# Clinical Research Fellowship Learning Objectives

**Department of Emergency Medicine**  
**Denver Health Medical Center, Denver, Colorado**

1. **Identification of Area of Focus**

2. **Hypothesis Generation**

3. **Research Design**
   - 3.1 Definition of Study Population or Model System
   - 3.2 Definition of Endpoints
     - 3.2.1 Relevance
     - 3.2.2 Reliability
     - 3.2.3 Validity
   - 3.3 Experimental and Quasi-Experimental Designs
   - 3.4 Observational Designs
   - 3.5 Sample Size Determination / Power Analysis
   - 3.6 Planned Comparisons and Analyses
     - 3.6.1 Primary Endpoint
     - 3.6.2 Multiple Endpoints versus Composite Endpoints
     - 3.6.3 Subgroup Analyses
     - 3.6.4 Adjustment for Covariates
     - 3.6.5 Modeling

4. **Data Collection Methods**
   - 4.1 Data Collection Instrument (DCI) and Case Report Form (CRF) Design
   - 4.2 Testing and Revision of DCIs and CRFs
   - 4.3 Database Design
   - 4.4 Data Verification and Query Resolution

5. **Data Monitoring and Interim Data Analysis**
   - 5.1 Data Monitoring Committees
   - 5.2 Statistical Aspects of Interim Data Analysis / Efficacy Monitoring
   - 5.3 Safety Monitoring

6. **Data Analysis**
   - 6.1 Verification of Data Quality
   - 6.2 Verification of Data Assumptions
     - 6.2.1 Quality of Randomization
     - 6.2.2 Characteristics of Study Population
     - 6.2.3 Sample Size Assumptions
   - 6.3 Data Analysis
     - 6.3.1 Independent Variables
     - 6.3.2 Primary and Secondary Dependent Variables
     - 6.3.3 Advanced Methods
       - 6.3.3.1 Multivariable Linear and Logistic Regression Techniques
       - 6.3.3.2 Classification and Regression Tree Analysis
       - 6.3.3.3 Decision Analysis
       - 6.3.3.4 Cost Analysis
       - 6.3.3.5 Sensitivity Analysis
     - 6.3.4 Exploratory Data Analysis
       - 6.3.4.1 Data-Motivated Analyses

7. **Presentation of Research**
   - 7.1 Abstract Preparation and Submission
   - 7.2 Oral Presentation of Research Results
   - 7.3 Poster Presentation of Research Results
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<td>8. Manuscript Preparation, Submission, and Revision</td>
<td>8.1 Manuscript Outline, 8.2 Manuscript Preparation, 8.3 Manuscript Revision and Interaction with Editors, 8.4 Responding to “Letters to the Editor”</td>
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<td>9. Grant Preparation, Submission, and Revision</td>
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<td>10. Project Management</td>
<td>10.1 Budget Management, 10.2 Personnel Management, 10.3 Progress Reports, 10.4 Interaction with External Agencies</td>
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<td>11. Ethical Aspects of Medical Research</td>
<td>11.1 Institutional Review Board, 11.2 Human Subject Protection (11.2.1 Elements of Informed Consent, 11.2.2 Elements of HIPAA), 11.3 Uses of Animal Subjects, 11.4 Research Fraud and Misconduct</td>
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<td>12. Informatics</td>
<td>12.1 Personal Productivity Software (12.1.1 Word Processing and Data Management, 12.1.2 Scientific Tables and Figures, 12.1.3 Personal Information Management), 12.2 Scientific Graphics, 12.3 Poster Creation, 12.4 Web Page Design, 12.5 Database Design and Translation, 12.6 Statistical Software</td>
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<td>13. Teaching Skills</td>
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