BIOS 6611 Final Project

Due by Thursday, December 10, 2020 by 10:00 pm to Canvas Assignment Basket

The Overview

This project is intended to give you hands-on experience with a topic that you will choose from the list of six below that involve analysis of data from actual studies. Alternatively, if you have a topic or dataset of interest, you can email/talk with Alex about using that for your project instead.

For your chosen topic, you'll prepare a <u>3-page</u> summary (single spaced; strict <u>maximum</u>; references can extend beyond the 3-page limit) in the form of a brief scientific report. For the data analysis projects, you'll find a general outline for this format on p. 3 of this document. An example is posted on the Final Project page of the Canvas course.

The rubric that will be used for grading is posted on our Canvas Final Project assignment page. In general, you will be expected to write in the style of a journal article/brief scientific report (i.e., avoiding overly casual language and overuse of "I/we feel"). The following sections/subsections will be expected (although you don't have to necessarily use these names):

- Introduction or Background
- Materials and Methods, Study Design, etc.
- Statistical Methods, Statistical Analyses, etc.
- Results (including a "Table 1" summarizing descriptive features of the data, at least one figure, a table of the analytic results or results in-text if brief, etc.)
- Discussion or Conclusion

The structure and a brief outline is discussed a little more on Page 3, with some resources highlighted.

The six available datasets have brief descriptions at the end of the document and in separate files, but come from either UCD studies or real studies with data contributed by the American Statistical Association's TSHS Section:

UCD Datasets:

- Parkinson's Exercise Trial
- Mole Development in Colorado Kids

TSHS (Teaching Statistics in the Health Sciences) Datasets:

- Colorectal Cancer: Seasonal Effect and Vitamin D Study
- Surgery Timing and Outcomes
- Prostatectomy and Blood Transfusion
- Licorice Gargle for Thoracic Surgery

Analysis of a UCD/TSHS Dataset (or propose a different dataset)

You'll formulate <u>one</u> research question, develop an analytic plan to address the question, and present the results and interpret them. You can choose one of the datasets provided for your project, or propose a different dataset you are working with or find interesting.

The UCD datasets have the file names, variable names, and descriptions at the end of this document. The TSHS datasets have their own PDFs with background and study variables. Each of the data analysis projects has its own subsection on the Canvas page for the Final Project. On Canvas, you will find the data and the resources available for each project. You can use either R or SAS, or some of each, to conduct your analysis.

Develop one question and analyze data to answer it

The resource material for each project will give you an idea of the potential interrelationships among the variables included. Use those materials to develop <u>one</u> question that could be answered with the data you have.

Many of these datasets include longitudinal data. If you choose to use longitudinal data you should choose two time points of your choice to compare (e.g., baseline and 1 year). You will learn to work with the longitudinal data in detail next semester. For now, you will use methods appropriate for uncorrelated data, e.g. by taking differences and treating the difference as the outcome of interest. For any observational study it will be important to identify *potential* confounders of the relationships between the variables you choose to focus on.

Your project must include the following aspects:

Apply resampling to understand sampling variability of parameters of interest *or* to calculate a permutation test p-value

You should investigate and summarize the bootstrap sampling distribution of at least one parameter estimate of interest related to your study question or calculate the permutation test p-value for your comparison.

Apply Reproducible Research (RR) principles for reporting

In addition to the 3-page summary, you should include a <u>brief</u> Appendix with the R or SAS code that you used to perform the analysis. This will ensure that anyone looking at your analysis and summary will be able to know exactly what you did.

<u>Be sure to:</u> Comment your program, attach useful names to any variables you create and analyze, and attach labels to variable values using formats.

