What is an Entrepreneur?

entrepreneur: A person who organizes and operates a business or businesses, taking on financial risk to do so

• Almost all definitions of entrepreneurship include:
  - Initiative taking
  - Organizing and reorganizing social/economic mechanisms to turn resources/situations into some gain
  - Acceptance of risk and potential failure

• Some attributes of successful entrepreneurs:
  - Driven, motivation based on achievement
  - Strives for personal independence
    • Self image is NOT related to their role in the corporation
  - Job satisfaction arises from a desire to be in control
  - Goal oriented
  - Not afraid to fail, not afraid of risk
What is the Entrepreneurial Process?

Entrepreneurial Process

- Identify and evaluate the business opportunity
  - secure intellectual property (patents)
- Form a corporation
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Evaluating Business Opportunity

Where do you start?

- Idea
  - What are your *capabilities*? Can you make it? Can you sell it?
  - What are your *resources*? Financial, People, Intangible?
  - Product → Does it create OPPORTUNITY?

Is the business a sound idea?

- What is the Opportunity?
  - A need, want, problem or challenge that can be satisfied by implementing your idea
  - Does your idea (product, company):
    - Create something completely new?
    - Create ADDED Value to some product or service?
      - Value: what is it to you? what is it to your customers?
    - Serve a population of people?
  - Obviously, you must believe YES!
Opportunity Assessment

- Carefully screening and evaluating the business opportunity is the most critical part of the entrepreneurial process.

**MARKET RESEARCH**

- How big is the market?
- How long is your window of opportunity?
  - How long until marketability of the product?
  - Once marketed, how long before follow-ons or overtakes?
- Are there other opportunities that might be easier and have a better risk/reward ratio?
- Will someone buy it?
  - Segmentation - WHO?, WHAT?, WHY?

**Business Analysis**

- What is the upside of success? The downside?
- Can you put in the time and effort?
- Will it continue to be successful - what is its sustainability?
  - Is it easily imitated? Can you create barriers for others to enter?
- How is your competitive advantage protected? Intellectual property

These questions should be answered within a business plan

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Intellectual Property

1. **Trade Secrets** - $1,000
   - a formula, practice, process, design, instrument, pattern, etc. which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors or customers

2. **Copyrights** - $50

3. **Trademarks** - $250-$1,000

4. **Patents**
   - a set of exclusive rights to an inventor for a limited period of time in exchange for the public disclosure of an invention
     - right to exclude others from making, using, selling, & importing the invention
   - a patent application must include one or more claims defining the invention which must meet the relevant patentability requirements such as novelty and non-obviousness
     - Design - $1,000-$1,500
     - Utility - $5,000 and up (say $20,000)
     - Provisional - $700-$1,200
     - Litigation - $100K-$4 million
Patents

- Timeline
  - Utility filing due 12 months from Provisional filing
  - National filings (outside USA) due 30 months after first filing
- How to capture the IP
  - Carefully document R&D.
  - Eureka moment (the moment of discovery) - carefully document.
  - Search prior art.
  - Brainstorm broad applications and alternatives.
  - Submit Invention Disclosure.
  - File for protection.
- Documenting invention: laboratory notebooks
  - Evidence for “first to invent.” Dates are critical especially ideas.
  - Reproducible for one skilled in the art and witnessed.
  - Include raw data, failure data (as anti-obviousness record), methods, analysis, and conclusions.
  - Submit Invention Disclosure well ahead of public presentations

Patent Screening Analysis and Criteria

- Commercialization
  - Type of Technology (obsolete to revolutionary)
  - Technology Readiness Level (concept to ready for production)
  - Ease of Adoption by Industry (switching costs)
- Market
  - Range of Applicability (single to many industries)
  - Market Size (niche to very large sales per year)
  - Market Growth/Potential (declining to rapid growth)
  - Market Maturity (passed to emerging)
- IP landscape
  - Potential for or current coverage
  - Breadth of coverage

These issues should be covered within the business plan
Patent Search

- Must know if any related/overlapping patents exist
  - vital to patent application
  - vital to business plan
    - know your competition
    - clearly identify your competitive advantage

- Where to search?
  - U.S. Patent and Trademark Office
    - http://www.uspto.gov/patents/process/search/index.jsp
  - Google Patents
    - https://www.google.com/patents

