Introduction

- The use of adaptive designs in clinical trials has been increasing due to its flexibility and efficiency gains, besides being more ethical as they assign fewer subject to treatment arms with inferior outcomes [1][2].

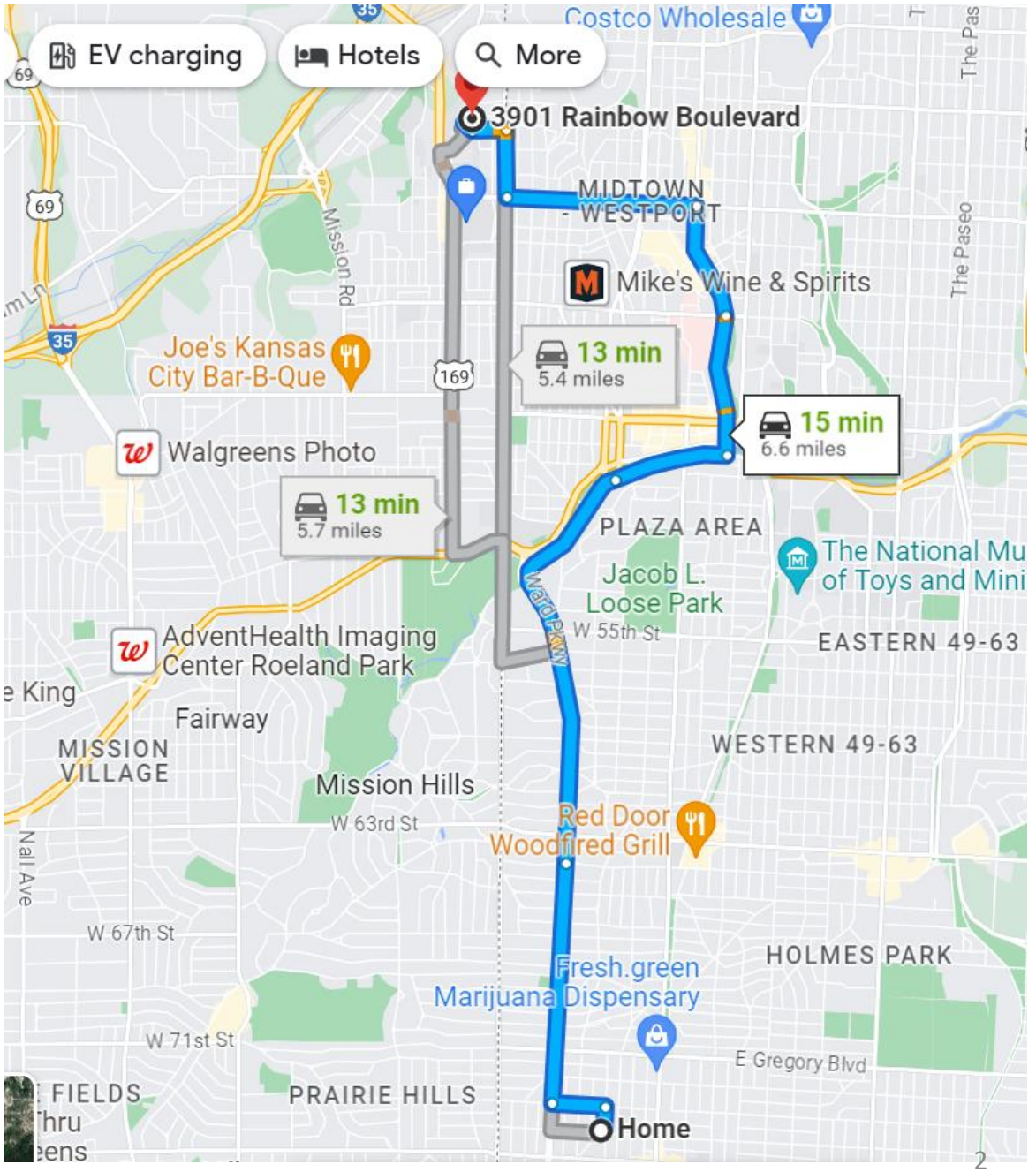
- Their use is gradually being extended to other areas to capture the already realized benefits [1][3][4].

