**Protocol Training**

Topics Covered

[date]

**Protocol #**:

**Title:**

***Discussion Items***

1. **Scientific Rational**
   * Target Condition
   * Study Efficacy & Safety Endpoints
2. **Investigational Agent**
   * Characteristics, safety, accountability management
3. **Screening**
   * Inclusion/Exclusion Criteria
   * Screening tests
4. **Enrollment & Randomization**
5. **Procedures & Laboratory testing**
6. **Safety Oversight**
   * Medical Monitoring & documentation
   * Safety Reporting
7. **Data management**
   * Source documentations
   * Data collection & data management
   * Managing data discrepancies

***Training Materials Used***

1. Study Protocol
2. Inclusion/Exclusion check list
3. Screening & Enrollment tracking forms

***Attendees***

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| **Name** | **Signature** |
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