OUTLINE

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Types of Corporate Status

- **General Partnership.** Two or more individuals as co-owners of a for-profit business, operated under a written Partnership Agreement
  - All partners are responsible for the liabilities and debts of the partnership. For tax purposes, partnerships enjoy single taxation on each partner’s personal income
- **Corporation.** Legal entity created by filing Articles of Incorporation
  - The Corporation itself assumes all liabilities and debts of the Corporation.
  - Owned by shareholders who enjoy protection from the corporation’s debts and liabilities. From a taxation perspective, income is taxed twice: 1) at the corporate level; and 2) at the shareholder level when distributed as a dividend
- **S-Corporation.**
  - Corporation may seek S Corporation status whereby income is taxed only once: at the employee or shareholder level. To qualify, may not have more than 75 shareholders and must meet other certain Internal Revenue Service criteria.
- **Nonprofit Corporation.** A corporation whose purpose is to engage in activities which do not provide financial profit to the benefit of its members.
  - Must obtain nonprofit or tax exempt status from IRS to be free from tax burdens.
- **Limited Liability Company (LLC).**
  - Combines the advantage of a corporation’s limited liability and the flexibility and single taxation of a general partnership. Members enjoy protection from the liabilities and debts of the LLC.
  - Should operate under an Operating Agreement; like a Partnership Agreement.
  - May be taxed only once, like a partnership, at the employee or member level without the same restrictions of an S-Corporation.

How to Form a Corporation

- **Filing with the state is rather easy**
  - One form - $65 filing fee!
  - www.michigan.gov/businessstartup
- **Get a Federal ID after you receive confirmation**
  - Needed to open a bank account

- **Why incorporate?**
  - Protects your personal assets from your business assets/debts
  - Helps to manage the risk of a startup business
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Business Plan

• Why create a business plan?
  - Helps to determine if business has long term viability
  - Shows investors your business is worth investment
  - Proves to YOU that the idea will work

• Your plan needs to answer questions about the following:
  - External Factors
  - Internal Factors
  - Sustainable Competitive Advantage

• A LOT of work – no one pushes you to complete it – easy to put off...
**Business Plan II**

- **What do Great Business Plans Include?**
  - Excerpts from: *How to Write a Great Business Plan* by William A. Sahlman
  - Four independent factors that are most important to the investor
    - The People
    - The Opportunity
    - The Context
    - Risk and Reward
  - The People: Investors are investing in YOU
    - “...without the right team, none of the other parts really matter.”
    - 3 Questions
      - What do they know?
      - Whom do they know?
      - How well are they known?
    - Candidly describe each team member's knowledge of the new venture’s type of product or service
      - prove their value to the company

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**Business Plan III**

- **External environment understanding**
  - Political / Legal
    - antitrust laws, taxation laws, deregulation philosophies, labor training laws, educational philosophies and policies
  - Economy
    - inflation rates, interest rates, growth
  - Socioeconomic
    - women in the workforce, workforce diversity, attitudes about the quality of life, concerns about the environment
  - Demographic changes
    - population size, age structure, income distribution, geographic distribution, ethnic mix
  - Technological changes
    - product innovations, applications of knowledge, new communication technologies, private or government R&D initiatives
  - Globalization
    - newly industrialized countries, important political events
Outline of a Business Plan

I. Introductory Page
   A. Name and address of business
   B. Name(s) & address(es) of principal(s)
   C. Nature of business
   D. Statement of financing needed
   E. Statement of confidentiality of report

II. Executive Summary
   Three to five pages summarizing the complete business plan

III. Industry Analysis
   A. Future outlook and trends
   B. Analysis of competitors
   C. Market segmentation
   D. Industry and market forecasts

IV. Description of Venture
   A. Product(s)
   B. Service(s)
   C. Size of business
   D. Office equipment and personnel
   E. Background of entrepreneur(s)

V. Production Plan
   A. Manufacturing process (amount subcontracted)
   B. Physical plant
   C. Machinery and equipment
   D. Names of suppliers of raw materials

VI. Operational Plan
   A. Description of company's operation
   B. Flow of orders for goods and/or services
   C. Technology utilization

VII. Marketing Plan
   A. Pricing
   B. Distribution
   C. Promotion
   D. Product forecasts
   E. Controls

VIII. Organizational Plan
   A. Form of ownership
   B. Identification of partners or principal shareholders
   C. Authority of principals
   D. Management-team background
   E. Roles and responsibilities of members of organization

IX. Assessment of Risk
   A. Evaluate weakness(es) of business
   B. New technologies
   C. Contingency plans

X. Financial Plan
   A. Assumptions
   B. Pro forma income statement
   C. Cash flow projections
   D. Pro forma balance sheet
   E. Break-even analysis
   F. Sources and applications of funds

XI. Appendix (contains backup material)
   A. Letters of support/agreement
   B. Market research data
   C. Leases or contracts
   D. Price lists from suppliers
The 10 Most Important Questions a Business Plan Should Answer

1. Is the business just an idea, or is it an opportunity with real potential?
2. Does the firm have an exciting and sensible business model? Will other firms be able to easily copy it?
3. Is the product or service viable? Does it add significant value to the customer? Was a feasibility analysis completed?
4. Is the industry in which the product or service will be competing growing, stable, or declining?
5. Does the firm have a well-defined target market?
6. Is the management team experienced, skilled, and up to the task of launching the new firm?
7. Is the firm organized in an appropriate manner? Are its strategy and business practices legal and ethical?
8. Are the financial projections realistic, and do they project a bright future for the firm? What rate of return can investors expect?
9. How will the firm's competitors react to its entrance into their markets?
10. What are the critical risks surrounding the business, and does the management team have contingency plan if risks become actual problems?

