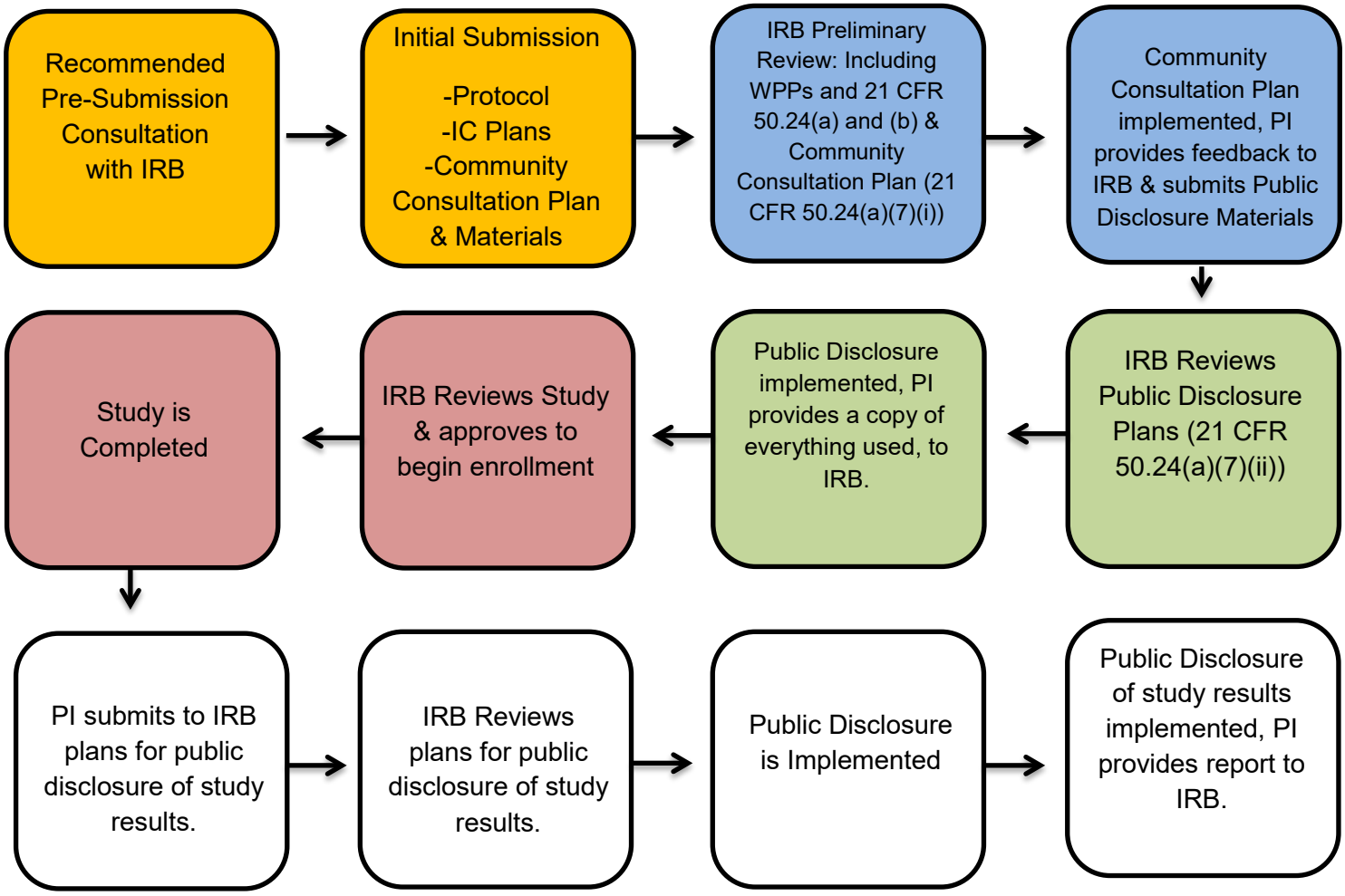
VCU
Office of the Vice President
for Research and Innovation

