SESSION 1 Group Discussions Worksheet
THEME: CLINICAL TRIALS RULES & REGULATIONS

TOPIC: Dealing with Adverse Events (AEs) and Serious AEs ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Michele Demetroff **Lead Scriber: Ellen Cohen**	
WHY DOES IT MATTER?	• **Important for maintaining participant safety** • **Health Canada and REB requirements**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Having a MD available to sign off	• Regular meetings with MD • Assist with paperwork - prep for signatures • Develop rapport with MD • Use text or other strategies to avoid lost e-mails • Avoiding confidential information • Send notices/reminders, not PHI over text
#2 - Not having a flagging system to track AEs; having access to clinical documents to identify AEs/SAEs	• Rely on patients' reporting • Ask at every interaction/study visit if there are any changes in health, etc • Access to medical records for RCs • Use sticky notes • Some institutions include Research Coordinators in the circle of care • Some may get a notification from the local pharmacy stating that they don't have the study meds
#3 - Number of AEs that may occur and how broad the reporting requirements are	• Forewarn sponsor that there will be AEs • Follow participants for a limited time • Only report AEs if they are related to study drug as determined by the sponsor (defined in protocol/product monograph) • Develop processes for communicating AEs between sites, e.g weekly meetings
#4 - EMR vs paper charts and across multiple sites	• Specific screens for researchers, some read only but can request read write permissions • Ensure communication (and access if possible) across sites • Research should be involved in transition from paper to electronic charting

SESSION 1 Group Discussions Worksheet
THEME: CLINICAL TRIALS RULES & REGULATIONS

TOPIC: Dealing with Delegation Logs & Training ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Alexandra McKinnon **Lead Scriber: Olga Yaroslavtseva**	
WHY DOES IT MATTER?	• **Important to ensure standardized training for standardized execution** • **Important to ensure appropriate oversight of clinical trial activities** • **Health Canada and REB requirements**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Getting all signatures (paper or electronic) following regulations and institutional rules	• Being persistent in tracking individuals • Using validated tools and methods (docusign) as opposed to copy and paste; making sure signatures and dates are valid
#2 - Trials may have different rules on who can be delegated a task (PTs, MDs, coordinators)	• Clear communication from sponsor • Keep track of professional licenses and renewal dates • Check trial protocol and SOPs • Follow local and provincial regulations • Keep certificates current/valid
#3 - Making sure all training is done	• Make sure that at least one person is trained and delegated for each task, have backup • Have trainers available to train new staff
#4 - Expired certification/lapses in certification	• Systems for sending automatic notices/reminders to renew expiring certificates in e-mail, study calendars • Have a delegated/central person responsible for tracking and reminding people • Automatic e-mails from database/system to staff and coordinator • Revoke ability to perform task (e.g. enrolling participants • Assign a study team member (e.g. summer student) to track
#5 - Dealing with Lapses in certification	• Write a document explaining the reason for the lapse, list all activities that the person performed during the lapse • Document all attempts to remind staff member; • write a note to file • Identify the processes that led to lapse; plan to fix the processes
#6 - Defining roles	• Standardize role descriptions (Sponsor or PI)

#7 - Defining start and stop dates	• E.g. - start date - first study activity, SIV; end date - study closure • Consult with sponsor for directions • Define what marks the start and end date for each study member or task

SESSION 1 Group Discussions Worksheet
THEME: CLINICAL TRIALS RULES & REGULATIONS

TOPIC: Dealing with Protocol Deviations and Cappas ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Shuhira Himed **Lead Scriber: Melanie Dunlop**	
WHY DOES IT MATTER?	• **Important for standardization** • **Important for disseminating solution and future prevention** • **Health Canada and REB requirements**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Accessibility issues (transportation, financial concerns, social engagement) that prevent form meeting time windows	• Be adaptable, provide personalized participant support, • Communication, early QI PI engagement • Create protocol/sop for reporting and signing • Doing a dry run with teams, process for reporting and addressing issues • Regular meetings
#2 - Unexpected patient change of status	• Communication strategies to set up steps including scheduled rounds with the research team and established terms of reference (role expectations for all parties) and pathway to communicate with QI/PI • Considering safety and integrity of data
#3 - Issues outside control	• Monitor dates, adjust protocol if needed • Develop a running log of mild protocol deviations that QI/PI can sign.
#4 - Have PDs and Cappas signed by PI/QI	• Have set expectations
#5 - Difference between NTF and Protocol deviations - need to re-define and sign	• In case of difference of opinion between sponsor and PI - consult with REB

SESSION 2 Group Discussions Worksheet
THEME: FUNCTIONAL COMPONENTS FOR SUCCESSFUL TRIALS