Investor's Interests

- Executive Summary of Business Plan
  - prepare LAST after all other sections completed
- Financials
- Balance Sheet
- Sources and Uses
- Expected rewards – Return on Investment
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Sources of Start-up Financing
- Friends and Family
  - "Dumb money": not too many questions
  - Investment based on faith in YOU
- Angel Investors: affluent individual who provides capital in exchange for convertible debt or ownership equity
  - Usually around $80k investments
  - More savvy - Accredited Investors
- Venture Capital Money
  - provided capital to early-stage, high-potential, high risk, growth startup companies in return for significant control over company decisions, in addition to a significant portion of the company's ownership
- Bank Financing
  - Requires information about: Character, Capacity to Pay, Capital Required, Collateral, Conditions (economic, segment)
  - Will evaluate if the entrepreneur expects to be carried by the loan for an extended period of time
**OUTLINE**

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Business management will not be covered in ECE445
But we’ll end with a few other relevant things…

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**15 Critical Business Success Factors**

1. Unique benefits and superior value to the customer.
2. Market-driven/customer focus (not technology in search of a problem).
3. International orientation.
4. Good homework.
5. Precise product definition early.
6. Well managed launch with strong marketing plan.
7. Right organizational structure.
8. Top management support.
9. Tough and quick go/no go decisions.
10. Quality of execution.
11. Resources in place.
12. Timely execution.
14. Leverages core competencies.
15. Attractive market.

Commercialization of Biomedical Devices

- A lot of research investment does not have a clear application to medical devices (does not address an “unmet clinical need”) and never becomes part of a functional system

<table>
<thead>
<tr>
<th>MEDICAL DEVICES</th>
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<tbody>
<tr>
<td>Technologies &amp; Methodologies</td>
</tr>
<tr>
<td>- Biosignal processing</td>
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<tr>
<td>- Biomedical imaging: Molecular, X-rays, CT, MRI, PET, ultrasound and optical imaging</td>
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<tr>
<td>- Medical instrumentation &amp; sensors</td>
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<tr>
<td>- Medical and nanotechnology</td>
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<tr>
<td>- Medical engineering</td>
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<td>- Rehabilitation engineering</td>
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<td>- Birobotics</td>
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<tr>
<td>- Biosystems modeling</td>
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<td>- Computational bioengineering and bioinformatics</td>
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<td>- Biomechanical engineering</td>
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<tr>
<td>- Molecular engineering</td>
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<tr>
<td>- Diagnostic systems</td>
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<td>- Conventional systems</td>
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<tr>
<td>- Point-of-care diagnostics</td>
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<td>- Imaging and other tests</td>
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<td>- Therapeutic systems</td>
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<td>- Neuromuscular devices</td>
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<td>- Cardiovascular devices</td>
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<td>- Cancer treatment</td>
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<td>- Drug delivery</td>
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<tr>
<td>- Artificial tissues &amp; organs: Silicon retina, cochlear, tactile sensors</td>
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<tr>
<td>- Healthcare and bioinformation systems</td>
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<tr>
<td>- MIS</td>
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<tr>
<td>- E-medicine &amp; telemedicine</td>
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<tr>
<td>- EHRs</td>
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<tr>
<td>- Genomics, proteomics, and physiology</td>
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<tr>
<td>- Tools in drug discoveries</td>
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Research | Medically Useful Devices


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Commercialization of Biomedical Devices

- Biomedical commercialization must overcome the investment “valley of death”

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<thead>
<tr>
<th>INNOVATION &amp; TECHNOLOGY COMMERCIALIZATION STAGES</th>
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<tbody>
<tr>
<td>(expensive) clinical trials reliability studies etc.</td>
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<tr>
<td>Basic research discovery</td>
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<tr>
<td>Valley of death</td>
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<tr>
<td>Feasibility study prototype</td>
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<tr>
<td>Product development</td>
</tr>
<tr>
<td>FDA, CMS</td>
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<tr>
<td>Clinical use</td>
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Investment ($)