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## Guidance on the Conduct of Clinical Trials at PHC During the COVID-19 Pandemic

**1. Scope:**

This policy will cover the measures on the following aspects of clinical trials and researches involving human subject: conduct of onsite visit, informed consent provisions, protocol deviations, and conduct of COVID-19 trials. The effectivity of this document is limited only up to the time that the COVID-19 pandemic has been declared controlled.

**2. Objective:**

The COVID-19 Pandemic has greatly affected the conduct of clinical trials globally. Guidance on the conduct of outpatient visits has been implemented in the institution. However, there are certain peculiarities that distinguish onsite visit for clinical trials from the usual clinic visit for routine patient care. As such, this separate guidance document will help the site staff and the clinical trial participants regarding onsite visit. Moreover, COVID-19 has impacted clinical trial procedures and may lead to potential clinical trial disruption. The purpose of this policy is to provide guidance to assist clinical trial personnel, sponsors and investigators in assuring subject safety, compliance to Good Clinical Practice and counteracting potential trial conduct disruption due to the COVID-19 pandemic.

**3. Policy Guidelines:**

3.1 Conduct of On-site Visit1.Clinic / Site Preparedness

3.1.1 Face-to-face visit should be conducted per appointment basis only. The clinical trial staff should coordinate with the Concierge and Triage of the institution regarding the scheduling of appointments the clinical trial participants. The health assessment contact tracing form should be filled-out by the clinical trial participant (if applicable) and their caregiver.

3.1.2 As per hospital policy, only those asymptomatic patients for COVID-19 shall be allowed to enter the hospital. For clinical trial participants with mild symptoms, arrangement for teleconsult is suggested as the clinical trial protocol will allow. If

clinical evaluation of respiratory symptoms is required, the medical triage should direct the clinical trial participant to the appropriate evaluation areas (e.g. emergency room) as per hospital directive.

3.1.3 The allotment for the allowable number of clinical trial participant (and their caregiver) should depend on the clinical trial procedures to be done during that particular visit. The general rule is that there should be no more than four (4) persons (trial participants and their care giver) in the clinic at any given point of time. Only one (1) caregiver shall be allowed per clinical trial participant.

3.1.4 Clinical trial staff should conduct daily health care self-monitoring. If with symptoms, the clinical trial staff should restrict himself/herself from going to the clinic and should undergo evaluation for COVID 19 according to current standards.

3.1.5 There should be provisions for 70% alcohol, hand sanitizers, and personal protective equipments for the clinical trial staff.

3.1.6 Routine cleaning and disinfection procedures using products recommended to combat against SARS-COV-2 should be done by the clinical trial staff. Equipments and instruments should be disinfected with appropriate solutions in-between patient use.

3.1.7 Consider designing and installing engineering controls to reduce or eliminate exposures by shielding staff and other patients from potentially infected individuals.These measures may include provision of HEPA Filter air Purifier, acrylic shields, and UVC light.

3.1.8 Minimum personal protective equipment (PPE) for clinical trial participants should be based according to their age. Since there are instances wherein prolonged close contact with clinical trial participant and clinical trial staff (i.e. interviews, consent process, questionnaires, clinical procedures) cannot be avoided, face mask with face shield for clinical trial participant (and their accompanying caregiver) is required, except for children less than 2 years of age.

3.1.8.1 Newborn to 2 years old: As per Philippine Pediatric Society guidelines, wearing of face mask or face shields should be avoided for newborn. Face mask is also not recommended for children under 2 years of age.

3.1.8.2 Children greater than 2 years old: Properly-fitted face mask with face shields is recommended.

3.1.8.3 Adults: Properly-fitted surgical face mask with face shield should be worn by clinical trial participants or accompanying caregiver during their onsite visit. Clinical trial site should provide for surgical mask and face shield

3.1.9 Minimum personal protective (PPE) for clinical trial staff should be at least Level II. (face mask (either N-95 or its equivalent), face shield (or eye shield/goggles), isolation gowns, and gloves). For aerosol generating procedures that will be done as part of the clinical trial protocol procedures, the clinical trial staff should wear a Level III PPE. The clinical trial staff should be trained on the proper donning and doffing of PPEs.

3.1.10 Social distancing, hand-washing and wearing of face mask should be observed both by the clinical trial participants and clinical trial staff. Signages with appropriate language and pictures to teach/remind regarding these health practices should be posted within the clinical trial site.