

iRehab Site Initiation Visit Agenda

Site Initiation Meeting to run for approximately 1hr 30mins and to include the following delegates:

- WCTU Trial Team
- Principle Investigator
- Lead Research Nurse(s)
- Site Research Champion (if different to above)
- Any other member to be added to the initial delegation log

Running Order (1hr approx.):

- Introduction & Main Contact Details
- Background
- Study Aims
- Study Design
- Trial Timelines
- Summary of Trial Processes
- Data & Data Entry
- Eligibility & Screening
- Consent & Registration
- Baseline & Randomisation
- Intervention
- Follow Up
- Unscheduled Events
- Withdrawals, Readmissions and Notification of Death
- AE's & SAE's
- Training, Responsibilities & Study Oversight
- API Scheme
- Protocol Non-Compliances & Monitoring
- Co-enrolment
- Next Steps
- Stop Go Criteria
- Questions

Database Training (30 min approx.)