TOPIC: Engaging Clinical Teams and People with Lived Experience (PWLE) ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Melanie Dunlop **Lead Scriber: Olga Yaroslavtseva**	
WHY DOES IT MATTER?	• **Important to get relevant input and diverse opinions & feedback on successful feasibility and engagement** • **Important to get input and engagement from PWLE to ensure alignment with priorities important for PWLE** • **For clinical team engagement it is important to have buy-in and someone championing the study on site or else it will just be buried beneath general workloads.**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Maintaining professional boundaries	• Establishing role expectations early • Developing PWLE contracts for research participation • Engaging PWLE in all aspects of research activities
#2 - Fast paced nature of research	• Engaging PWLE in all aspects of research activities • Fostering a culture of respect and inclusion • Adding additional time and funding in research proposals for additional cost/time requirements
#3 - Lack of diversity	• Avoiding approaching the same individuals multiple times • Recruiting target populations of PWLE • Making an effort to make PWLE engagement in research more accessible to equity deserving groups; recognizing that some groups may have social determinants that make participation more difficult • Fair and equitable compensation for PWLE experience and expertise • Gift cards/gas cards/parking is provided
#4 - Engagement of PWLE as "check boxes" for inclusion	• Fostering a culture of inclusivity • Engaging PWLE in all aspects of research engagement • Fair and equitable compensation for PWLEs • Creating research proposals based on the values of PWLEs and through collaboration with PWLE researchers and leaders.
#5 - Functional challenges	• Optimize environments for individual needs (cognitive, auditory, physical) • Consider impact of fatigue and environmental/social stimulation and develop processes to optimize engagement in research without aggravating stroke symptoms

	• Equitable compensation • Consider ability or inability to independently drive; provide parking/gas coverage

SESSION 2 Group Discussions Worksheet
THEME: FUNCTIONAL COMPONENTS FOR SUCCESSFUL TRIALS

TOPIC: Successful Participant Recruitment & Retention ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Ellen Cohen **Lead Scriber: Michele Demetroff**	
WHY DOES IT MATTER?	• **Important to maximize recruitment and retention which are often tied to budget** • **Important to facilitate faster trial completion** • **To enable studies to reach sufficient sample size for proper statistical analysis** • **To improve access and experience for potential patient participants**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Language barriers/communication issues	• Translators/google translator • Possibly family members help • SLP/OT communication tools
#2 - Time windows	• Physician engagement
#3 - Clinical vs research team collaboration	• Site to site differences
#4 - Physician engagement	• Text message vs email • Education days-ongoing studies • Posters/pocket notes
#5 - Address/transportation	• Taxis • Purolator • Drop off meds to patient

SESSION 2 Group Discussions Worksheet
THEME: FUNCTIONAL COMPONENTS FOR SUCCESSFUL TRIALS

TOPIC: Juggling Multiple Responsibilities - Time Management & Task Prioritization ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Shuhira Himed **Lead Scriber: Alexandra McKinnon**	
WHY DOES IT MATTER?	• **Important for successfully completing trials with reduced errors and deviations** • **Important for successfully completing trial in a timely manner and on budget** • **Important for maintaining a less stressful work life** • **Important for maintaining deadlines and due date/renewals to minimize delays and study disruptions** • **Helps with effective collaborations between team members & different teams across multiple sites** • **Helps with improving experience with study participants and their caregivers**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Working on multiple studies at a time	• Having one main coordinator per study but also other team members on-call for certain days to help recruit • Prioritize tasks based on study windows and relative importance (i.e., exercise session vs MRI) • Utilize shared and personal calendar functions
#2 - You can plan your day in advance and not complete anything because other things come up	• Personality factors: flexibility, ability to adapt to changes, problem solve on the spot, and use critical thinking
#3 - Coping with fewer staff/smaller teams	• If it's possible, involve more trainees/fellows/volunteers • Plan ahead as much as possible
#4 - Physical space - using shared spaces or spaces not dedicated to research	• Booking in off times (i.e., early mornings, lunch time) • Clear communication with all personnel using the space
#5 - Training volunteers - can be a great resource, but training and supervision can be a significant time commitment	• Have volunteers commit to a certain duration and specific time(s) - i.e., every Thursday from 12-4pm for 6 months • Emphasize the importance of the task(s) given to the volunteer - i.e., data transcription can be boring, but having a correct database is critical for data analysis

#6 - Workload - capacity to take on new studies/tasks	• Communicate with your investigator and team (one-on-one and team meetings/discussions) • Team support! Research is a TEAM SPORT

