

Massachusetts Medical Device Development Center (M2D2) Recommended Outline by Section

1. Executive Summary

Research Plan

2. Specific Aims (use list below as subheadings) [1-2 pages]

- Brief Introduction
- Problem to be solved and its magnitude
- Gap in knowledge that your technology will fill
- What is the product?
- The technological innovation
- Long term goal
- Rationale for the goal
- Phase I hypothesis
 - Specific Aims (list them)
Specific Aim 1 ...
 - Criteria for acceptance
Specific Aim 2 ...
 - Criteria for acceptance
- Commercial implications

3. Background and Significance (use list below as subheadings) [2-3 Pages]

Description of the problem to be addressed

1. The value of the solution to the problem
2. Current state of the science
3. Current state of the market
4. Other applications of the underlying technology
5. Competition

- i. Competing technologies
- ii. Competitors

6. Summary

4. Preliminary Studies/Progress Report [1-2 pages]

1. Summary of aims of the preliminary studies
2. Results and conclusions of relevant preliminary studies
3. Publications resulting from relevant preliminary studies
4. Summary of all preliminary work

5. Research Design & Methods (use list below as subheadings) [7-8 pages]

1. <Research Aim Restated> (note: repeat this and subsections for each aim)

- i. Rationale
- ii. Experimental Design & Methods
- iii. Data Analysis & Interpretation
- iv. Potential Pitfalls/Alternative Approaches
- v. Expected Outcomes