COMPETENCY/TRAINING NEEDS: POINTS TO CONSIDER

The competencies/skills presented are by no means an extensive list of staff competencies to carry out the CCP.

For a more in depth assessment, consider exploring the Global Health Network's Professional Development Scheme, visit https://globalhealthtrainingcentre.tghn.org/pds/core-competencyframework/'.

Text highlighted in pink is a guide to better practice[1]. In all instances you must ensure that you adhere to local and national guidelines.

1. An understanding of the research
☐ The specific primary and secondary research aims of this study
☐ The clinical infrastructure requirements for the sites chosen recruitment tier
☐ What "clinical research" is and its benefit to society
☐ The purpose of ethics in research
☐ How high ethical standards, data quality and uniformity are maintained in a study
☐ What a cohort study is
☐ What acute respiratory infections are, how they are transmitted and how to assess the risk of infection
2. Study recruitment, consent and research participants
☐ Understand the importance of informed consent in research and why it's necessary
☐ Be able to confidently explain the study, and consent form
☐ Understand what to do when participants require translation of patient information sheets and informed consent forms so that the participant understands the study
☐ Understand the benefits and risks to participants taking part in this study
☐ Accurately explains to participants the benefits and risks of taking part in this study
☐ Understands the study's inclusion and exclusion criteria
3. Study management
☐ Understand the mechanisms in place for adverse event reporting at their site
☐ Understand the follow up procedure for enrolled participants at their site
☐ Knows how to access the Study Master File
4. Data entry
Confident in accessing and using the electronic data capture software e.g. If site is using the ALERRT COVID-19 database
Can confidently complete:
☐ Paper based case report forms (CRF)
☐ The web based "eCRF"

All documents adapted for ALERRT
Competency/Training Needs: Points to consider, Version 1, 4th May 2020 [Based on the WHO/ISARIC Clinical Characterisation Protocol (CCP), Version 3.1/3.2; Citation: Dunning, J. W., et al. (2014). "Open source clinical science for emerging infections." Lancet Infect Dis 14(1): 8-9].

5. Clinical sampling

- ☐ Understand the hygiene measures required to protect themselves when in contact with study participants including use of personal protective equipment (PPE)

Is confident in the procedures for obtaining required clinical samples at each stage of study follow-up including;

- ☐ Procedures for serial sampling including the appropriate timings of serial samples as per the protocol (Tiers 2 and 3)
- ☐ Procedures for obtaining clinical specimens at baseline/presentation including blood, cerebrospinal fluid (if CNS disease), infected sites/sores, sputum, respiratory tract specimens, urine and stool or rectal swab (Tiers 1, 2 and 3)
- ☐ Procedures for pathogen only serial sampling (Tiers 2 and 3 sites)
- ☐ Procedure for additional sampling for pharmacokinetic /pharmacodynamics studies including use of the pharmacokinetic record form (Tier 3 sites only)

- ☐ Understands the patient specific clinical sampling guidelines including sampling volume by patient weight and cerebrospinal fluid volume guidance (see protocol)

6. Laboratories and samples (skip if Tier 0)

- ☐ Is confident in the documentation required for sample processing and has an understanding of input and retention of data for samples and labelling
- ☐ Understands the protocol in place for sending samples to those not listed in the Protocol and Material Transfer Agreement
- ☐ Understands the laboratory biosafety procedures at the site and the appropriate BSL2, BSL3 or BSL4 safety management and guidelines, dependent on local/national guidelines
- ☐ Is confident in monitoring laboratory resources and informing relevant staff of replenishments
- ☐ Is confident in the procedures for biological sample processing involving manual techniques and/or use of laboratory equipment (as specified in the protocol)

Is suitably qualified in using the following equipment as per the requirements of the site

- ☐ Centrifuge equipment
- ☐ Serological testing equipment
- ☐ Freezers for storage of samples (at least -80°C)

[1]The Global Health Network has a wealth of on-line courses. All of which are free, and each can be taken offline if needed. To view other eLearning courses please visit The Global Health Training Centre. All eLearning courses offer certificates for those who score over 80% in the final quiz. The quiz requires internet access.

Single module courses:

1. Introduction to clinical research (available in: Français, Español, 中文, Português, Việt,Swahili)
2. ICH Good Clinical Practice (available in: Français, Español, Baasa Indonesia, Việt)
3. Introduction to Good Clinical Laboratory Practice (available in Espanol, Portugues, Francais) 4. Children and Clinical Research (available in Espanol)

Modular Courses:

1. Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care
2. Research Ethics Online Training.