# SYLLABUS

CLRE-258 – Project Management and Clinical Research Administration emphasizing Budgeting, 2 Units

**Spring 2024**

**Course Instructors**

Jennifer J. Ford, MBA: Email: [jjford@ucsd.edu](mailto:jjford@ucsd.edu), Phone: 858-534-3335

Andrew J. Sarkin, Ph.D.: Email: [asarkin@ucsd.edu](mailto:asarkin@ucsd.edu), Phone: 858-622-1771 ext. 7001

**Teaching Assistant**

Chelsea Spohn, MSc: Email: [cspohn@health.ucsd.edu](mailto:cspohn@health.ucsd.edu), Phone: 619-626-6968

Canvas will also include TA contact information under Course Introduction & Information 🡪 Course Assistant.

Office Hours: As needed, contact Chelsea via Canvas and/or email to schedule.

**Quarter and Class Time**

Spring 2024: Monday from 4:00 PM to 7:00 PM, Monday, April 22 – Monday, June 10th

Week 7: Final class on June 10th will be held from 4:00 PM to 6:00 PM (2 hours).

**Location:** UC San Diego Extension University City Center Suite 150, Room 308

The following sessions will be held IN-PERSON: Week 1 (4/22), Week 2 (4/29), Week 3 (5/6), Week 5 (5/20).

The following sessions will be held over zoom: Week 4 (5/13) and Week 6 (6/3), with the option for in-person or Zoom session for the final class, Week 7 on June 10.

Remote sessions will have a zoom link posted on canvas under Modules.

**Course Description**

Explores the broad scope of the multi-faceted profession of project management for medical research projects, including research administration from budgeting for NIH federal grants to clinical trials. Students will gain a basic understanding of budgeting and planning for sponsored clinical research.

In the Clinical Research Administration portion, the student will gain an understanding of basic pre-award and post-award management of clinical/medical research projects. The first half of this course will concentrate of research administration areas, such as study set-up and management, effective study budget preparation and negotiation, billing and financial management, auditing, and research compliance and other ethical considerations.

Research Project Management is the application of knowledge, skills, and techniques to execute research projects effectively and efficiently. It is a strategic competency for organizations, enabling them to tie project results to research and development goals — and thus, better compete in their markets or increase their ability to get and maintain research funding. Topics include planning and managing resources, monitoring progress, managing risk, tools for project management, setting and meeting goals, quality monitoring, multi-site studies, and maximizing the chances of successfully carrying out clinical and health research studies.

**Course Organization**

This course will be in lecture format with exercises, case studies, and discussion. Online discussion board postings on materials provided and responding to classmate postings is required.

**Course Goals**

Students, as potential Principal Investigators (PI) administering active and varied sponsored research portfolio, will obtain basic understanding to manage the pre-award and post-award, management including study set-up and management, effective study budget preparation and negotiation, billing and financial management, auditing, and research compliance and other ethical considerations. Students will also learn basic knowledge and skills in research project management.

**Course Objectives**

Participants will obtain an understanding of:

* Clinical research budget administration and project management.
* Life cycle of sponsored clinical research.
* Critical elements for various clinical research budgets, including common budget pitfalls.
* Coverage Analysis under the Medicare billing rules, and other regulations such as the Sunshine Act and Conflict of Interest.
* Responsible fiscal management after award acceptance or study activation, including payment scheduling and invoicing.
* Research project management that will serve as a foundation from which to apply specific techniques in various research settings.
* The role and responsibilities of a project manager and the importance of project management.
* The distinction between implementation failure and theory failure, and how to minimize the chances of implementation failure.
* Managing people, time, money, and other important resources, and creating a Gantt chart.
* How to manage and reduce risk (adverse events, loss of staff, loss of sites, missed deadlines, etc.).
* Setting SMARTER goals and track progress with milestones and other tools.
* General project management techniques that increase productivity and quality.
* Understand informatics tools designed to enhance project management.

**Course Materials/Resources**

Resources will be provided on Canvas.

