CSRC Mini Think Tank
Topic: Informed Consent Working Group

January 29, 2021 10:00-13:00 (EDT)

Meeting Goals:

Goal 1 To review and refine key Informed Consent issues and possible solutions identified in 2020
Goal 2 To identify workflows for deliverables in 2021 and beyond

Zoom Link	https://duke.zoom.us/j/91353536198?pwd=NW1OSDhSTXlRYStYcXJVR1hnT3ltdz09
Zoom Passcode	csrc

10:00—10:30 Session 1: *Introductions*

Introductions and recap of CSRC Informed Consent initiative John Sapirstein, MD (FDA) and Nick West, MD (Abbott Vascular)(15 min)

Proposed 'Matrix' Framework for Consent in Shock Trials Mitch Krucoff, MD (Duke)(15 min)

10:30-12:00 Session 2: *Working Group Break Outs*

Group 1: Central IRB/Role of Centralized Knowledge and Expertise
Moderator: Ian Gilchrist, MD (Penn State)

- ***Discussion: Can a centralized repository of knowledge and experience be established at large scale to streamline the clinical-regulatory-ethical processes needed for consent in shock trial? Should there be a national or regional approach to IRB? Can the relationship between local and central IRBs for shock trials be standardized and get enough "buy-in" to be applied to any investigation? What are the logistics for establishing such a body, and where should the funding come from?***

Group 2: ICF Templates and Comprehensive Consent Process
Moderator: Dave Morrow, MD (Brigham and Women's)

- ***Discussion: Goal is to formulate generalizable informed consent processes and document(s) for shock trials. Can one design a template consent approach that facilitates reproducible and timely enrollment of subjects reflective of the "real-world" shock populations? What are the requirements and nuances of Informed Consent regulations, and how can they be practically implemented in trials with EFIC, non-EFIC, and "mixed" populations? Are there ways to standardize the determination as to whether an individual shock patient can give consent, and could "staged" informed consent be used for shock trials that otherwise might be considered needing EFIC?***

Group 3: Harmonization with other Stakeholders
Moderator: Ileana Pina, MD (FDA)

- ***Discussion: Most discussions of informed consent in shock center around the US 50.24 regulations, but there is benefit to multi-national shock trials. Can a consent paradigm ever be designed that harmonizes the informed consent requirements of the US with other countries'? Although not all shock trials in the US need FDA involvement, informed consent will still be necessary for many shock trials not conducted under IDE, IND, or post-marketing approval/clearance requirements. What is industry's perspective on the impact of informed consent requirements on industry-sponsored investigations?***

12:00 – 13:00 Session 3: Wrap-up Discussion and Next Steps

Moderators: John Sapirstein, MD and Nick West, MD