

# TENTATIVE SCHEDULE

Date	Topic
Week 1 Jan 23	Class Organization, Introduction
Week 2 Jan 30	History of Medicine & Devices
Week 3 Feb 6	Entrepreneurship & Conceptualizing a Medical Device
Week 4 Feb 13	Intellectual property and Patents
Week 5 Feb 20	FDA Regulatory Strategy for Biomedical Devices
Week 6 Feb 27	Regulatory Strategy II
Week 7 March 5	Clinical Trial Strategy & GCPs for Medical Device
Week 7 March 12	Midterm
Week 8 19	Tom Goff - Case Studies of Medical Device I
Week 9 26	Spring break
Week 10 April 2	John Hendrick – Case Studies of Med Device Dev II
Week 11 April 9	Tom Afzal – CTs & Strategies
Week 12 April 16	Turnitin submission- Design Validation & Failure Mode Analysis
Week 13 April 23	Term Paper Slides Submission-Field Trip to Medical Device Co
Week 14 April 30	Term Project Poster Presentation
Week 15 May 7	QSRs + Applications of Nanotechnology in Medical Devices
Week 16 ?	? Final Examination

# PRESENTATIONS

All students are required to turn in

- 10-15 slide power point by April 23 and then do a
- Poster presentation of your term paper on April 30<sup>th</sup>

# TERM PAPER

- It should include the following:
  - (a) A general description
  - (b) The related physiology
  - (c) The market it serves and the potential size of the market
  - (d) The regulatory aspects related to the device
  - (e) The clinical trials required for the device
  - (f) How the device is manufactured.

Students interested in writing their term paper on a case history of a medical device failure are required to discuss this with the course instructor first.

# TERM PAPER

- **The term paper carries 25% of the total credit for this class.**
- Out of this 25%, 2% will be assigned for submission of the Abstract and Table of Contents
- Another 3% will be assigned for completing and turning in the literature search on time.
- Items turned in late will not receive the credit assigned to them. However, in order for the subsequent item to be graded and credited, the preceding item must be turned in.

The deadline for turning in the final term paper is the twelfth week of classes i.e., April 16

# TERM PAPER

- TWO copies of the term paper, with evaluation sheet, must be turned in.
- ONE copy of the term paper, with the evaluation sheet will be returned to the student, and the other will be retained by the instructor.
- ONE e-copy of the term paper, in MS Word format, must be turned in.
- **Students will also be required to submit the paper to turnitin.com**  
**Class Name: Engr274 Password: Devicef1 Class ID: 2239574**
- Term papers must be original work. Reports written for other classes, including reports written by other individuals, cannot be resubmitted, with or without revisions.
- Students are encouraged to select topics of interest to them; however, these must be approved by the instructor. Students who are currently working in industry may select a topic that is of relevance to their work environment.

# TERM PAPER EVALUATION

<b>1. Significance of Problem</b>		
1.1 Related Physiology/Problem Addressed	10	
1.2 Potential Market		5
<b>2. Technical Content</b>		
2.1 Device Description		10
2.2 Clinical Trials		10
2.3 Regulatory Aspects		5
2.4 Manufacturing Method		5
<b>3. Figures, Tables</b>		5
<b>4. Referencing and References</b>		10
<b>5. Conclusions</b>		
5.1 Assessment		5
5.2 Future Direction		5
<b>6. Grammar</b>		10
<b>7. Typewritten</b>		5
<b>8. Overall Impression (subjective)</b>		15
		<hr/>
		100

# HOME ASSIGNMENTS

Submit by April 5th (Saturday)

1. Do market research and list the competition for the medical device that you have chosen for your term paper. Write a flow chart on how will your device will get reimbursed.

Submit by April 9th (Wednesday)

