trial zones such that they are equally and rationally distributed to avoid competition in subject recruitment.

- 3.2.4 For outbreak situations, WHO Solidarity Trial Vaccine Teams can move into the affected barangay provided that no independent Clinical Trial is going on or is being conducted at such time. In such a case, the most adjacent barangay may be considered for the WHO ST Vaccine Teams.
- 3.2.5 To address shortfalls in recruitment by specific barangays, the deficit can be taken over by other barangays with faster recruitment to meet the total target sample size.
- 3.2.6 A communication plan for the COVID-19 vaccine clinical trials should consider different levels of LGU and the criteria and considerations for recruitments (e.g., transmission rate cut offs). Close coordination with the LGU for zoning in barangays will be made. The barangays should be informed to prepare for immunization in case there is an outbreak. There should be a meeting with City Health Officers to discuss the data needs and considerations for recruitment.
- 3.2.7 Considering the restriction in mobility due to enforcement of general community quarantine in some areas, alternative modes of follow up should be put in place such as the use of Barangay Health Workers or local barangay volunteers, including utilization of cellphones for reminders.

3.3 For its part, the DILG shall:

- 3.3.1 Enforce the guidelines on the participation of LGUs up to the barangay level in the PROJECT and other independent COVID-19 vaccine trials based on the guidelines adopted by the IATF-EID;
- 3.3.2 Enjoin cooperation of local officials in the implementation of the PROJECT;
- 3.3.3 Provide logistic support or other non-monetary assistance needed by the Project Teams through the LGUs relating to the conduct of the PROJECT. The

LGU support or assistance may include, among others:

- a. Transportation of potential participants to the trial sites for screening, vaccination, and scheduled follow-up visit;
- b. Locating participants who do not come to the Trial Site for the scheduled visit:
- c. Bringing participants to the hospital site in the event of an exposure to or presentation of signs and symptoms of COVID-19 or the development of suspected adverse reactions. Information about these signs and symptoms will be provided by the PROJECT Team.
- d. Coordination with the PROJECT Team in organizing meetings related to the clinical trials such as orientation of potential participants.
- 3.3.4 Assign other focal persons from the LGUs who will coordinate with the implementing institutions for matters related to the PROJECT; and
- 3.3.5 Provide other forms of non-financial assistance to the PROJECT such as, but not limited to, facilitation and coordination as may be necessary and relevant to the PROJECT.
- 3.4 All information, data, and related documentation in whatever form provided in connection to the conduct of the COVID-19 vaccine clinical trials shall be used solely for the purpose for which it was furnished; be treated in the strictest confidence and protected; and not be reproduced, except as necessary for its authorized used. Any breach or violation of confidentiality and data privacy are punishable under Republic Act No. 10173 or the "Data Privacy Act of 2012".
- 3.5 This Memorandum Circular applies to DILG regional/field offices and LGUs (a) that are identified to participate in the WHO Solidarity Trial, and (b) those that will participate in independent COVID-19 vaccine clinical trials.

4. Policy Compliance and Monitoring

- 4.1 All concerned DILG Regional Offices are hereby directed to cause the immediate and widest dissemination of this Memorandum Circular in their respective areas of jurisdiction; coordinate with concerned/identified LGUs, DILG field offices, and Project Teams on the zoning and implementation of the COVID-19 vaccine clinical trials; and provide logistic and other non-monetary support necessary to the COVID-19 vaccine clinical trial Project Teams.
- 4.2 For monitoring purposes, all concerned DILG Regional Offices are hereby also directed to submit monthly situation reports (on the 5th day of the ensuing month) regarding the implementation of the COVID-19 vaccine clinical trials in their respective areas of jurisdiction to the DILG Central Office through the Bureau of Local Government Development.

5. Effectivity

This Memorandum Circular shall take effect at the start of the COVID-19 vaccine clinical trials.

6. Approving Authority

UNDERSECRETARY BERNARDO C. FLORECE, JR. Officer-In-Charge

DIG-OSEC 01157021-017

7. Feedback

For inquiries, you may contact the Bureau of Local Government Development (BLGD) at telephone no. <u>8876-3454</u> loc. <u>4107</u> or email at <u>blgd.ladd2020@gmail.com</u> and <u>blgd.gad@gmail.com</u>.

