

Common Types of Research Projects

1. Retrospective Chart Reviews (aka Retrospective Cohort Studies) – Observational Research

Analysis of data that are normally collected from clinic patients, such as patient data collected at the 1st and 5th visit in the OCOM clinics (i.e. demographics, chief complaint, other health problems, pain, physical functioning, mental and physical health); or regularly collected questionnaire data from students, alumni, patients, or analyses of electronic health records.

- May require entering information from paper forms into a computer database. If such data are already in a database, then this is referred to as “an analysis of existing data.”
- Requires [Institutional Review Board](#) oversight to ensure that patient confidentiality is maintained.
- Requires a written research proposal summarizing the background literature and rationale for this study, and the methods of collecting and analyzing that data. See below (Item 5) for basic requirements and format.
- [OCOM’s IRBQ form](#) must be completed as well as the Research Proposal and all supporting documents.
- All IRBQs and supporting documents are first reviewed by the [College Research Committee \(CRC\)](#) which meets monthly. The time for review and approval of exempt student can range from at least one month to several months (depending on the quality of the IRBQ application) and may require several revisions based on CRC and IRB requirements.
- If no patient identifying information (such as names, phone numbers, addresses, medical record numbers, birthdates) is captured along with the data, the study may be certified by the IRB as “Exempt” from oversight.
- If the CRC determines the potentially Exempt IRB application is complete, it will be forwarded to the Chair of the IRB for review and approval. If the application is not complete, the CRC will recommend needed revisions.
- OCOM’s IRB Chair takes less than one month to review and approve exempt studies.
- If the study is Non Exempt, meaning that patient identifying information *will* be used, the application form requires detailed explanation of processes to ensure confidentiality.
- The full IRB must review all Non-Exempt research. This process takes at least a month and may take considerably longer to review and to revise the IRB application as required by the CRC and IRB.
- After IRB approval is obtained, the research can begin.
- See the research department [website](#) for required forms and examples of approved IRBQ forms for Retrospective Cohort Studies (Exempt).
- For Non-Exempt studies in which personal identifiers are to be maintained, see examples on the [website](#) for Prospective Survey/Data Collection (Non-Exempt) to see how patient confidentiality will be maintained.

2. Surveys of Practitioners and/or Patients – Observational Research

Can be a cross-sectional one-time-only survey or a survey completed at various time points.

- Requires IRB oversight to ensure that respondent’s confidentiality is maintained and that risks are minimized.
- [OCOM’s IRBQ form](#) must be completed along with a copy of the survey and all recruitment materials.

- If no identifying information (such as names, phone numbers, addresses, medical record numbers, birthdates) is captured along with the data, the study may be certified by the IRB as “Exempt” from oversight.
- All IRBQs and supporting documents are first reviewed by the [CRC \(College Research Committee\)](#).
- If the CRC determines the IRB application is complete, it will be forwarded to the Chair of the IRB for review and approval.
- If not Exempt, requires full IRB review and approval.
- The time for review and approval of Non-Exempt studies can range from at least one month to several months, and may require several revisions based on CRC and IRB requirements.
- After IRB approval is obtained, the research can begin.
- See the Research Department [website](#) for all required forms and examples of approved IRBQ forms for Surveys (Exempt) and Prospective Survey/Data Collection (Non-Exempt).

3. Prospective Data Collection – Observational Research

Patients (or students if the results will be disseminated through publications or presentations at conferences) will be asked to complete questionnaires at one or more times during the course of their treatment (or education).

- Requires IRB oversight to ensure that confidentiality is maintained.
- OCOM’s IRBQ form must be completed along with all required supporting documents.
- If no identifying information (such as names, phone numbers, addresses, medical record numbers, birthdates) is captured along with the data, may be certified by the IRB as “Exempt” from oversight.
- All IRBQs and supporting documents are first reviewed by the College Research Committee.
- If the CRC determines the IRB application is complete, it will be forwarded to the Chair of the IRB for review and approval.
- If not Exempt, requires OCOM’s IRBQ along with detailed explanation of processes to ensure confidentiality.
- The time for review and approval of non-exempt studies can range from at least one month to several months, and may require several revisions based on CRC and IRB requirements.
- After IRB approval is obtained, the research can begin.
- See the Research Department [website](#) for all required forms and examples of approved IRBQ forms for Surveys (exempt) and Prospective Survey/Data Collection (non-exempt)

4. Clinical or Interventional Trials – Experimental Research

Prospective clinical trials with human subjects (such as pilot studies) require Institutional Review Board (IRB) oversight to ensure potential risks of the interventions are minimized and participant’s confidentiality is maintained.