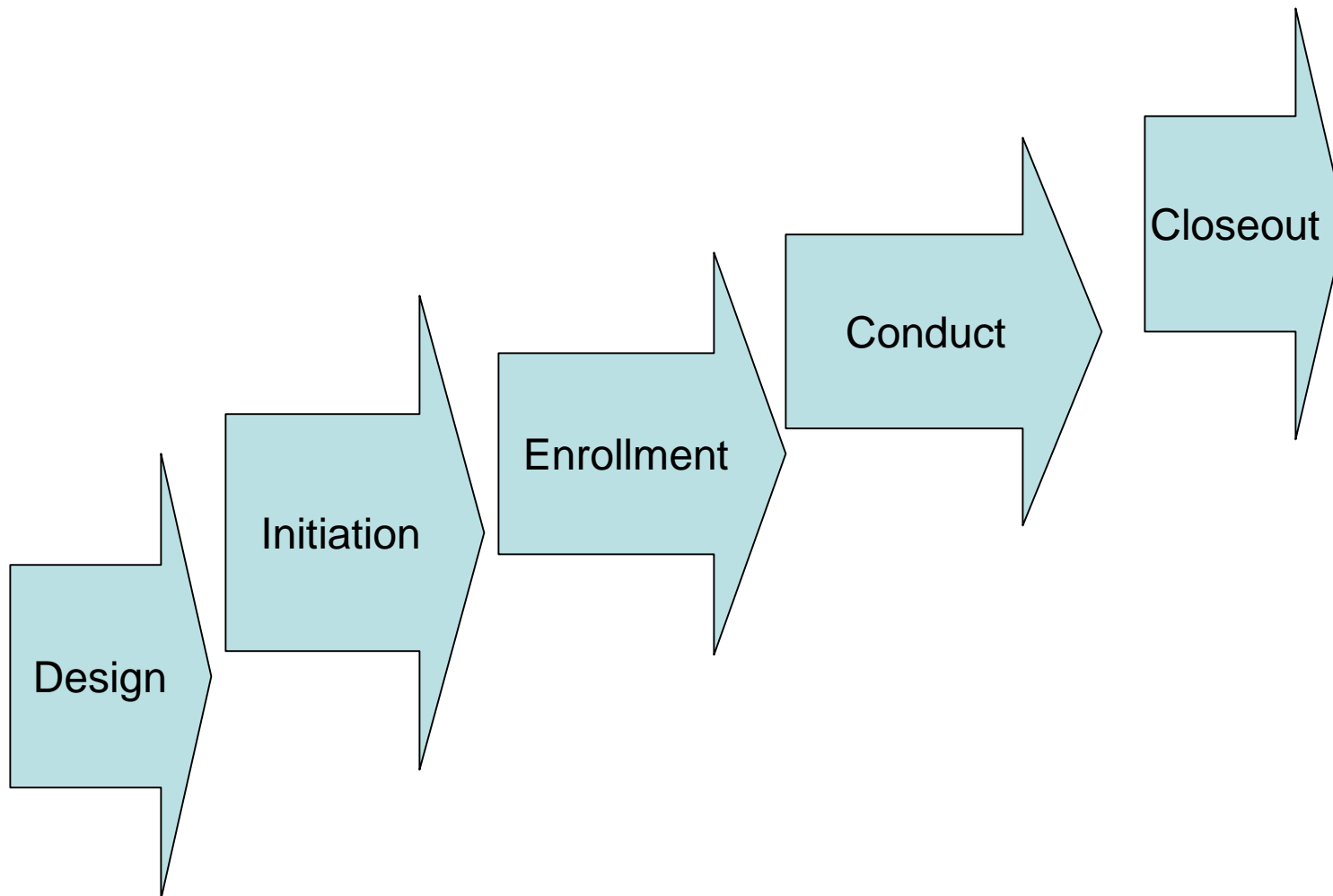
2. John Hendrick's talk

List all Medical Devices for the replacement/assistive /repair of the

- a. Spinal Vertebra
- b. Intervertebral Disc -

and write a couple of sentences on each one of them

# The Clinical Trial Process Flow



# Study Design

- Research Plan – Study Protocol
- IRB review of Protocol
- IRB written notification of approval/disapproval/modification
- \*IRB members must be qualified, must have written procedures, meeting minutes must be documented

# Study Initiation

- Sponsors responsible for selecting qualified investigators
- IDE must contain statement of investigators qualifications (CV)
- IDE must have formal approval by FDA /IRB
- Sponsor must provide IB (Investigators' Brochure) to Investigator
- Investigator provides sponsor with financial info to allow sponsor to be able to certify or disclose financial interests
- Sponsor can transfer responsibility for obligations in writing to CRO

# Subject Enrollment

- Informed consent to be documented, signed by subject
- Subject written consent for direct access to medical records
- List of qualified staff at site delegated responsibility by Investigator
- IRB might require Investigator to give subjects a written statement about the research/trial and some other additional information
- Documentation of Parental Consent for

# Study Conduct

may be subdivided into following subphases

- Device/Drug Accountability
- Data Collection
- Study Monitoring
- Adverse Event Reporting

# Study Conduct

- Package label for IDE/IND
- Written procedures for handling/storing device/drug
- Sponsor records of receipt, shipment or other distribution of device/drug (including Investigator name, date, quantity and batch identifier for each shipment)
- Investigator records of disposition of device/drug (including dates, quantity and use by subjects)

# Study Conduct

- Sponsor use of qualified staff for protocol and CRF (Clinical Report Forms) creation and analysis
- Investigator prepares and maintains adequate and accurate case histories that record all observations and other data pertinent to the investigation
- Case histories including signed and dated consent forms, any medical records, and nurses' notes shall document that informed consent was obtained PRIOR to participation in the study
- Document that data processing systems are validated
- Investigator Progress Reports
- IRB statement of reasons for terminating research, and prompt reporting to investigator, institution, and FDA
- Sponsor list of who is allowed to change/modify data

# Study Conduct

## Study Monitoring

Sponsor SOPs for QA/QC, use of electronic data handling systems, monitoring

Sponsors must ensure proper monitoring of Clinical Investigations conducted under the IDE – a Monitoring Report reqd by ICH

Sponsor shall select qualified monitors

If investigator is found to be noncompliant, sponsor should promptly secure compliance or discontinue shipments of device/drug and notify FDA

IND/IDE includes a list identifying each clinical

# Study Conduct

- Investigator safety reports to sponsor
- Investigator follow-up reports
- Sponsor review of reports of information related to safety of drug/device
- Written IDE/IND reports: 15-day serious and unexpected; 7-day unexpected fatal or life threatening
- Sponsor review of evidence from Investigator of drug's safety and effectiveness
- Sponsor reports AEs to FDA
- Sponsors must ensure prompt info to FDA and all participating investigators on significant new AEs or related risks to the device/drug

# Study Closeout

- Investigator final study report to sponsor
- Sponsor final study report
- Sponsor may authorize alternative disposition of supplies of IDE device/IND drug
- Sponsor must maintain written records of any disposition of IDE device/IND drug