# Course Schedule and Component

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| **Date** | **Topic** | **Learning Objectives** | **Class Participation** | **In-Class Exercise** | **Homework** |
| Week 1:  April 22  Instructor: Jennifer  In-Person Class | Clinical Research Overview  Federal agencies and Non-Profit Budget  Preparation and Negotiations | Building knowledge of sponsored research and the life cycle of sponsored clinical research.  Building knowledge of critical elements and requirements for various federal and non- profit clinical research budgets, including common budget pitfalls. | **X** | **X** | Week 1 Assignment, and  two Chat Room postings  due April 29  Preparation: Pre-read  articles and view Pre-  recorded lecture assigned  for this session |
| Week 2:  April 29  Instructor: Jennifer  In-Person Class | Clinical Trial Budget Preparation and Negotiations | Building knowledge of critical elements and requirements for various federal and non- profit clinical research budgets, including contract language. | **X** | **X** | Week 2 Assignment, and two  Chat Room postings due May 6  Preparation: Pre-read articles  assigned for this session |
| Week 3:  May 6  Instructor: Jennifer  In-Person Class | Regulatory Requirements: Clinical Trial Billing and Coverage Analysis and other Sunshine Act, Conflict of Interest  Fiscal Management after Study Activation | Building knowledge of various regulatory requirements, such as, the Medicare billing rules to design coverage analysis.  Continuing to build knowledge of other regulatory requirements, such as, the Sunshine Act and Conflict of Interest. Building knowledge of post award fiscal management after study activation or award acceptance. | **X** | **X** | Week 3 written Midterm  Project and two Chat Room  postings due May 13  Preparation: Pre-read articles  assigned for this session |
| Week 4:  May 13  Instructor: Andy  Remote Class – Zoom Link on Canvas | Overview of Clinical Research Project Management. Setting SMART Goals and Planning, Tools for  Making Decisions and Implementing Action | Understand the role and responsibilities of a project manager and the importance of project management.  Know how to set SMARTER goals and track progress with milestones and other tools. | **X** | **X** | Week 4 Assignment and two  Chat Room postings due May 20  Preparation: Pre-read articles  assigned for this session  Babler Chapters 1 and 10  Thomas & Hodges Chapter 8 |
| Week 5:  May 20  Instructor: Andy  In-Person Class | Managing Staff and Colleagues, Meetings and Trainings, Communication, Delegation, Working Effectively with Other Organizations | Know how to manage time, money, and other important resources, and create a Gantt chart.  Improve communication with staff, colleagues, and other organizations. | **X** | **X** | Week 5 Assignment and two  Chat Room postings due  June 3  Preparation: Pre-read articles  assigned for this session  Babler Chapters 5  Thomas & Hodges Chapter 10 |
| Week 6:  June 3  Instructor: Andy  Remote Class – Zoom Link on Canvas | Project Management Structures, Outsourcing, Risk Management, Audits and Auditing, Software Tools for Management | Know about informatics tools designed to enhance project management.  Understand how to manage risk (adverse events, loss of staff, loss of sites, missed deadlines, etc.). | **X** | **X** | Week 6 Assignment and two  Chat Room postings due  June 10  Preparation: Pre-read articles  assigned for this session  Babler Chapter 13  Thomas & Hodges Chapter 9 |
| Week 7:  June 10  Instructors:  Jennifer and Andy  In-Person or Remote Class with both available – Zoom Link on Canvas | Summary Overview and Final Examination (2 hours) | Summary Overview and complete Online examination | **X** |  | Complete Non-Cumulative  Final Exam  Complete Course Evaluation |

**Course Evaluation:Class Participation, Canvas Chat Room Postings, Assignments, and Mid-Term Exam and non-cumulative Final Exam**

Your grade for the class will be determined by your grades on the assignments, the final, class attendance/participation, chat room discussion postings, and submission evaluations. In-class and chat room participation are required.

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| **Types of Course Grade** | **Breakdown of points** | **Totals** |
| Class Participation | Ask questions in class meetings and/or participate in in-class assignments. | 20 |
| Chat Room Discussion | 1 point per posting.  Every week assigned (six times) with two postings each (for a total of twelve postings) | 12 |
| Graded In-Class Activity | 3 points per activity | 18 |
| Assignments | 3 points per assignment (except week 3) | 15 |
| Take-Home Midterm Project | 19 points  Note: there is no week 3 Assignment | 19 |
| Final Exam | 16 points for in-class examination  (written exercises) | 16 |
| Total Points Possible |  | 100 |

Final Course Grades [(http://blink.ucsd.edu/instructors/academic-info/grades/system.html)](http://blink.ucsd.edu/instructors/academic-info/grades/system.html))

98 - 100% = A+

94 - 97% = A

90 - 93% = A-

88 - 89% = B+

84 - 87% = B

81 - 83% = B-

78 - 80% = C+

**Accommodations**

If you have a disability that may impact your academic performance, you may request accommodations by submitting documentation to: [*https://students.ucsd.edu/well-being/disability-services/*](https://students.ucsd.edu/well-being/disability-services/)

**Course Policy and Expectations (Online rules of conduct)**

* We will be communicating with you regarding grades and assignments through Canvas.
* If you need to get in touch with us, the best method is through the Canvas inbox. Generally, we will reply to emails within 24 hours and will provide feedback on assignments within 48 hours.
* If you are having trouble with this course or its material, you should contact us the Canvas inbox to discuss the issues.
* Announcements will be posted to this course whenever necessary, so please be sure that the email you check regularly is set in Canvas. While you may choose to deactivate/adjust Canvas-related notification preferences, **you are still responsible for staying up to date on any changes that are communicated via syllabus updates, announcements, and/or email.** If you primarily use another email account, you should make sure that your Canvas user profile is linked to that address. It is your responsibility to ensure that your email accounts are accessible to you.
* Authorization for Accommodation. If you know that you will not be in class, please send TA, an email or message via Canvas. Please let TA know as soon as possible if you are requesting academic accommodation. If approved, the TA will schedule a time with you for a make-up.
* Authorized absences. Students should notify TA by email of any planned absences for religious observance or approved university events. The University Policy File includes the following statement on absence for religious observances: “By the end of the second week of classes, students should notify the instructors of affected courses of planned absences for religious observances.”
* Late work is usually not accepted; please contact the course instructors via the Canvas Inbox promptly if there are concerns.
* During instruction, minimize the distractions such as cell phones.
* Academic Integrity (Plagiarism): <https://academicintegrity.ucsd.edu/>
* See your grades on TritonLink <https://students.ucsd.edu/> (if in MAS program) or on My Extension: <https://myextension.ucsd.edu/> (in non- MAS program)

**Student Evaluation of Course and Faculty**

Course and faculty evaluations provide important feedback to instructors to improve course content and teaching methodology. Teaching evaluations are also an important factor in faculty advancement, merit, and promotion. This is also part of developing professional conduct and behavior. We will send you an online evaluation at the end of the quarter. We appreciate your feedback helping us to improve the course delivery.