Polymeric Biomaterials

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Office hours: by appointment only or immediately following class

Course Objective
This course will provide an overview of the interactions between polymeric materials and cells, in vitro and in vivo. It will cover topics from molecular designs of polymeric biomaterials, modern synthetic and bioconjugation techniques, materials surface engineering, interfacial characterization, processing of polymeric scaffolds, materials for drug and gene delivery, combination products, to manipulation of cellular behavior through incorporation of bioactive components. Specific examples of biomaterials for cell/tissue engineering, and drug/gene delivery from the recent literature will be discussed.

Format
Lecture w/ discussion of topics from the recent primary literature.

Text Book and References
None required: will include examples and references from the recent literature.

Grading
Grades will be assigned for this course and will include: 2 exams, 1 research proposal, a journal presentation and active participation. Attendance is required. No make-up exam will be given.

LATE AND INCOMPLETE WORK WILL NOT BE ACCEPTED.

1) Exams – 40%
2) Proposal – 30%
Each student will prepare an NIH R21-style funding proposal on a topic of their choice. These are hypothesis driven and may be related to your thesis research if so desired. Only the introduction, proposal and references are required. Documents not in the correct format will not be accepted. A style guide is attached as an appendix to this syllabus. References should be in designated format. Appropriate bibliography software (e.g. Endnote) is strongly recommended to do this efficiently. It may be related to your thesis work if appropriate.

4) Research Presentation – 10%
5) Participation – 20%

Other Requirements
Reading assignments (e.g. journal articles) may be given in advance of class
Topics to be Covered – Not Exhaustive

Biomaterials – the basics
FDA process and role in materials innovation
Ring opening polymerization
Step growth polymerization
Amino acid based polymers
Artificial protein synthesis
Degradation mechanisms
Peptide and DNA chemistry
Functionalization chemistries
Click reactions & bioconjugates
Surface vs bulk characterization
Surface energetics & characterization
Characterization and molecular design strategies

Examples of bone, nerve and cartilage tissue engineering
Evolving needs

Ethics and policy information

Students are expected to comply with and follow the policies and regulations as specified in the Student Code of Conduct (http://www.uakron.edu/ogc/UniversityRules/pdf/41-01.pdf). Copies are available through the Office of Student Conduct, Gardner Student Center 104, (330) 972 – 7021. It is the student’s responsibility to know and understand these policies as stipulated through the Student Code of Conduct at The University of Akron.

Academic dishonesty will not be tolerated under any circumstances. It is the responsibility of the student to know what constitutes academic dishonesty. One should ask for clarification from the instructor if it is unclear if an action would constitute academic dishonesty. There are many potential actions that fall under academic dishonesty as listed below (non-inclusive list)

- Submission of work that is not your own, including, but not limited to plagiarism
- Use of technology (cell phones, tablets, computers) not authorized by the instructor during an exam
- Possession of solution manuals
- Assisting another student’s work when not part of standard group activity

A student accused of academic dishonesty will first meet with the course instructor. This matter can be resolved at the College level; these actions can include imposition of an academic sanction. A student can appeal this decision to the College Dean. Conversely, the matter can be referred to the Office of Student Conduct, whereby the office can take formal action against the student, including suspension or dismissal from The University of Akron. Procedures associated with academic dishonesty are detailed in the Student Code of Conduct.

Course enrollment and withdrawal policies are administered by the Office of the Registrar. Students with questions should contact the office at (330)-972-5400. The current registration and withdrawal policy can be found at http://www.uakron.edu/ssc/withdrawal-policy.dot

Class attendance policy: Students are encouraged to attend all classes and events associated with the class. However, the College of Polymer Science and Polymer Engineering believe that graduate students in the college are mature adults that are capable of making their own
decisions and do not need to be further penalized for not attending classes unless specified in advance by the instructor.

The timeline provided with the syllabus is tentative and might be changed depending upon class feedback and if difficulties with critical topics are encountered. It is the responsibility of the student to adhere to all deadlines associated with sessions, assignments or other tasks associated with the class.

Ethics: Students are expected to behave in an ethical manner at all times. Respective discourse is encouraged to facilitate learning. Disrespectful behavior towards your peers, including teasing for asking questions, will not be tolerated. The consequences associated with non-ethical behavior will be severe and may include, but not limited to, referral to the Office of Student Conduct and dismissal from the college.

