Experiment Protocol Process

- **Administrative**
  - Protocol Name
  - Protocol ID Number
  - Version History
- **Background**
  - Description of the Process
  - Motivations
    - Instructions from Management
    - Voice of the Customer (VOC)
  - References to Process Information
    - Calibration to establish accuracy
    - GR&R study to demonstrate measurement reliability
    - First Principles
    - Process documentation, SOPs
    - DFMEA & PFMEA
    - SPC records
    - Process capability studies
    - Corrective Actions
  - Problem to be Solved
  - Review of Previous Investigations
- **Experiment Design**
  - Input-Process-Output (IPO) Diagram
    - Response(s)
      - CTQs
      - KPOVs
      - Ordinary POVs
    - Factors
      - Controlled
      - Uncontrolled
        - Can't be measured
        - Can be measured
      - Type
      - Qualitative
        - Fixed Levels
        - Random Levels
      - Quantitative
  - Chosen Design
    - Design Family
      - Low resolution designs, e.g. screening experiments for many PIVs
      - Intermediate resolution designs, e.g. two-level factorials and fractional factorials
      - High resolution designs, e.g. response surface designs
    - Variables Matrix
    - Design Matrix
    - Alternative Designs Considered
    - Sample Size Calculation
      - Using the intended analysis/model
      - Standard deviation estimate
      - Effect size estimate and power
    - Randomization Plan
      - Validate by analyzing the run order as the response
    - Blocking Plan
    - Create the data collection worksheets
      - Run number
      - KPIVs
      - CTQs
      - Covariates
      - Notes/comments
    - Validate the design by analyzing a fictional response
- **Experiment Procedure**
  - Personel required
  - Equipment and hardware required
  - Material required
  - Safety plan
  - Plan for managing interruption to production process
  - Experimental procedure
  - Data recording process
  - Contingency Plan
  - Review
    - Management Review
    - Technical Review
    - Customer/Process Owner Review
    - Institutional Review Board (IRB)
    - Animal Review Board (ARB)
- **Statistical Analysis**
  - Software to be used and version number
  - Analysis Method
    - ANOVA/Regression
    - Regression
    - Binary Logistic Regression
    - Poisson Regression
    - Regression with Life Data
    - Other
  - Models
    - Full Model
    - Post-Occam Model
    - Alternative Models
    - Tests of Assumptions
      - Requirements of Residuals
        - Homoscedasticity
        - Normality
        - Freedom from Outliers
      - Goodness of Fit
      - Contingencies
    - Model Acceptance Criteria
    - Contingency Model
  - Model Confirmation Study
    - Design of
    - Analysis of
    - Acceptance Criteria
  - Model Application
    - Maximize
    - Minimize
    - Hit target value
    - Simultaneous requirements on CTQs
    - Reduce process variation
    - Robust design
- **Cost Analysis**
  - Cost of the experiment
    - Adminstrative cost
    - Cost per cell of the experiment design matrix
    - Cost per replicate observation
    - Cost of analysis and interpretation
    - Cost to implement the recommended actions
  - Risks of not doing the experiment
- **Experiment Report Format**
  - Administrative Information
  - Findings (abstract or executive summary)
  - Introduction
    - Background information
    - Goal
  - Experiment Design
    - Variables matrix
    - Design Matrix
    - Sample size, randomization, and blocking plan
    - Alternative designs considered
  - Experiment Administration
    - Experiment Procedure
    - Experimental Data
    - Deviations from Protocol
  - Analysis
    - Software and Version Number
    - Graphical analysis
    - Statistical analysis
      - Full Model
      - Post-Occam Model
      - Assumption Checks
        - Normality
        - Homoscedasticity
        - Goodness of Fit
      - Contingency analysis
    - Interpretation of the model
    - Evaluation against decision criteria
  - Discussion
    - Success or failure of the experiment
    - Consequences of deviations from protocol
    - Recommendations for future experiments