8. Annex

- 8.1 DOST-DILG Memorandum of Agreement on the Zoning and Implementation of the COVID-19 Vaccine Clinical Trials
- 8.2 DILG COVID-19 Vaccine Clinical Trials Monitoring Sheet Template (sample)

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") made and entered into by and between:

The **DEPARTMENT OF SCIENCE AND TECHNOLOGY** (hereinafter referred to as the "**DOST**"), a government agency created and existing pursuant to Executive Order No. 128, Series of 1987, with principal office address at DOST Science Community Complex, General Santos Avenue, Bicutan, Taguig City, herein represented by its Secretary, **Fortunato T. de la Peña**;

-and-

The **DEPARTMENT OF THE INTERIOR AND LOCAL GOVERNMENT**

(hereinafter referred to as the "DILG"), an agency of the national government, created and existing under the laws of the Republic of the Philippines, with principal office address at DILG-NAPOLCOM Center, EDSA corner Quezon Avenue, West Triangle, Quezon City, represented herein by its OIC, Undersecretary Bernardo C. Florece, Jr.;

DILG and **DOST** may hereinafter be referred to individually as a "Party" and collectively as "Parties".

WITNESSETH: That -

WHEREAS, **DOST** is the lead science and technology agency in the Philippines charged with the twin mandate of providing central direction, leadership and coordination of all scientific and technological activities, and of formulating policies, programs, and projects to support national development;

WHEREAS, DILG exercises general supervision over local government units and is mandated to promote peace and order, ensure public safety, and further strengthen local government capability aimed towards the effective delivery of the basic services to the citizenry;

WHEREAS, Presidential Proclamation No. 922, series of 2020, declared a State of Public Health Emergency in recognition of the Coronavirus Disease 2019 (COVID-19) as a threat to national security, and prompted a whole-of-government approach in addressing the COVID-19 situation in the country;

WHEREAS, Presidential Proclamation No. 929, series of 2020, likewise declared a State of Calamity in the entire country, and enjoined government agencies and Local Government Units (LGUs) to render full assistance to undertake critical, urgent, and appropriate disaster response aid and measures in a timely manner, in light of the COVID-19 situation;

WHEREAS, Presidential Proclamation No. 1021, series of 2020, entitled "Extending the Period of the State of Calamity throughout the Philippines due to the Coronavirus Disease 2019 declared under Presidential Proclamation No. 929, s. 2020" was issued by President Rodrigo Roa Duterte on 16 September 2020;

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WHEREAS, the Memorandum from the Executive Secretary, dated 18 March 2020, Re: Additional Guidelines for the Community Quarantine over the Entire Luzon and Management of the Coronavirus Disease 2019 (COVID-19) Situation provides that all heads of departments, agencies, offices, and other instrumentalities of the government, are directed to adopt, coordinate, and implement such other guidelines which the Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF-EID) may subsequently issue on the COVID-19 situation, without need of further approval from the Office of the President, consistent with respective agency mandates and relevant laws;

WHEREAS, on 22 May 2020, IATF-EID Resolution No. 39 was issued approving the recommendation of the DOST for the participation of the Philippines in the clinical trials for COVID-19 vaccines. In connection thereto, a Sub-Technical Working Group chaired by the DOST was formed to coordinate with other government agencies for matters relating to said clinical trials ("Sub-TWG on Vaccine Development");

WHEREAS, IATF-EID Resolution No. 47 dated 19 June 2020 adopted the recommendation of the Sub-Technical Working Group on Vaccine Development for the participation of the Philippines in the World Health Organization (WHO) Solidarity Trial for a COVID-19 vaccine;

WHEREAS, subsequently, pursuant to IATF Resolution No. 65 dated 20 August 2020, the Sub- TWG on Vaccine Development was directed to issue zoning guidelines on vaccine clinical trials;

WHEREAS, on 3 September 2020, IATF-EID issued Resolution No. 68 adopting the recommendations of the Sub-TWG on Vaccine Development on the zoning guidelines to smoothly implement the COVID-19 vaccine clinical trials, including the execution of a Memorandum of Agreement between the Parties herein;

NOW, THEREFORE, for and in consideration of the above-premises, the Parties have mutually agreed as follows:

I. PURPOSE

This Agreement shall provide the framework for mutual cooperation and collaboration between the parties pursuant to the directives provided for in the relevant IATF-EID Resolutions and related issuances.