**Americans with Disabilities Act (ADA) Policy Statement**
The Americans with Disabilities Act (ADA) is a federal non-discrimination statute that provides comprehensive civil rights protection for persons with disabilities. Among other things, this law requires that all students with disabilities be guaranteed a learning environment that provides for reasonable accommodation of their disabilities. Any student with a disability that limits learning will be accommodated following the recommendations of the Office of Accessibility. Students should contact the office at (330) 972 – 7928 (voice) or (330) 972 -5764 (TDD), or via the web at [http://www3.uakron.edu/access/](http://www3.uakron.edu/access/)

**Important Dates**
- January 23: No Class
- February 13: Exam 1
- March 18: No Class – ACS Meeting
- March 25 & 27: No Class – Spring Break
- April 22, 24 & 29: Research presentations
- May 1: Research presentations cont
This document contains information from the NIH document “Details of Application Changes for Research Grants and Cooperative Agreements (for due dates on or after January 25, 2010)” as well as general formatting guidelines. Principal investigators should refer to the SF 424, PHS 398 and funding notices (e.g., requests for applications, requests for proposals, funding opportunity announcements) and other official NIH documents when preparing their applications. 

Important Information to Know When Using this Document

For Current and Specific information for R01s and other Unsolicited or Investigator-Initiated Applications, see


Table of New Page Limits

All applications for NIH funding must be self-contained within specified page limits. Observe the page number limits provided in the table below, unless the Funding Opportunity Announcement (FOA) specifies otherwise. Page limits for activity codes not listed below should follow the page limits specified in the FOA.

<table>
<thead>
<tr>
<th>SECTION OF APPLICATION</th>
<th>PAGE LIMITS *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Also refer to the relevant section of the application instructions and the FOA.</td>
<td></td>
</tr>
<tr>
<td>Specific Aims</td>
<td>1 page</td>
</tr>
<tr>
<td>Research Strategy (Item 5.5.3 of Research Plan)</td>
<td>6 pages</td>
</tr>
<tr>
<td>For Activity Codes R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3</td>
<td></td>
</tr>
<tr>
<td>References</td>
<td></td>
</tr>
<tr>
<td>No page limits, but content limitations. See relevant section of instructions and FOA</td>
<td></td>
</tr>
</tbody>
</table>

- FOA instructions always supersede these instructions.
Formatting and Scoring Guidelines
Writing the Application
General Formatting Guidelines
(SF424 R&R)

Font
Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.

Paper Size and Page Margins
Use standard paper size (8 ½” x 11).

Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI’s name and page numbers.

Page Formatting
Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

URLs
Unless otherwise specified in the FOA, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites.

Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes
You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

Grantsmanship
Use English and avoid jargon. This is graduate school. Proper grammar and spelling is expected. Please have someone else proofread this.

If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.
R21 Review Criteria

**Overall Impact:** Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria (as applicable for the project proposed). (Scored 1 [Exceptional]-9 [Poor])

**Significance**
Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Investigator(s)**
Are the Project Directors/Principal Investigators, collaborators, and other researchers well suited to the project? If the investigators are “Early Stage Investigators” or “New Investigators,” do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-Project Directors/Principal Investigators, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

**Innovation**
Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach**
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

**Environment**
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
**R21 Template**

**How to Use the Template:** Fill in the blank areas beneath each question, criterion and suggestion and delete the template text, leaving the bold-faced headings. This template is to serve as a *guideline only* and should be modified as needed based on the specific research project and NIH funding notice (e.g., funding opportunity announcement, request for application or request for proposal). Though this template reflects the general formatting guidelines on page 6, please ensure that you have correctly formatted your own application before submitting it.

*The template is formatted in 11-point Arial font*

*Template Begins on Next Page*
Specific Aims (1-Page Limit)

NIH Instructions: State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Specific Aims

- What is your project about? State your goal/objective/outcome.

- Why is it important? State the significance and overall impact.
  - Medical significance
  - Long-term goal/objective of the project

- What is known? Provide background related to your research question.
  - This could include data from your lab as part of this background

- What is unknown? What do you hope to accomplish?

- Why is the gap in this knowledge a problem and how do you propose to address it?
  - Rationale of this study – why are you doing THIS project
  - What have you accomplished to date that suggests this approach? (Preliminary Data)

- What is your hypothesis (hypotheses)?
  - Objective of this application

- Explain how you will address your hypothesis (hypotheses) using your Specific Aims. (Suggested transition sentence to this section: “We proposed to address this (these) hypothesis (hypotheses) using the following specific aims:”). You may also list a hypothesis for each aim here.
  - Address “why” questions rather than “what”: no “demonstrate” or “describe” words should lead the aims, which should be very succinct and include expected outcomes
  - If you can briefly include an indication of the expected outcome/significance here, do so
  - KEEP THE AIMS SHORT – a full paragraph/aim is too much

- Summary paragraph: what you propose to do,
  - Why it is relevant/SIGNIFICANT to medical science and the field
  - Why your research team is the best team for the project
  - INNOVATION
  - Other salient features (e.g., multidisciplinary investigative team, outstanding clinical and/or laboratory environments)
Research Strategy (6-Page Limit)
Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section headings: (a) Significance, (b) Innovation, (c) Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References cited section of the application.

***Begin Research Strategy Template Below***

(a) Significance

Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).

Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach (Include Preliminary Studies in this section)

Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Tip: make it clear what tasks are related to each specific aim. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.

Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in Sections 19 and 21.

***End Research Strategy Template***