**FASTEST SITE-SPECIFIC EFIC PLAN**

***(To be submitted for review by the Advarra IRB prior to implementation)***

***(The StrokeNet National Coordinating Center (NCC) must sign off prior to submission to the Advarra IRB)***

**SITE NAME:**

**SITE PI:**

**SECTION 1: COMMUNITY CONSULTATION PLAN**

***Note: Advarra acknowledges the challenges for community consultation (CC) raised by the current COVID-19 pandemic and intends to leave the decision about whether or when to initiate in-person CC to individual sites. Advarra encourages online and web-based interactions with the community and regards them as capable of satisfying CC obligations.***

1. **Goals**: The FASTEST model Exception from Informed Consent (EFIC) proposal describes the goals of community consultation:

1. *To ensure that all relevant communities have the opportunity for input into the IRB’s decision-making process before initiation of the study at a research site.*
2. *To present information so that community members understand the proposed investigation, its risks & benefits.*
3. *To be sure community members understand that the investigation will take place without informed consent.*

**Provide a brief overview of how the site-specific CC plan intends to meet the goals described:**

2. **Community**: The CC process is meant to solicit input from the community regarding the study. For the purposes of EFIC, the definition of communities is “the community in which research will take place,” which includes the geographic area where the hospital or study site is located, and the “community from which participants will be drawn,” which includes the group of patients who share particular characteristics (i.e., patients with the disease of interest or those “at-risk” for the disease or condition of interest). Communities have many subgroups that can be defined by innumerable characteristics such as race, ethnicity, religion, age, gender, wealth, education, employment, neighborhood, and other factors. Community consultation should consider the heterogeneity of the community and seek diverse input. It is understood, however, that it is impracticable to reach every possible subgroup, but each site will complete activities that reflect a sufficient portion of the spectrum of their relevant communities.

**a. Provide a brief description of the communities from which participants will be drawn:**

**b. Provide a brief description of how the CC plan will provide opportunities for broad community discussion:**

**c. Provide a brief description of how the CC plan will ensure that representatives from the communities involved in the research participate in the consultation process:**

**d. Provide any additional information on subgroups within the community, languages spoken, and efforts that are planned to involve these subgroups. Include any plans to engage groups that have historically been vulnerable or under-represented in clinical research:**

**e. Explain how individuals wishing to be excluded may indicate this preference:**

**f. If applicable, provide a brief description of how CC events will be coordinated with other sites that share the same community, and how input from the community will be shared amongst the sites (please include the names of the other sites):**

3. **Types of Events**:The FASTEST model EFIC proposal CC plan includes the following events:

|  |  |
| --- | --- |
| A (Interactive - Direct ) | B (Asynchronous - Delegated) |
| A presentation and discussion by an investigator visiting a meeting of an existing group (visits to existing meetings) |  |
| **Focus group (moderated small group session)** | Web-based survey |
| In-person individual interviews or meetings | Social media messaging |
| A booth or table at community events involving interactive discussions (not just surveys) [A booth/table discussion of sufficient length to meet Column A criterion (as opposed to Column B) is approximately 5 minutes of interaction.] | In-person solicited survey (e.g., waiting room survey, without other interaction) |
| Meetings convened by the investigators inviting the targeted audience (preferably with RSVP) | A booth or table at community events handing out study materials and surveys with limited interactive discussions |

Required mix is at least 6 total CC events or activities. Among these 6 events or activities, at least 2 events or activities must be of a type in column A, and at least 1 event or activity must be of a type in column B. One of the 2 events in column A, 1 must be a focus group. The other events may be of the same type, for example, they could both be focus groups or visits to existing groups. Events should include participants representing a sufficient breadth of the diversity of both the geographic community primarily served by the enrolling site’s institution, and the community either at-risk for, or familiar with, stroke. There is no expectation that all of the subgroups of either community can be engaged.

