October 2, 2019 (Wednesday)

**8:00 AM**  BREAKFAST

**8:30 AM**  WELCOME & OPENING REMARKS  
Tamim Nazif, MD, Columbia University Medical Center

**8:45 AM**  HISTORY OF THIS COLLABORATION  
Jaime Walkowiak, JD, Baylor Scott and White Research Institute

**9:00 AM**  INTRODUCTION AND PRESENTATION OF SURVEY  
Liliana Rincon-Gonzalez, PhD, Medical Device Innovation Consortium

**9:15 AM**  OVERVIEW OF REGULATORY TOOLKIT  
Elizabeth Cothran, MS, Baylor Scott and White Research Institute

**9:30 AM**  CONSENT TEMPLATE – Key Information Section  
Brenda Carroll, Intermountain Medical Center

**10:00 AM**  CONSENT TEMPLATE – General Risks of EFS  
Keren Dunn, Cedars Sinai Medical Center

**10:20 AM**  CONSENT TEMPLATE – General Benefits of EFS  
Anna Huskin, Northwestern Medicine

**10:40 AM**  CONSENT TEMPLATE – Confidentiality Section  
Jennifer Thomas, Baylor Scott & White Research Institute

**11:10 AM**  CONSENT TEMPLATE – Subject Injury Section  
Lauren Privitera, Columbia University Medical Center

**11:30 AM**  CONSENT TEMPLATE – Costs, Billing, Payments  
Matthew Watts, Baylor Scott & White Research Institute

**12:00 PM**  LUNCH  
Presentation from EFS Patient

**1:30 PM**  SPECIAL CONSIDERATIONS FOR IRB REVIEW  
Robert Romanchuk, Advarra

**2:00 PM**  SINGLE IRB INITIATIVE – PROS/CONS/PREFERRED  
Greg Voss, Boston Scientific
2:30 PM  FACILITATIVE/ADMINISTRATIVE REVIEW PROCESS – Panel
Ashley Dowell, Stephanie Price, Heather Whitacre, Baylor Scott & White Research Institute

3:00 PM  CLINICAL TRIALS TRANSFORMATIVE INITIATIVE PRESENTATION
Sara Calvert, Clinical Trials Transformation Initiative (CTTI)

3:30 PM  QUESTIONS & ANSWERS WITH THE FDA
Andy Farb, MD and Maureen Dreher, PhD, Food and Drug Administration

4:30 PM  BREAK

6:00 PM  Leave for off-site reception dinner
Mi Cocina’s - Lakewood, 6332 La Vista Dr., Dallas, TX 75214
Meet outside Ballroom A; shuttle will be available for transport

October 3, 2019 (Thursday)

8:30 AM  BREAKFAST

9:00 AM  REVIEW OF TEMPLATE CONSENT FORM

10:30 AM  REVIEW OF OTHER TOOLKIT ITEMS

11:30 AM  MEETING ADJOURNED

MEETING LOCATION
Home2 Suites by Hilton – Ballroom A
3301 Gaston Ave.
Dallas, TX  75204

MEETING DIAL-IN INFORMATION
(Conference line will be activated at 8:30 am on 10/2 and 9:00am on 10/3)

Oct 2, 2019
Conference Call #: 469-291-6700
Access code: 995 190 689

Oct 3, 2019
Conference Call #: 469-291-6700
Access code: 990 280 681