SESSION 3 Group Discussions Worksheet
THEME: MAKING RESEARCH ACCESSIBLE

TOPIC: Using Online Tools in a Study ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Alexandra McKinnon **Lead Scriber: Shuhira Himed**	
WHY DOES IT MATTER?	• **Important for standardized delivery of trial tools** • **Important for recognizing the potential for remote use** • **Important to be prepared since online tools are becoming more common in trials**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Encountering internet connection issues when using tablets to complete assessments. Time consuming.	• Engage with the participant until the issue is resolved. • Set-up the tablet/ or device to be used the day before the visit to identify any technical issues to resolve prior to visit. • Inform the participant of the issue and let them know the time it will take. Reschedule visit if possible.
#2 - Participant capability using technology. Some demographics are not used to new devices and how to use them.	• Ask family members to help during the visit. • Provide training to participants prior to use of tablet/ or device.
#3 - Must use the provided tool (i.e. tablets) to complete assessment and not provide a back-up paper CRF.	• Call IT to resolve the issue early. Reschedule the visit. • If device to use break communicate with sponsor/ CRO importance of having a back-up paper CRF.
#4 - Transcription error if the paper CRF is used as a back-up for a study that is set-up to collect data electronically only.	• Avoid using paper CRF and only collect data electronically. • Plan ahead to resolve issues prior to planned study activity.
#5 - Lack of capacity: using REDCap to upload imaging large files	• Create a share point to upload images. Approved by REB and institution. Can be used across the province. • Using OneDrive
#6 - Challenges with ethics to get approval to use online tools. Privacy issues.	• Use tools that are approved throughout your institution or known to be used in research. • Communicate with REB to identify tools that can be used and the requirements for ethics approval for newer tools.

#7 - Privacy requiring location and storage. IT demanding a rationale for using a specific tool or database	• Using similar platforms across the country • Communication that it was used in prior studies if that's the case.
#8 - Managing access/ password storage for different tools.	• Create a document with a list of studies and passwords lock file and save it where it's easily accessible.
#9 - Difficulties with shifting from paper to electronic	• Providing training modules would be helpful • Depend on individual being able to adapt to change and if available team support.
#10 - Online training is time consuming. Possible that some staff have to complete training after hours.	• Keep a deadline • Playground versions and training modules. • If available can download training and forward to your team to review and acknowledge email. Store a training log once complete.

SESSION 3 Group Discussions Worksheet
THEME: MAKING RESEARCH ACCESSIBLE

TOPIC: Being Part of a Multi-Site Trial ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Olga Yaroslavtseva **Lead Scriber: Michele Demetroff**	
WHY DOES IT MATTER?	• **Important for standardized delivery across sites** • **Important to be aware of as most sites are increasingly involved in multi-site trials** • **Important for building networks and team engagement** • **Being part of a multi-site trial likely means that the results from the trial will be more diverse and generalizable** • **May increase accessibility to participate in a trial**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Start-up	• CSC • Open communication/collaboration with other sites
#2 - Communication CRO vs sponsor	• CSC • Relationship with sponsor/monitor
#3 - Developing rapport at the beginning of the trial vs the end of the trial	• Asking questions • Going to/being involved in meetings
#4 - Pharma studies	
#5 - Time differences	
#6 - Legal/REB blocks	

SESSION 3 Group Discussions Worksheet
THEME: MAKING RESEARCH ACCESSIBLE

TOPIC: Using Wearable Technologies ***What are the top challenges and best strategies to deal with them?***	
Lead Facilitator: Ellen Cohen **Lead Scriber: Melanie Dunlop**	
WHY DOES IT MATTER?	• **Important for standardized delivery across sites** • **Important to be aware of as trial are increasingly using them** • **Important since wearables are allowing remote data capture of a lot of data that couldn't be easily captured in a clinic setting**
TOP CHALLENGES	**BEST STRATEGIES**
#1 - Technology becomes obsolete	• Avoiding the newest devices; going with a product that is well established • Updating the devices before delivered to participants • Providing internet data cards • Provide front-loading instructions to health care staff, family, participants
#2 - Functional issues-delivery of devices	• Have the full kit delivered to the treating therapist so they can demonstrate solutions to tech issues in real time • Set up device at first clinical visit or prior to discharge from hospital • Front load participants and family members about devices and common challenges
#3 - Patient comfort	• Provide real time feedback • Choosing right device; consider cost, ability to doff/don, risk for skin breakdown • Participant access to timely support to reduce stress • Involve a patient with lived experiment in protocol
#4 - Reliability/Accuracy	• Regularly scheduled data checks • Scheduled calibration • Collaborate with unit clinicians
#5 - Privacy	• Complete a privacy impact survey • Use de-identified data • Ensure privacy contracts are in place • Informed consent includes discussion about how and where device data is stored