| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|---|--|---|-------------------------------------|---|
| Welcome Overview of a clinical research process Overview of a study protocol | IRB & ancillary committees Informed consent Contracts | Budgets Research billing Recruitment plan | IT systems PTrax Remuneration | Study set-up: Pharmacy, biospecimens, study operations, subject visit checklist |
| | Afte | rnoon job shadow with | in unit | |
| Day 6 | Day 7 | Day 8 | Day 9 | Day 10 |
| Study set-up: Regulatory files Site initiation/training | Simulation center Screening Consenting & subject advocacy | Subject management | Study management | Teamwork Study team panel Study publication & closure Wrap-up |
| | Afte | rnoon job shadow with | in unit | |

Supplemental Figure 1: Mayo Clinic Clinical Research Orientation schedule

Supplemental Figure 2: Penn State University College of Medicine Clinical Research Orientation schedule

| DAY 1 Idea Generation & Study Development | DAY 2 Study Startup and Conduct | DAY 3 Study Conduct | DAY 4 Study Conduct | DAY 5 Study Closeout and Dissemination |
|--|---|---|---|---|
| Expectations/Goals Research process Concept/Proposal development Grant, contract & budget development | •Research protocol •IRB & HRPP •Study operations •CTSI resources | Recruitment & retention Grant, contract & budget Management Consenting | Responsible conduct of research Reporting Research administration and regulatory topics Data | Study closeout Dissemination Communication styles |

Supplemental Figure 3: University of Mississippi Medical Center Clinical Research Orientation schedule

| Day 1 - Study Assessment and Activation | Day 2 - Study Conduct and Closure |
|---|--|
| Welcome, Introductions, and Overview | Recruitment: a General Overview |
| Completion of Confidence Questions | Unconscious Bias in Recruitment |
| Acronyms/Terms | Informed Consent |
| Teamwork and Communication | Consenting Simulation |
| Clinical Trial Process Overview | E-Consent Overview |
| Study Initiation and Confidential Disclosure Agreements | Regulatory and Other Study Documentation |
| Protocol Review | Lab Draws and Processing |
| Feasibility/Recruitment Plan | Research Billing |
| Contracts and Budgets | Study Closeout |
| IRB, RSO, and BSO Submission, Review, and Approval | Study Team Panel |
| Coordinator Basics | Wrap-Up/Q&A |
| Velos Training | Completion of Confidence Questions |



Day 1 – Idea Generation & Study Development

| TIME: | TOPIC: |
|-------------------|---|
| 9:00-9:15 am | Welcome |
| 9:15-9:45 am | Ice Breaker/Get-to-know Participants Activity |
| 9:45-10:00 am | SMaRT Orientation Expectations & Goals |
| 10:15-10:45 am | Overview of Research Process |
| 10:45 am-12:00 pm | Concept & Proposal Development |
| 12:30-2:00 pm | Grant, Contract, & Budget Development |
| 2:00-2:15 pm | Day 1 Recap/Q&A |
| | |

Day 2 – Study Startup and Conduct

| TIME: | TOPIC: |
|----------------|-----------------------------------|
| 9:00-9:15 am | Day 1 Recap; Day 2 Learning Goals |
| 9:15-10:00 am | Overview of Research Protocol |
| 10:15-11:30 am | IRB & HRPP |
| 12:00-1:15 pm | Study Operations |
| 1:15-1:45 pm | CTSI resources |
| 1:45-2:00 pm | Day 2 Recap/Q&A |



Day 3 – Study Conduct

| TIME: | TOPIC: | |
|-------------------|--------------------------------------|--|
| 9:00-9:15 am | Day 2 Recap; Day 3 Learning Goals | |
| 9:15-10:15 am | Recruitment & Retention | |
| 10:30 am-12:00 pm | Grant, Contract, & Budget Management | |
| 12:30-1:45 pm | Consenting | |
| 1:45-2:00 pm | Day 3 Recap/Q&A | |
| | | |

Day 4 – Study Conduct

| TIME: | TOPIC: |
|-------------------|--|
| 9:00-9:15 am | Day 3 Recap; Day 4 Learning Goals |
| 9:15-10:30 am | Responsible Conduct of Research |
| 11:00-11:30 am | Reporting |
| 11:30 am-12:15 pm | Research Administration & Regulatory Topics Panel |
| 12:45-2:15 pm | Data |
| 2:15-2:30 pm | Day 4 Recap/Q&A |



Day 5 – Study Closeout and Dissemination

| TIME: | TOPIC: | |
|-------------------|--|--|
| 9:00-9:15 am | Day 4 Recap; Day 5 Learning Goals | |
| 9:15-9:45 am | Study Closeout | |
| 9:45-10:45 am | Dissemination | |
| 11:00 am-12:00 pm | Communication Styles | |
| 12:30-1:00 pm | Day 5 Recap/Q&A/Additional Resources | |
| 1:00-2:00 pm | Orientation Program Evaluation and Closing | |

Supplemental Figure 5: University of Mississippi Medical Center Sample Clinical Research Orientation agenda



| Day 1 - Study Assessment and Activation | Times |
|--|---|
| Welcome, Introductions, and Overview | 8:30 - 9:00 |
| Unconscious Bias in Recruitment | 9:00 - 10:15 |
| Break | 10:15 - 10:30 |
| Acronyms/Terms | 10:30 - 10:40 |
| Teamwork and Communication | 10:40 - 10:50 |
| Clinical Trial Process Overview | 10:50 - 11:05 |
| Study Initiation and Confidential Disclosure Agreements | 11:05 - 11:30 |
| Protocol Review | 11:30 - 12:00 |
| Lunch | 12:00 - 1:00 |
| Feasibility/Recruitment Plan | 1:00 - 1:30 |
| Contracts | 1:30 - 2:15 |
| Budgets | 2:15 - 3:00 |
| Break | 3:00 - 3:15 |
| IRB, RSO, and BSO Submission, Review, and Approval | 3:15 - 4:00 |
| Day 2 - Study Start-Up/Conduct | Times |
| Research Resources (IDS, CRTU, tech info) | 8:30 - 9:30 |
| Coordinator Basics | 9:30 - 10:15 |
| Break | 10:15 - 10:30 |
| Recruitment | 10:30 - 11:30 |
| | 10:30 - 11:30 |
| Consenting plus simulation | 10:30 - 11:30 |
| | |
| Consenting plus simulation | 11:30 - 12:00 |
| Consenting plus simulation Lunch | 11:30 - 12:00 12:00 - 1:00 |
| Consenting plus simulation Lunch Breakout for group consenting simulations | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break Regulatory and other study documentation | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 2:15 - 4:00 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break Regulatory and other study documentation Day 3 - Study Conduct and Closure | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 2:15 - 4:00 Times |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break Regulatory and other study documentation Day 3 - Study Conduct and Closure Lab Draws and Processing Research Billing Study Closeout | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 2:15 - 4:00 Times 8:30 - 9:00 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break Regulatory and other study documentation Day 3 - Study Conduct and Closure Lab Draws and Processing Research Billing | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 2:15 - 4:00 Times 8:30 - 9:00 9:00 - 10:00 |
| Consenting plus simulation Lunch Breakout for group consenting simulations Group consenting presentations Break Regulatory and other study documentation Day 3 - Study Conduct and Closure Lab Draws and Processing Research Billing Study Closeout | 11:30 - 12:00 12:00 - 1:00 1:00 - 1:30 1:30 - 2:00 2:00 - 2:15 2:15 - 4:00 Times 8:30 - 9:00 9:00 - 10:00 10:00 - 10:30 |