- [OCOM’s IRBQ application form](#) must be completed along with a brief proposal describing the rational and methods and all supporting documents including consent form and recruitment materials.
- All procedures and analyses must be fully described in the proposal and briefly summarized in the IRBQ.
- All IRBQs and supporting documents are first reviewed by the College Research Committee (CRC).

- If the CRC determines the IRB application is complete, the application packet will be forwarded to the IRB for review and approval.
- The full IRB must review all Non-Exempt research. This process takes at least a month after submission to the CRC, and may take considerably longer to review and revise the IRB application as required by the CRC and the full IRB.
- After IRB approval is obtained, the research can begin.
- See the Research Department [website](#) for all required forms and examples of approved IRBQ forms for Surveys (exempt) and Prospective Survey/Data Collection (Non-Exempt).

5. Research Proposals

Most often the proposal is for a survey or a clinical trial. It is strongly encouraged to consider a trial design that could occur at the OCOM clinic. The proposal format presented below is a modified version of the format required by the NIH and NCCAM for research study proposals. A similarly structured research proposal must be submitted to the CRC along with the IRBQ for all research involving human subjects.

- Title Page: 1 page. Include title of project, name, date, and information about the course and OCOM.
- Specific Aims: 1 page. Concisely state your research question(s) and the steps you will take to answer it/them. Briefly describe the need for such research and what is already known about the subject matter. Then summarize the specific question(s) your study will answer and briefly describe your methods to answer each question. It is helpful to write this section first and to revise it as you progress; the specific aims of your project often evolve as you consider the methods and the tasks you must perform.
- Background and significance: 4-10 pages. This section is where you review research that is directly related to your project, and outline the reasons why this project needs to be done. Discuss background information regarding epidemiology of disease, failings or successes or relevant past research in regard to treatment of the disease, efficacy of treatment to be tested, etc. Give a brief history and overview of the areas of TCM that are relevant to your study. Elaborate on the brief supporting statements you made in the specific aims sections. Include citations to all references, either by Author's last name and years of publication or numerically in the order the material is cited.
- Preliminary Studies (optional): Varies from 1 paragraph to 5 pages. Ideally, this is where you discuss your research experience (or that of your colleagues, if any) and any other studies you or your more experienced colleagues have done that are directly related to this project. Discuss research directly related to how you will design your study. This section allows you to demonstrate to the reviewers that you and your colleagues are qualified and have done the preliminary work to conduct this project.
- Research Design and Methods: 2-8 pages. In this section, you must provide specific details on how you will answer the specific research questions. Include the following sections:
 1. Study design/overview
 2. Inclusion/exclusion criteria
 3. Treatments
 4. Treatment protocol
 5. Criteria for early withdrawal from study

6. Outcome measures
 7. Data analysis/statistics
- F. Discussion of possible results: 1-3 pages. What do you expect to happen and why? What would you potentially do next based on various potential outcomes? What could go wrong?
- G. References: You need to cite at least 12 (25 ideally) references throughout the text of the proposal. List them here with the appropriate citations in the text using AMA format.
- H. Appendix: This would include any supporting documents such as timelines, questionnaires, consent forms, surveys, or any additional information such as the herbs and formulas with ingredients, ratios, preparation, dosages, etc.

The final proposal must be 12-20 pages long, single spaced, not including the title page, reference section, and appendix, in 12 pt. font. *It must meet the above criteria and be fully cited before the first draft is turned in.*

If the ultimate goal is to submit a grant application to a funding agency, contact the Research Department as soon as you have identified a potential grantor. ***The complete grant application must be submitted to the Research Department at least 4 weeks before the agency due date for the application.*** The application and budget will be reviewed to ensure feasibility and compliance with the agency requirements. Only complete and fully compliant applications will be submitted to the agency.