EFIC – Exception from Informed Consent

Planned Emergency Research and Waiver of Informed Consent

FDA Guidance | HHS Guidance | VCU WPP



Initial Submission & Preliminary Review

1. Guidance for FDA-regulated research in the planned emergency setting:
   - Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research – DRAFT Guidance, July 2006

   - The IRB reviews the protocol and subsequent informed consent procedures to ascertain 'approvability.' For this step, the IRB must find and document specific requirements as per 21CFR50.24(a) Click here for specific requirements.

2. Guidance for non-FDA-regulated research in the planned emergency setting:
   - "Informed Consent Requirements in Emergency Research. "

The following regulations must be met for EFIC research:

1. The human subjects are in a life-threatening situation, and available treatments are unproven or unsatisfactory.
2. Obtaining informed consent is not feasible within the therapeutic window.
3. Participation holds out the prospect of direct benefit
4. Study could not practicably be carried out without the waiver of informed consent
5. The length of the potential therapeutic window is based on scientific evidence, and there is an attempt to consent LARs
6. The informed consent procedures and informed consent document are in accordance with Sections 46.116 and 46.117 of 45 CFR Part 46

Community Consultation

The submitted protocol must include a plan for community consultation. Community consultation activities are "designed to help ensure that the communities in which the emergency research will be conducted and from which subjects will be drawn are adequately informed about the risks and expected benefits of the research and are given the opportunity to ask questions about it as well as express their views prior to the IRB making a determination about the research." (2006 Draft Guidance Document). ***Section VIII of the Draft Guidance Document provides extensive information about community consultation.***

Tips for Community Consultation Approval:

- The plan will be evaluated on its ability to reach a reasonable sample from the target communities
- Identify community groups whose geographic location, illness condition, or other characteristics increase their susceptibility or risk for being involved in the research.
- Identifying group 'leaders' who are willing to function as intermediaries for continued communication
- **PI and/or IRB consultation with the VCU community research liaison**
- The plan for community consultation requires full board approval.
- All materials utilized in community consultation are to be IRB approved.
- Community consultation should make every effort to reach out to limited-English proficient individuals who may be susceptible to becoming research subjects in the study.
- The community consultation plan may include a variety of methods for reaching the targeted population. The IRB is more likely to approve plans that will reach a broad audience through __ methods. The more you are able to demonstrate your plan will reach a large sample, the more likely the IRB is to approve. See next page for community consultation ___ from the literature.
- When the community consultation has been completed, the IRB must approve that community consultation has been 'adequate.' 'Adequacy' generally means that an acceptable number of individuals have been directly exposed to consultation activities and the preponderance of the feedback has been positive toward the research.

Community Consultation Considerations Based on Recent Literature

Method	Rationale	Reference
Survey	• Proved to be an efficient way to obtain representative input. • Allows for random selection/better chance of being representative • Reaches highest number of participants when associated with existing meetings • Less interactive methods (ex. surveys) are a more conservative estimate of public opinion and might be preferred for providing fair assessment of risk.	(Beshansky et al, 2014) (Holsti et al, 2015) (Callaway, 2013)
Focus Groups - Opportunity for participants to ask questions & provide feedback	Community becomes "partners" in the research process. *Although: Focus groups had a predominance of females (79%) and whites (72%) compared to the existing group participants (52% females and 43% whites). (Govindarajan, 2013)	(Sims, 2012)
Facebook Advertisements	• Target certain populations • Google analytics may also be used to generate statistics of website use. • They are also cost effective.	(Stephens, 2016)
Educate the Community about Study	They are able to provide meaningful feedback.	(Vohra, 2014)
Family members to provide consent	Universal consensus that participants supported contacting a family member to obtain consent in emergency settings.	(Sims, 2012)
Extend beyond geographic community	Reach more participants & more representative	(Sims, 2012)
Social Media	• Scale, breadth, and reach of social media are clearly appealing • Patient-centered approach to CC/PD - it uses favored communication modality & allows individuals to choose if and how they will respond to solicitations	(Stephens, 2016)

