**GUIDE 624 – for Planned Emergency Use Research**

**Planned emergency research**: Planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived ([21 CFR 50.24](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24)).

1. The research plan must be approved in advance by the FDA and IRB.
2. The research plan must also be disclosed to the communities:
   1. where the research will be conducted and
   2. from where participants will be drawn,
   3. include presentation of the risks and expected benefits of the research.
3. An independent data monitoring committee (DMC) must be established to exercise oversight of the research.
4. Advance notice of these protocols will be provided to the Office for Human Research Protections pursuant to federal regulation 45 CFR 46.101(i).
   1. PIs who wish to conduct planned emergency research should consult with IRB staff prior to submission of the protocol to the IRB.
   2. Planned emergency research is usually not eligible for emergency use approvals.

See [Exception from Informed Consent Requirements for Emergency Research](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf) [FDA].

The University of Hawaii has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.  (AAHHRPP Element I.7.C)

If you have questions, contact the UH Human Studies Program at 808.956.5007