Example Outline of Brief Scientific Report

Introduction with brief background – 0.5 page

Question or hypothesis – 0.125 page

Materials and Methods - 0.25 page

Analysis Plan – 0.25 page

Results – 1.5 page
"Table 1"

Descriptive or other plot(s)

Analytic results table

Discussion and Conclusion – 0.375 page Include limitations

References (not included in 3-page limit)

Appendix for Reproducible Research Goal (not included in 3-page limit): SAS or R code

Refer to example: AJPH Example Brief Report.pdf, located on the Final Project Canvas page

General Writing Resource: Tips on Writing Results for a Scientific Paper Amstat News - Cummins - Sept 2009.pdf, located on the Final Project Canvas page

Reproducible Research

You will need to follow Reproducible Research principles in carrying out your project. Adherence to the principles of reproducible research is essential to the reporting of scientific results.

Be sure to familiarize yourself with some of the resources on this topic listed below.

An outstanding example of reproducible research by Keith Baggerly and Kevin Coombes of the MD Anderson Cancer Center Bioinformatics and Computational Biology department is posted in the Paper Repository ("Deriving Chemosensitivity from Cell Lines: Forensic Bioinformatics and Reproducible Research in High-Throughput Biology" in the *Annals of Applied Statistics* by Baggerly and Coombes, and *Cancer Letter* 1, 2, and 3 by Paul Goldberg).

RR Resources: (Canvas Paper Repository)

Gentleman and Temple Lang paper – Statistical Analysis and Reproducible Research; from the Bioconductor Project

Roger Peng 2009 Editorial in Biostatistics

Roger Peng 2011 article in Science

Frank Harrell presentation on the use of R in clinical trials research

IOM Report on Evolution of Translational Omics

Lehrer 2010 New Yorker The Truth Wears Off

Dynamic/computable documents using R
http://yihui.name/knitr/
http://rmarkdown.rstudio.com/

Dynamic/computable documents using SAS http://sites.northwestern.edu/stattag/

Recommended, but not required:

Use one of these (or another) computable document applications.

Git and GitHub – version control, collaboration tools https://git-scm.com/

https://github.com/

<u>UCD Data Analysis Project</u> – A Randomized Clinical Trial of Exercise in Early to Mid-Stage Parkinson's Disease

Lead Investigator: Margaret Schenkman PhD

Data are in a .csv file: PD Exercise RCT Selected Secondary Outcomes - Wide.csv

Summary:

121 participants randomized into one of 3 exercise groups

33 variables

Repeated outcomes: Baseline (0 months), 4 Months, 10 Months, 16 Months; some missing data; suffix for outcome measures below denotes when the measure was taken

Data Dictionary:

Variable/Field Name	Label/Attributes
Participant	id number
Group	4 = Home Exercise
	5 = Flexibility, Balance, and Functional Training
	6 = Aerobic Conditioning
Gender	1 = Male
	2 = Female
Age	years
YearsDx	Years with PD
HYStage0, HYStage4, HYStage10, HYStage16	Hoehn and Yahr stage of PD – scale from 1
	(lowest) to 4 (worst) in increments of 0.5 at
	baseline, 4, 10, and 16 months
FiveM_Wk0, FiveM_Wk4, FiveM_Wk10,	Five meter walk in number of steps at baseline, 4,
FiveM_Wk16	10, and 16 months
FiveM_Tm0, FiveM_Tm4, FiveM_Tm10,	Five meter walk in seconds at baseline, 4, 10, and
FiveM_Tm16	16 months
TUG0, TUG4, TUG10, TUG16	Timed Up and Go in seconds at baseline, 4, 10,
	and 16 months
UPDRS0, UPDRS4, UPDRS10, UPDRS16	Total score on UPDRS (see scale information in
	resource document) at baseline, 4, 10, and 16
	months
SixMn_Wk0, SixMn_Wk4, SixMn_Wk10,	Six Minute Walk in meters at baseline, 4, 10, and
SixMn_Wk16	16 months
LEDD0, LEDD4, LEDD10, LEDD16	Levodopa equivalents (mg/day) (commonly
	prescribed medication for PD) at baseline, 4, 10,
	and 16 months