**a. Provide a brief description of:**

* **each planned event**
* **the planned length of time for the event**
* **whether a PI or study team member will be attending and their role (e.g., speaker, moderator). If the PI will not be present, the qualifications of study team members to answer questions about the study**
* **whether the event is intended to reach a geographic or condition-oriented community**
* **the number of participants expected**
* **any other relevant details, including if the event is a shared event with other sites (if so, which other site(s))**

**b. Describe how community members will be recruited for each event:**

**c. Describe efforts that will be made to survey the community and collect data about community views and preferences, including:**

* **what method will be used (written or online survey, interviews, etc.)**
* **the venue(s) in which the surveys or data collection will take place; how surveys will be distributed**
* **how efforts will be made to reach a roughly representative sample of the site’s catchment area**
* **how efforts will be made to collect information from at-risk populations**
* **how efforts will be made to collect information from minority and historically vulnerable groups**

**SECTION 2: PUBLIC DISCLOSURE PLAN**

1. **Goals**: The requirements of 21 CFR 50.24include informing the community of the performance of a research study that may impact members of the local population. Public disclosure (PD) activities should take into consideration the anticipated audiences, and should include audiences representing a sufficient breadth of the diversity of both the geographic community primarily served by the enrollment site, and the community either at-risk for, or familiar with, stroke. Public disclosure will be done prior to the initiation of the project, and during and after the project is completed. The content of the public disclosure messages will be implemented following the Advarra IRB’s review of the public disclosure plan.

**Provide a brief overview of how the site-specific PD plan intends to meet the goals described:**

2. **Community and In-Hospital Activities**:

**a. Provide a brief description of planned presentations of the proposed study to Neurology, Emergency Medicine, and Neurosurgery residents, faculty:**

**b. Describe whether brochures, posters, and flyers will be displayed in the Emergency Department (ED), Neurology and Neurosurgery Clinics before and during the trial:**

**c. Have plans been made for an announcement on the institutional intranet informing hospital staff of the proposed trial, or by e-mail announcement to faculty and staff:**

**d. Describe plans to provide training for the emergency clinicians who will be identifying potential participants in the ED or mobile stroke units, attending/fellow physicians and nurses who treat ICH/stroke patients:**

3. **Key Community Contacts**:

**Describe plans to work with local organizations, such as local chapters of the American Heart Association, to develop information for public notification aimed at the general public about FASTEST and EFIC, and posting this information on their website:**

4. **Types of Activities**:

|  |  |  |
| --- | --- | --- |
| A (networking) | B (paid advertising) | C (conventional outlets) |
| National or local study website | Newspaper advertisement (and similar print advertising) | Press release |
| Social media postings | Television and radio ads (broadcast advertising) | News stories, interviews (print, radio, or television) |
| Mailings (including e-mail circulars/bursts and direct paper mailings) | Outdoor advertising (placards, bus ads, billboards, etc.) | Newsletters (articles or informational ads, print or electronic) |
| Booth/table community event | Paid online advertisements (banner, block, or video ads purchased from Google, Facebook, YouTube, etc.) | Brochures, flyers, handouts, bulletin boards |
|  |  | Radio or television PSA (public service announcements) |

The required mix is at least 6 total PD activities including at least 2 of a type in column A, and at least 1 of a type in column B or column C. Distribution of activities should be cognizant of the anticipated audiences, and should include audiences representing a sufficient breadth of the diversity of both the geographic community primarily served by the enrollment site, and the community either at-risk for, or familiar with, stroke. There is no expectation that all potential audiences will be reached. It is expected that PD efforts will represent a good faith effort to provide transparency across the relevant communities.

1. **Provide a brief description of:**

* **each planned PD activity**
* **the timeline for the activity**
* **the anticipated audience and number of community members planned to be reached by the activity**
* **the implications (if any) of the activity for informing minority, historically vulnerable, and under-served populations about FASTEST**
* **mechanism for permitting members of the public to contact the research team for more information and/or opt-out**
* **any other relevant information, including if the activity is a shared activity with other sites (if so, which other site(s))**

***Note: The FASTEST PD plan requires investigators to document all inquiries from the public or interested parties on an Initial Public Notification Feedback Form. E-mail questions, comments, and feedback will also be documented. Investigators will collate and report results to the Advarra IRB before the start date of the study.***

**NCC REVIEW:**

Name of person reviewing site-specific EFIC plan:

Date site-specific EFIC plan reviewed:

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_