



Urology Clinical and Translational Sciences (UCATS)

Urologic Oncology Outcomes Data Sets: Research guidelines for new investigators & trainees

- UCSF investigators work regularly with data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) and the Urologic Oncology Database (UODB) prostate, renal, and bladder studies
- Study descriptions for CaPSURE and UODB are on the Urology Department web site.
- Residents, fellows, and other UCSF investigators are first authors on presentations and manuscripts.
- New projects and analyses generally begin between July and September.
- Data requests must be topic-specific, there are no data sets available for exploratory use.
- Peter Carroll must review and approve all requests before work begins.
- A faculty epidemiologist (June Chan or Stacey Kenfield) must approve all data analysis plans.
- First authors work with a Urology Department statistical analyst who provides data analysis support.

http://www.urology.ucsf.edu/research/cancer

Project cycle

The **project proposal** includes background and a brief literature review supporting the need for the study, objective, description of the patient cohort, exposure variable of interest, outcome, measures, and types of statistical analyses.

Steps

- First author meets with faculty advisors to decide the study topic and them submits data request and data use agreement via the <u>Urology</u> <u>web site</u>.
- 2. First author checks with Imelda Tenggara to comply with CHR regulations.
- Peter Carroll & faculty review and approve study proposal and the study is assigned a project ID by Janet Cowan.
- First author's project team is finalized and includes faculty mentors/senior authors, coauthors, and statistical analyst.

The **analysis plan** specifies study questions, cohort inclusion/exclusion criteria, independent exposure variable and covariables, dependent outcome variable, description of measures, exposure & outcome definitions, and statistical methods.

Steps

- 5. First author arranges initial meeting with the project team to create an analysis plan.
- Project team sets timeline for project completion and identifies upcoming deadline dates.
- Statistical programmer analyzes the data and presents results in a series of analytic summary reports.
- 8. Project team reviews each set of results to interpret findings and refine the analysis.

The **initial findings** are presented as a conference abstract that includes background & literature review (from the proposal), cohort, measures & statistical methods (from the analysis plan), results (from the analytic summary reports), and conclusions.

Steps

- 9. First author circulates <u>draft abstract</u> to the project team 2 weeks before deadline; coauthors review it and provide comments to first author.
- First author incorporates all comments and circulates <u>revised</u> <u>abstract</u> to all coauthors; coauthors review it and provide approval to first author.
- 11. Statistical analyst completes a technical review of all content, numbers, tables, graphs.
- First author or other reader carefully proofreads abstract for content, flow, grammar, and spelling and sends <u>final abstract</u> to all coauthors.
- 13. First author submits abstract to professional conference and notifies coauthors after submitting and upon acceptance/rejection.





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The **final manuscript** is published in peer-reviewed professional journal. Feedback from conference presentations should be used to enhance the analysis and final paper. The first author then outlines in detail the paragraphs for the background, methods, results, and discussion, presenting content in the same order in each section. S/he collaborates with mentor and senior author on interpretation and discussion and with the statistical analyst on the methods, results, tables and figures.

Steps

- 1. The project team meets to plan and outcome the manuscript.
- 2. First author and selected team members draft the manuscript, carefully proofreading for content, flow, grammar, and spelling.
- 3. First author circulates <u>draft manuscript</u> to the project team; coauthors review it and provide comments to first author.
- 4. First author incorporates all comments and circulates <u>revised manuscript</u> to all coauthors; coauthors review it and provide approval to first author.
- 5. Statistical analyst completes a thorough technical review of all content, numbers, tables, graphs.
- 6. First author or other reader carefully proofreads abstract for content, flow, grammar, and spelling and sends <u>final manuscript</u> to all coauthors.
- 7. First author consult with a faculty member to identify an appropriate journal, checks that journal's guidelines for authors and submission, and collects all authors' disclosure and copyright forms.
- 8. First author submits manuscript to professional journal and notifies coauthors after submitting and upon acceptance/rejection.

Revising and resubmitting manuscripts

- 9. Rejected manuscripts: the project team decides whether to revise and/or to which journal to submit to next, utilizing any reviewer comments received.
- 10. Accepted manuscripts: first author works closely with all coauthors and statistical analyst to revise the paper according to reviewers' comments, and prepare a response letter to accompany the revised manuscript.
- 11. First author notifies coauthors after resubmission and at final acceptance.

Key faculty and staff contacts

Complete contact information is on the Urology Department web site for the following people:

Faculty

Peter R. Carroll, MD, MPH June M. Chan, ScD Matthew R. Cooperberg, MD, MPH Maxwell V. Meng, MD Stacey Kenfield, ScD

Scheduling for Peter Carroll Kim Goldfien

Director, Data Procurement and Quality Assurance Jeanette (Jenny) Broering, RN, MPH, PhD

Statistical Programmer/Analyst Janet Cowan

Clinical Trials Office Imelda Tenggara

Professional urologic oncology organizations & meetings	ABSTRACT DEADLINE	ANNUAL MEETING
Western Section AUA	Jun 17, 2012 Closed	Nov 3-7, 2013 Monterey, CA
UCSF Prostate Cancer Retreat	Aug 30, 2013 Closed	Sep 9, 2013 Mission Bay, UCSF
Society of Urologic Oncology (SUO)	Sep 9, 2013 Closed	Dec 4-6, 2013 Bethesda, MD
ASCO Genitourinary Cancer Symposium (GUCS)	Oct 1, 2013 Closed	Jan 30-Feb 1, 2014 San Francisco, CA
American Urological Association (AUA)	Nov 11, 2013 Closed	May 16-21, 2014 Orlando, FL
American Association for Cancer Research – Prostate Cancer Foundation	Nov 11, 2013 Closed	Jan 18-21, 2014 San Diego, CA
American Society of Clinical Oncology (ASCO)	Jan 2014	May 30-Jun 3, 2014 Chicago, IL