Additional Resources:

UPDRS,H&Y, S & E_MedEl_tool.doc UPDRS Background Paper.pdf Schenkman at al 2012 PTJ Exercise Early MidStage PD 16 Month RCT.pdf

UCD Data Analysis Project - Mole Count Study in Colorado Children

Lead Investigator: Lori Crane PhD

Data are in an Excel spreadsheet: Mole Count Data 2004-2008.xls

Summary:

472 children age 6 followed from baseline to age 10

15 variables

Longitudinal study of mole development over five years

Data Dictionary:

Variable/Field Name	Label/Attributes
Respondent Code Number	id number
oca2 status	0 = gg
	1 = ga
	2 = aa
	9 = missing
gender	1 = Female
	2 = Male
Hispanic	0 = No
	1 = Yes
molecount2004	Number of moles in 2004
molecount2005	Number of moles in 2005
molecount2006	Number of moles in 2006
molecount2007	Number of moles in 2007
molecount2008	Number of moles in 2008
eyecolor	1 = blue, green or combo
	2 = light/dark brown
	3 = hazel
baseskincolor	Skin color based on a continuous score, higher is
	darker
haircolor	1 = blonde
	2 = red
	3 = brown
	4 = black
number vacs birth thru 2005	Total number of waterside vacations from birth
	through 2005
number vacs birth thru 2006	Total number of waterside vacations from birth
	through 2006
number vacs birth thru 2007	Total number of waterside vacations from birth
	through 2007

Additional Resources:

Mole Study R01 July 2009 Draft.doc

Crane et al. 2009 – Nevus development in children (pdf)

Pettijohn et al. 2009 – Waterside vacations and nevus development (pdf)

Crane et al 2012 AJPM Mailed Intervention Sun Prot Children RCT (pdf)

TSHS Data Analysis Project - Colorectal Cancer and Seasonal Effect

Data are in a .csv file: Seasonal_Effect.csv

Summary:

Prospective cohort study

2919 participants divided into seasons (spring, summer, fall, winter)

14 variables

Repeated outcomes: none

Additional Resources:

Data dictionary: SeasonalEffect_dictionary.pdf

Introduction/Background: SeasonalEffect_Introduction.pdf

TSHS Data Analysis Project - Surgery Timing and Outcomes

Data are in a .csv file: Surgery_Timing.csv

Summary:

Retrospective cohort study 32001 participants

25 variables

Repeated outcomes: none

Additional Resources:

Data dictionary: Surgery Timing Data Dictionary.pdf

Introduction/Background: Surgery Timing Dataset Introduction.pdf

Published Paper: Sessler et al., "Operation Timing and 30-Day Mortality After Elective

General Surgery" (pdf)

TSHS Data Analysis Project - Prostatectomy and Blood Transfusion

Data are in a .csv file: Blood_Storage.csv

Summary:

Retrospective cohort study

316 participants

20 variables

Repeated outcomes: none

Additional Resources:

Data dictionary: Blood Storage Data Dictionary.pdf

Introduction/Background: Blood Storage Dataset Introduction.pdf

Published Paper: Cata et al., "Blood Storage Duration and Biochemical Recurrence of

Cancer After Radical Prostatectomy" (pdf)

TSHS Data Analysis Project - Licorice Gargle for Thoracic Surgery

Data are in a .csv file: Licorice_Gargle.csv

Summary:

Randomized control trial 236 participants divided into seasons (spring, summer, fall, winter) 19 variables

Repeated outcomes: none

Additional Resources:

Data dictionary: Licorice Gargle Data Dictionary.pdf

Introduction/Background: Licorice Gargle Dataset Introduction.pdf

Published Paper: Ruetzler et al., "A Randomized, Double-Blind Comparison of Licorice Versus Sugar-Water Gargle for Prevention of Postoperative Sore Throat and

Postextubation Coughing" (pdf)