II. THE PROJECT

IATF-EID Resolution No. 47 dated 19 June 2020 adopted the recommendation of the Sub- Technical Working Group on Vaccine Development for the participation of the Philippines in the World Health Organization (WHO) Solidarity Trial for COVID-19 vaccine ("the **PROJECT**"). The same consists of a global clinical trial facilitated by the WHO that will evaluate several vaccine candidates against SARS-COV-2, the virus which causes COVID-19.

The Philippine General Hospital (PGH) will be the Main Implementing Agency for the **PROJECT** and will be assisted by affiliate hospital sites. For its implementation, trial sites will be classified into three (3), as follows:

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- A. Hospital sites;
- B. Community-based sites-local health station close to the Hospital site with adequate facility for the vaccine trial implementation such as space for participant enrolment, vaccine storage, support equipment, and disposal. Local health workers will be trained to assist in the conduct of the vaccine trial and in regulatory compliance; and
- C. Mobile/ pop-up sites- Sites with sudden increase of COVID-19 Transmission Rate where the PROJECT can be immediately set up. It shall have the same requirements as a Community based site.

The following Hospital sites will implement the PROJECT in the following cities in Metro Manila and provinces:

Hospital Site	Areas of Implementation			
Philippine General Hospital	Manila			
Manila Doctor's Hospital	Wariia			
	Caloocan City			
	Navotas City			
San Lazaro Hospital	Malabon City			
	Quezon City			
Lung Center of the Philippines St. Luke's Medical Center-QC	Valenzuela City			
Research Institute for Tropical	Parañaque City			
Medicine	Las Piñas City			
Wodienio	Muntinlupa City			
	Makati City			
Makati Medical Center	Pasay City			
	Taguig City			
The Medical City	Mandaluyong City			
St. Luke's Medical	Pasig City			
Center- BGC	Marikina City			
	San Juan City			
	Pateros			
Vicente Sotto Memorial Medical Center and Chong Hua Hospital	Cebu Province			
De La Salle Health Sciences Institute	Cavite Province			
Southern Philippines Medical Center	Davao City			



The clinical trial protocol of the PROJECT will be implemented by Project Teams each composed of medical doctors, nurses, medical technologists, pharmacists and other allied health professionals with expertise in conducting clinical trials.

I. **OBLIGATIONS OF THE PARTIES**

A. The DOST shall:

- Coordinate with the Main Implementing Agency to constitute the Project Team/s for the WHO Solidarity Vaccine Trial;
- 2 Provide funding assistance for the implementation of

- **PROJECT**, subject to compliance with government budget, accounting and auditing rules and regulations;
- 3. Provide DILG the necessary technical information and operational requirements pertaining to the local implementation of the PROJECT;
- 4. Closely coordinate with the **DILG** for inter-departmental concerns pertaining to the implementation of the **PROJECT**;
- 5. Ensure that the Project Team/s of the WHO Solidarity Trial are in close coordination with the LGUs where the trials will be conducted in order to address concerns of local officials, including those overseeing the local health system; and
- 6. Provide other forms of assistance to the **PROJECT** in coordination with other government agencies and stakeholders in matters requiring their attention or cooperation, insofar as these are relevant to the **PROJECT** and within the capabilities of the **DOST**.

