University of California San Francisco
UCSF
School of Medicine
Department of Urology

CaPSURE™
Cancer of the Prostate Strategic Urologic Research Endeavor

# Urology Clinical and Translational Sciences (UCATS)

## UCSF UCATS Stats Group 2015

Example of a data analysis plan:

Da: *Date*
To: *Coinvestigators, coauthors, senior author*
Fr: *Investigator/first author*
Re: *Title*: Analysis Plan

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Study questions

- *What are the predictors of negative repeat biopsies after active surveillance for prostate cancer?*

*Patient cohort*

- *Active surveillance*
- *Consented for research*
- *Diagnostic and at least 1 follow up biopsy*
- *Minimum 10 biopsy cores taken at diagnosis*
- *Etc*

Independent variables

- Age at diagnosis
- Race and relationship status
- Gleason grade at diagnostic biopsy
- Number of cores taken at diagnostic biopsy
- Number and percent of cores positive at diagnostic biopsy
- *Etc*

Dependent variables/outcomes

- Increase in biopsy grade to at least 3+4
- Increase in volume to at least 34% positive cores or 51% positive in a single core

If AS+RP patients are included:

- Upgrade at surgpath from last repeat biopsy
- Upstage at surgpath from cT1/2 to pT3/4
- Any adverse pathology (pT3/pN1/positive margins)

Time-to-event outcomes

- Treatment free survival during AS for men with repeat biopsies
- Treatment free survival during AS for men with negative biopsies
- Biopsy progression-free survival
- *Etc*

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Cox proportional hazards regression model

- Covariates: age, cT-stage, diagnostic PSA or PSAD, % positive cores, negative first repeat biopsy
- Outcome: biopsy progression

Logistic regression model

- Covariates: age, cT-stage, diagnostic PSA or PSAD, % positive cores, % positive tissue, biopsy GS
- Outcome: biopsy progression