Memorandum and Guidance on EFIC Activities for the FASTEST Trial

The FASTEST Trial protocol, informed consent form, and model Exception from Informed Consent (EFIC) proposal for community consultation (CC) and public disclosure (PD) have been reviewed and approved by the Advarra IRB. The Advarra IRB is serving as the central IRB of record for the FASTEST Trial.

For the foreseeable future, the COVID-19 pandemic is anticipated to have an enormous impact on traditional EFIC activities, which rely substantially on person-to-person interaction. As person-to-person interaction for clinical research purposes is not currently allowable in most institutions and communities, to address this unprecedented situation, FASTEST Trial leadership has worked closely with the Advarra IRB to develop the following guidance:

- The goals of CC and PD remain the same -- (1) to inform the community in which the research is going to take place of the trial, including, in particular, those that are most at-risk; (2) to solicit their input; and (3) to provide individuals the opportunity to opt-out of participating, if they so choose.

- For CC, many of the activities listed in Column A (model EFIC proposal, pg. 7) -- visits to existing meetings, focus groups, individual interviews, and investigator-convened meetings -- are all highly adaptable to being done online (e.g., in the case of focus groups, as is frequently done for marketing purposes). A particular emphasis should be placed on focus groups and individual interviews. Individual interviews can target persons in a community liaison role.

  As many groups and organizations have transitioned in-person meetings to online, sites should capitalize on these existing meetings, as is outlined in the model EFIC proposal. Focus groups, individual interviews, and investigator-convened meetings can be set-up through any remote conferencing service (e.g., WebEx, Zoom, etc.). To the extent possible, video conferencing should be utilized over audio only conferencing.

  An in-person survey can be converted to a web-based survey for completion, with a link to the survey provided to individuals/focus group and meeting participants. A survey link can also be posted on an institution's website, as is outlined in the model EFIC proposal, or circulated via social media. A link to the IRB-approved surveys will be available on the FASTEST website for sites to utilize. The surveys have been modified to ask for the respondent's zip code so that the results can be included in any site's EFIC report whose community includes that particular zip code.

- For PD (model EFIC proposal, pg. 14), while less affected than CC, methods that utilize in-community and outdoor advertising should be minimized at this time. Additionally, as the modified CC activities above may have less of a reach than traditional CC activities, additional PD activities should be done to ensure the broadest reach possible.

For opt-out, traditional in-person distribution or mailing of bracelets is less feasible. An alternative method -- the method now being utilized by the FASTEST Trial -- is a card, which can be carried on the person. The card can be electronically obtained, which would require an electronic device and printer on the receiving end. In the case where one or both is unavailable, a person could write a card that relays the same information verbatim, contacting the site to opt-out, if needed.

FASTEST Trial leadership, the Advarra IRB, and the StrokeNet National Coordinating Center will work with each site to develop a creative and flexible approach to CC and PD that still achieves the goals set forth above.

06MAY2020