
ELEMENT I.1.H.

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COMMENTARY

Emergency preparedness and response should be an integral part of the entire HRPP. Ensuring the safety and wellbeing of research participants is paramount. Organizations should develop a risk-based emergency preparedness and response plan to ensure sustainability of the HRPP to ensure the rights and welfare of research participants are protected.

REGULATORY AND GUIDANCE REFERENCES

- DHHS: Effects of Disasters on Human Research Protections Programs Guidance (May 14, 2008)
- FDA: Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (March 2020)

REQUIRED WRITTEN MATERIALS

(1) Essential requirements:

- (a) The HRPP has an emergency preparedness and response plan, appropriate to the size and complexity of the HRPP, that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency. (Element I.1.A.)
- (b) The emergency preparedness and response plan is periodically evaluated and, when necessary, adjusted to ensure continuity of operations.
- (c) Organizations provide education about the organization's emergency response and preparedness plan for IRB members and staff, researchers and research staff, and other persons in the HRPP. (Element I.1.E.)
- (d) Persons in the HRPP are knowledgeable about the organization's expectations during emergencies.

COMMON TYPES OF MATERIALS THAT MAY BE USED TO MEET THE ELEMENT

- Plans
- Educational Materials
- Evaluation Reports

OUTCOMES

- The organization plans for emergencies, educates those in the HRPP, and responds effectively to ensure the sustainability of the HRPP.