COVID-19 Emergency Capacity Building Grants for FETPs

To help FETPs respond to the COVID-19 pandemic, TEPHINET is offering Emergency Capacity Building Grants. All tiers (basic/Frontline, intermediate, and advanced) of TEPHINET-member FETPs may apply. (This includes programs in the process of applying for membership. Contact secretariat@tephinet.org to learn about applying for membership.)

Program Directors must certify that funds will not be used for research activities. For more information on research determination, refer to the excerpts from CDC Policy 557: Distinguishing Public Health Research and Public Health Nonresearch, below.

Selection Process:

TEPHINET Secretariat and CDC WIDB staff will review applications and select for funding based on the following criteria:

- Stated need of the program for the assistance (40%)
- Strength of proposal; description of how the activity would contribute to COVID-19 response (40%). Strong proposals will include participation by FETP alumni.
- Feasibility of the activity (20%)

Eligible Activities:

Up to $20,000 may be awarded per program for eligible activities to strengthen the FETP for COVID-19 response and build capacity for future pandemics.

Examples of Activities that are **eligible** for Emergency Capacity Building Grant Funds (this is not an exhaustive list, and innovative activities will be considered):

- Epidemiologic investigations of conditions of public health importance, particularly COVID-19 (including procurement of supplies such as PPE or lab materials/reagents to support the investigation)
- Training activities related to conditions of public health importance, particularly COVID-19 (travel costs capped at 30% of total costs)
- Mentorship activities – shadowing/pairing
- Evaluation activities
- Software for data analysis that supports an investigation

Activities that are **not eligible** for Emergency Capacity Building Grant Funds:

- Regular operating costs
- Routine FETP activities (not related to COVID-19)
- Salaries of staff
- Purchase of computers or other hardware totaling more than 20% of the proposed budget for the activity
- Stipends for residents/trainees
• Internet service
• Some research projects of FETP participants (subject to review; refer to definitions below)
• Travel of residents to conferences

Application Process:

To submit an application, send the completed fillable application form, along with the budget and timeline as a separate attachment, to accreditation@tephinet.org.

Application and Review Timeline:

Applications will be reviewed within one week of submission, and funds will be awarded on a rolling basis contingent upon availability of funds.

Project Implementation Timeline:

All activities must be completed by September 30, 2020.

Please note: Programs will be awarded an advance of 75% of the awarded amount in order to start activities, and will be required to complete mid- and end-of-term reports.
Excerpts from CDC Policy 557: Distinguishing Public Health Research and Public Health Nonresearch

The full document can be viewed at https://www.cdc.gov/os/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

**General Attributes of Nonresearch** (pages 3-4) – The purpose of the activity is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants’ community; data collected are needed to assess or improve the program or service, the health of the participants or the participants’ community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental.

Other attributes, such as publication of findings, statutory authority (see discussion in next section), methodological design, selection of participants, and hypothesis testing or generating, do not differentiate research from nonresearch, because these types of attributes can be shared by both research and nonresearch activities.

A nonresearch activity can develop or contribute to generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original purpose. In this case, because the purpose was not to develop or contribute to generalizable knowledge, the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken to develop or contribute to generalizable knowledge, the analysis constitutes human research that now requires further consideration under 45 CFR part 46.

If a project includes multiple components and at least one of those components is designed to develop or contribute to generalizable knowledge, then the entire project is classified as research unless the components are separable.

**Emergency Response** (page 5)

Emergency response activities tend to be nonresearch because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. However, an emergency response might have a research component if, for example, samples are stored for future use intended to generate generalizable knowledge or additional analyses are conducted beyond those needed to solve the immediate health problem. For emergency responses, whenever a systematic investigation of a non-standard intervention or a systematic comparison of standard interventions occurs, the activity is research.

When unapproved drugs or devices are used or drugs or devices are used for unapproved purposes, their use might either fall under an Emergency Use Authorization (EUA) or under FDA regulations. Decision-making about these activities is particularly complicated, as they might or might not meet the definition of research at 45 CFR 46.102(d) and they might or might not meet the definition of clinical investigation at 21 CFR 56.102(c). Careful consideration and consultation with the Center ADS and the chief of HRPO is warranted in these situations.

**ACRONYMS AND DEFINITIONS** (pages 12-13)

Emergency response – A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The
primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).

Human subject or participant – A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. (See 45 CFR 46.102(f).)

Research – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (See 45 CFR 46.102(d).)