Emergency Research, Exception from Informed Consent (EFIC)

Modified: September 2019

Background:

FDA issued the regulations at 21 CFR 50.24 to permit the study under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) of potential treatments or improvements in the treatment of life threatening conditions where current treatment is unproven or unsatisfactory, in order to improve patient outcomes.

Because of ethical concerns involved in studying subjects who cannot provide consent, much of what has become standard, accepted, medical therapy for use in emergency settings has not been evaluated by adequate and well-controlled trials that demonstrate the treatment is either safe or effective. Controlled clinical trials have subsequently demonstrated that some therapies that have become standard medical practice are ineffective or even harmful. Other standard therapies, although shown to be effective in clinical trials, have significant limitations (e.g., they only work in a small percentage of those individuals who receive the therapies). FDA expects that permitting certain emergency research trials to proceed will (1) provide individuals in life-threatening situations access to potentially life-saving therapies; (2) advance knowledge through collection of information about effectiveness and safety; and (3) improve therapies used in emergency medical situations that currently have poor clinical outcomes.

1. Q: Does the University of Florida support studies involving EFIC?

Yes, however, the decision to allow such a research effort at UF is made on a case-by-case basis by the Vice President for Research at UF. First, the PI of the potential EFIC study must contact the IRB-01 Chair to discuss the proposed research. The PI must then send the protocol, via email, to the IRB-01 Chair. The IRB-01 Chair will review the protocol and send the protocol with his/her recommendation to the UF Vice President for Research. The IRB Chair will inform the PI of the decision whether or not to move forward with the submission.

2. Q: What are the additional responsibilities are imposed on the PI and study staff involved with studies conducted under EFIC (21 CFR 50.24)?

These additional responsibilities include consultation with representatives of the community(ies) in which the research will take place and from which the potential subjects may be drawn. There must be public disclosure of information before the start of the study and following its completion. Also, there must be a documented commitment by the investigator to try to locate the subject’s legally authorized representative or contact a family member to determine whether the family member objects to the subject’s participation. Finally, there must be study oversight by an independent data monitoring committee.

The PI and study staff must be familiar with the FDA guideline on this topic [https://www.fda.gov/media/72754/download](https://www.fda.gov/media/72754/download).

3. Q: What conditions must be met for the IRB to consider approving a study involving EFIC?

These conditions include the following:
a. Aspects of the disease and its treatment
   i. Patients must be in a life-threatening situation that necessitates intervention
   ii. Available treatments are unproven or unsatisfactory
   iii. Collection of scientific data are necessary to determine the safety and efficacy of the investigational drug

b. Aspects of the informed consent process
   i. Patients are unable to give informed consent because of their medical condition
   ii. The intervention is time sensitive and must be administered before an LAR can give consent on the patient’s behalf
   iii. Patients cannot be prospectively identified as potential participants

c. Participation in research holds out the prospect of direct benefit to the patients
   i. Nonclinical studies have been conducted, and the results of the studies and related evidence support the potential for direct benefit to the patients
   ii. The risks are reasonable compared to what is known about the patients’ medical condition, the risks and benefits of standard therapy (if any), and what is known about the potential risks and benefits of the investigational drug

d. The investigation could not be practicably carried out without the waiver

e. The protocol defines the length of the potential therapeutic window, and the principal investigator has committed to attempting to contact the LAR within the therapeutic window, and, if feasible, ask for consent. The clinical investigator must summarize efforts made to contact the patient’s LAR and make this information available to the IRB at the time of continuing review.

f. If a drug or device is involved, documentation of an EFIC specific IND from the FDA must be provided.

g. The IRB has approved an informed consent document and informed consent procedures to use when obtaining informed consent is feasible.

4. Q: If approved by the UF VP for Research, how is an EFIC study submitted to the UF IRB-01?

   The study is submitted to IRB-01 like any other into myIRB.

5. Q: Will UF allow ceding the review of an EFIC study to another institution?

   Yes, UF will allow ceding of a EFIC study provided the VP for Research at UF has agreed to allow the study to be conducted at UF (see question #1 above). However, UF will not allow the ceding of the EFIC recruitment strategy which includes the Community Consultation. UF considers the Community Consultation to be part of the local context review conducted by the UF IRB-01. If the IRB review of a study involving EFIC is being ceded, the EFIC Community Consultation plan must be submitted to the UF IRB-01 as a separate research project. Such a submission will be reviewed by a convened meeting of the UF IRB-01.

6. Q: What should be included in the EFIC Community Consultation plan?
The UF IRB-01 will need:

a) A description of the likely catchment area for the study
b) A description of the type of individuals that might likely qualify for the study (e.g. folks with CHF or some other disease type). If anyone in the general population, simply state that.
   i) A chart of the EICF events that the study team is proposing to present. This should include:
      (1) The proposed event name
      (2) Whether the event will be presented in person or not
      (3) Who will present the event(s)
      (4) When and where the event will take place
   ii) A justification as to catchment area targeted and how that relates to your protocol.

c) Any public disclosure advertisements for the study or to invite individuals to a EICF event. Information should include:
   i) The Community involved
   ii) How the feedback will be obtained (in person vs. email, etc.)
   iii) Copies of any fliers or announcements
   iv) Scripts of any radio or TV ads
   v) If a nationally supported trial, any national ads or announcements.

d) A copy of the written assessment tool used at each event. This typically is in the format of a very brief survey to be completed by Community members attending the events.

e) Post-trial disclosure activities:
   i) Any media (video or written) plans
   ii) Any UF plans
   iii) If a nationally supported trial, any national ads or announcements.

7. What is the UF IRB-01 Submission Sequence of Events?

a) If the study is being ceded to another IRB, the reviewing IRB must have reviewed and approved the study prior to the UF investigator submitting it to the UF IRB (See #1).
   i) The study must then be submitted via myIRB as a ceded study.
   ii) The EICF Community Consultation study must also be submitted via myIRB as a Full Board review type. (On the study type SmartForm, indicate by selecting ‘other’ that this is the submission of the EICF Recruitment Plan for the CED000000xxx submission)
   iii) When the Community Consultation plan is approvable, the myIRB submission will be approved with a contingency that the results of the approved community consultation plan are presented back and approved by the Board. The IRB will determine which events members of the IRB will attend.
   iv) The PI may then begin the EICF Community Consultation plan.
   v) Once completed, the results of each event must be reported back to the UF IRB-01 with at least a total of those who attended and copies of the written feedback obtained from those citizens.

b) If the UF IRB-01 is the reviewing IRB, then the study must be submitted as usual via myIRB. Once the IRB-01 approves the study and EICF plan:
   i) the IRB will determine which events members of the IRB will attend.
   ii) The PI may then begin the EICF Community Consultation plan.
   iii) Once completed, the results of each event must be reported back to the UF IRB-01 with at least a total of those who attended and copies of the written feedback obtained from those
citizens.

8. Do EFIC studies require the investigator to offer and opt-out strategy?

No, it is not required. If you plan to offer one, please make sure it is clearly described in your submission.

9. Does the PI of the study need to inform the UF IRB-01 regarding the results of informing the patient or their LAR regarding the patient’s participation in this study?

Yes, whether the main study is ceded to another IRB, or if the UF IRB-01 reviews the study locally, an annual report must be submitted to the UF IRB-01 summarizing the notification to the study subject (if that individual regains competency) or the study subject’s LAR.