Method	Rationale	Reference
Community Meetings/ Interactive Settings	• Often logistically complex, inefficient, and expensive. • Access a limited audience and typically yield few questions. • Low attendance and responsiveness at open public meetings. • Minimized their estimates of study risk	(Stephens, 2016) (Callaway, 2013) (Dickert, 2014)
Random Digit Dialing Phone SUrveys	• Expensive and laborious • May become obsolete as fewer people elect to maintain home telephones • Many also view uninvited phone calls as intrusive.	(Stephens, 2016)
Methods of Convenience	Meetings, study specific websites/questionnaires, interviewing patients in ED waiting rooms or being treated, or at public events, presentations to disease advocacy organizations, and call-in radio programs –not as generalizable to the geographic community.	(Beshansky et al, 2014)
Study Specific Websites	• Modest rates of study website access • Characteristics were skewed (primarily younger males and females)	(Stephens, 2016)

Public Disclosure

Public disclosure means dissemination of information about the emergency research sufficient to allow a reasonable assumption that the communities are aware of the plans for the investigation, its risks and expected benefits. At this phase, it is likely that the study will be conducted, however a largely negative response to public disclosure by the community may cause the IRB to reconsider.

See Section VIII-B in the Draft Guidance document for specific information about methods suggested by the FDA for public disclosure.

Tips for Public Disclosure Approval:

- Plan to send public disclosure materials to many, if not most, of the same venues receiving community consultation materials. Utilize identified group 'leaders' if possible.
- A lengthy description of risks and expected benefits may not be feasible in all of the disclosure materials. Ensure that a website and telephone number are included.
- The PI provides a summary of the information that was disclosed. The IRB will determine if the disclosure is adequate.
- Submit a plan for public disclosure to take place after completion of the study to inform the community of study results. This plan may include many of the same features as the plan for disclosure prior to the initiation of the study and must be approved by the IRB.
- At the IRB's discretion, the PI may be asked to provide plans for continued public disclosure at intervals during the course of the research, especially if the research will continue for a year or more.

IRB Approval for Enrollment

The IRB must also ***find and document*** the following, as per 21CFR50.24(a):

Additional protections of the rights and welfare of subjects will be provided, including, at least:

(iv) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and (v) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

See especially Sections II, III, IV, V, IX, and X in the EFIC Draft Guidance for full information on these regulatory requirements..

Tips for Approval to Enroll:

- Verify that an IND or IDE, as appropriate, exists for the agents used in an investigational manner in the study protocol
- Ensure that an independent data monitoring committee has been established
- See Section IX in the Draft Guidance document for further description of the PIs commitment to inform the legally authorized representative about the study prior to administration of the test article and after such administration.
- Ensure that all regulatory aspects are considered before final approval. For example, the EFIC criteria at 50.24 must be fully addressed, in addition to regulatory criteria for children.
- Ensure that a licensed physician concurs with the initiation of the study and with continuing review. The licensed physician member's affirmative vote or licensed physician consultant's concurrence should be recorded in the minutes.
- The IRB should consider the frequency of continuing review.
- The IRB promptly provides to the sponsor, in writing, a copy of the information that has been publicly disclosed about the initiation of the study under 50.24a7ii and 21CFR56.109g
- Any site additions or modifications to the protocol must be approved by the IRB prior to implementation, including site-specific community consultation and public disclosure.
- Protocol violations have the potential to lessen public support for the research if they are numerous or become widely known. Accordingly the approval letter should contain a statement encouraging the PI to act very promptly with a corrective action plan whenever violations of enrollment or treatment occur.