B. The DILG shall:

- Enforce the guidelines on the participation of LGUs up to the barangay level in the PROJECT and other independent COVID-19 vaccine trials based on the guidelines adopted by the IATF-EID;
- Assign an Undersecretary or Assistant Secretary from the Central Office or Regional Director for Regional Offices who may also be invited as a resource person by the **DOST** on Sub-TWG meetings or deliberations, whenever necessary;
- 3 Issue a memorandum circular to enjoin local government officials to:
 - Enforce the guidelines on LGU participation to the WHO Solidarity Trial and other independent private vaccine trials; and
 - Monitor and ensure compliance on the measures, guidelines and issuances relating to the PROJECT
- Enjoin cooperation of local officials in the implementation of the PROJECT;
- 5. Provide logistic support or other non-monetary assistance needed by the Project Teams through the LGUs relating to the conduct of the PROJECT. The LGU support or assistance may include, among others:
 - Transportation of potential participants to the trial sites for screening, vaccination, and scheduled follow-up visit
 - Locating participants who do not come to the Trial Site for the scheduled visit;
 - c. Bringing participants to the hospital site in the event of an exposure to or presentation of signs and symptoms of COVID-19 or the development of suspected adverse reactions. Information about these signs and symptoms will be provided by the PROJECT Team.
 - d. Coordination with the **PROJECT** Team in organizing meetings related to the clinical trials such as orientation of potential participants.

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- 6. Assign other focal persons from the LGUs who will coordinate with the implementing institutions for matters related to the PROJECT; and
- Provide other forms of non-financial assistance to the PROJECT 7. such as but not limited to facilitation and coordination as may be necessary and relevant to the PROJECT.

II. **ZONING GUIDELINES FOR THE CONDUCT OF COVID-19 VACCINE** CLINICAL

TRIALS

- A. The WHO Solidarity Trial shall be prioritized in the assignment of trial zones. This notwithstanding, independent trials should nonetheless be considered in such a way that they will not be deprived of trial sites.
- B. Vaccine Recipients under the WHO ST will be recruited from the top 5-10 barangays reporting high COVID-19 cases, based on the attack rates per 1000 population per barangay. The data will come from the DOH Epidemiology Bureau (EB). Trial sites will be at the barangay level, and randomization will be by households. The household census will be obtained from the barangay/s to identify residents to ensure follow up. Transient residents will be discouraged unless they can show proof that they will be staying in the area or the trial site for the next two (2) years. Independent clinical trials by private vaccine companies may also be assigned trial zones such that they are equally and rationally distributed.
- C. Independent clinical trials by private vaccine companies will also be assigned trial zones such that they are equally and rationally distributed to avoid competition in subject recruitment.
- D. For outbreak situations, WHO Solidarity (ST) Trial Vaccine Teams can move into the affected barangay provided that no independent Clinical Trial is going on or is being conducted at such time. In such a case, the most adjacent barangay may be considered for the WHO ST Vaccine Teams.
- E. To address shortfalls in recruitment by specific barangays, the deficit can be taken over by other barangays with faster recruitment to meet the total target sample size.
- F. A Communication plan for the COVID19 vaccine clinical trials should consider different levels of LGU and the criteria and considerations for recruitments (e.g. transmission rate cut offs). Close coordination with the LGU for zoning in barangays will be made. The barangays should be informed to prepare for immunization in case there is an outbreak. There should be a meeting with City Health Officers to discuss the data needs and considerations for recruitment.
- G. Considering the restriction in mobility due to enforcement of general community quarantine in some areas, alternative modes of follow up should be put in place such as the use of Barangay health workers or local barangay volunteers, including utilization of cellphones for reminders.

III. CONFIDENTIALITY

All information, data, and related documentation in whatever form provided, which the Parties may furnish or have furnished with each other in connection with this Agreement shall:

- A. Be used solely for the purpose for which it was furnished;
- B. Be treated in the strictest confidence and protected; and
- C. Not be reproduced, except as necessary for its authorized use

Each Party agrees to hold in strict confidence any confidential information disclosed to or obtained by it, and shall use such confidential information only in connection with the purposes of developing, implementing, and operationalizing the projects covered by this Agreement.

IV. DATA PRIVACY

Each Party shall, in accordance with the Data Privacy Act of 2012, ensure that appropriate organizational, physical, and technical security measures are in place to maintain the confidentiality, integrity, and security of all personal data that may come to its knowledge or possession by reason of any provision of this Agreement, and that its employees, agents, representatives, or any person acting under its authority shall hold personal information under strict confidentiality at all times.

V. MISCELLANEOUS PROVISIONS

- **A.** Amendments. Any modification, revision, or amendment hereto agreed upon by the Parties shall become valid and binding only when the same is in writing and signed by both Parties.
- B. Severability. If any provision contained herein is invalid, illegal, or unenforceable in any respect under any applicable law or decision, the validity, legality, and enforceability of the remaining provisions shall not be affected or impaired in any way. The Parties shall, so far as practicable, execute such additional documents in order to give effect to any provision hereof which is determined to be invalid, illegal, or unenforceable.
- C. Repealing Clause. Agreements of the Parties which are inconsistent or contrary to the provisions herein, including the programs, projects, and services covered by this Agreement, if any, are hereby repealed or modified accordingly.
- D. Dispute Resolution and Venue of Actions The Parties shall make every effort to amicably settle and resolve any dispute in connection with or arising out of this Agreement. Should the parties fail to reach an amicable settlement of their dispute, the same shall be submitted to arbitration in accordance with Executive Order 292 dated 25 July 1987. However, should the disputes between the parties reach the courts of law, the parties agree that suits for any breach of this Agreement shall be instituted by the court of competent jurisdiction in Taguig City.
- **E.** Effectivity and Termination. This Memorandum of Agreement shall take effect upon signing of all the herein parties and shall remain in full force and effect unless otherwise terminated by mutual agreement of the parties in writing. Grounds for termination of this Agreement may be any of the following:
 - 1. Breach of obligation/s or delay in the performance thereof;
 - Failure of the part of either party to comply with any of the terms and conditions of this MOA;
 - Misrepresentation and other fraudulent practices of either party; and

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4. Occurrence of force majeure when it is impossible for the undertaking on this Agreement to be carried out.

IN WITNESS WHEREOF, the Parties and their representatives have hereunto affixed their signature on the date and place first above written.

DEPARTMENT OF SCIENCE AND TECHNOLOGY

DEPARTMENT OF THE INTERIOR AND LOCAL GOVERNMENT

By:

By:

FORTUNATO T. DE LA

PEÑA

Secretary

USEC. BERNARDO C. FLOREÇE, JR.

Officer-in-Charge

SIGNED IN THE PRESENCE OF:

ROWENA CRISTINA L. GUEVARA

Undersecretary for R&D

MARIVEL C. SACENDONCILLO

Undersecretary for Local Government

ACKNOWLEDGMENT

REPUBLIC	OF	THE	PHILIPPINES)
CITY OF)
S.S.			

At the above stated place, on the__day of October 2020, before me personally appeared:

Name	Government Issued ID/No.	Expiry
FORTUNATO T. DE LA PEÑA	D0001828A (passport)	14 March 2022
EDUARDO M. AÑO		

known to me the same persons who executed the foregoing instrument and acknowledged the same to be their free and voluntary act and deed as well as of the entities herein represented.

Said instrument refers to a Memorandum of Agreement consisting of six (6) pages including this page whereon the Acknowledgement is written, signed by the parties and their witnesses on the signature page hereof, and initiated on the other pages and sealed with the notarial seal.

NOTARY PUBLIC

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Book No. ;
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Region:	
Report for the Month of _	
Submission Date:	

Vaccine Clinical Trial (Project Details)

		Demographics				Vaccine Clinical Trial Proper				
Type of LGU Name of LGU (P/C/M/B)	Total No. of Households Identified	Total No. of Individual Participants	Hospital Site / Clinical Trial Site	Age Bracket	Sex Ratio (M:F)	Name/Brand	Туре	Manufacturer/Company	Date of Clinical Trial	

^{*}Table may be expanded to accommodate all pertinent data or you may use another sheet.

DILG Field Support

Name of Regional/Field Focal Person	Identified LGU Participant	Project Team Head	Support Provided	Notes

^{*}Table may be expanded to accommodate all pertinent data or you may use another sheet.