- Reducing the amount of time spent driving from home to work can help maximize productivity in the work place.

- This study utilizes adaptive designs to determine the optimal driving route from Dr. Gajewski's home to his work place at KUMC.

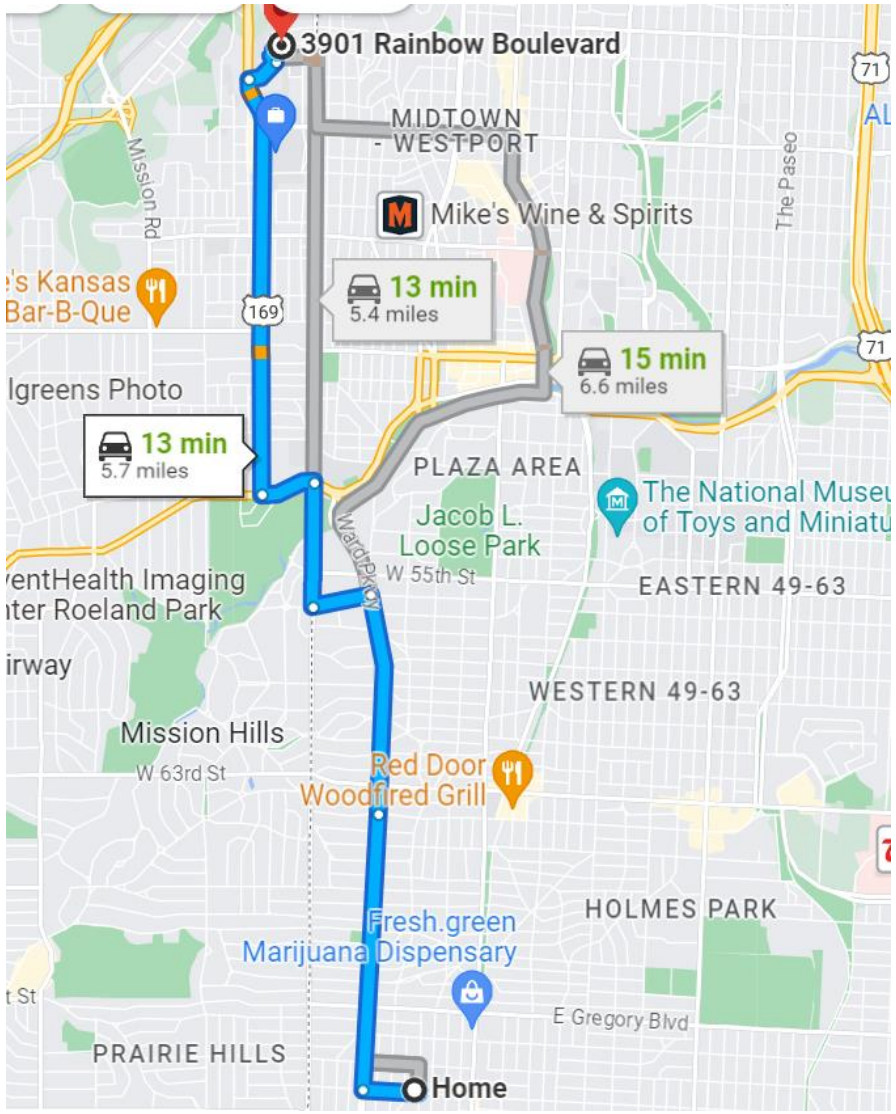
Plaza Route (Control)

- Three lanes (faster speed)
- Aesthetic (goes through Plaza)
- First route when moving to KC
- Indirect (slow?)



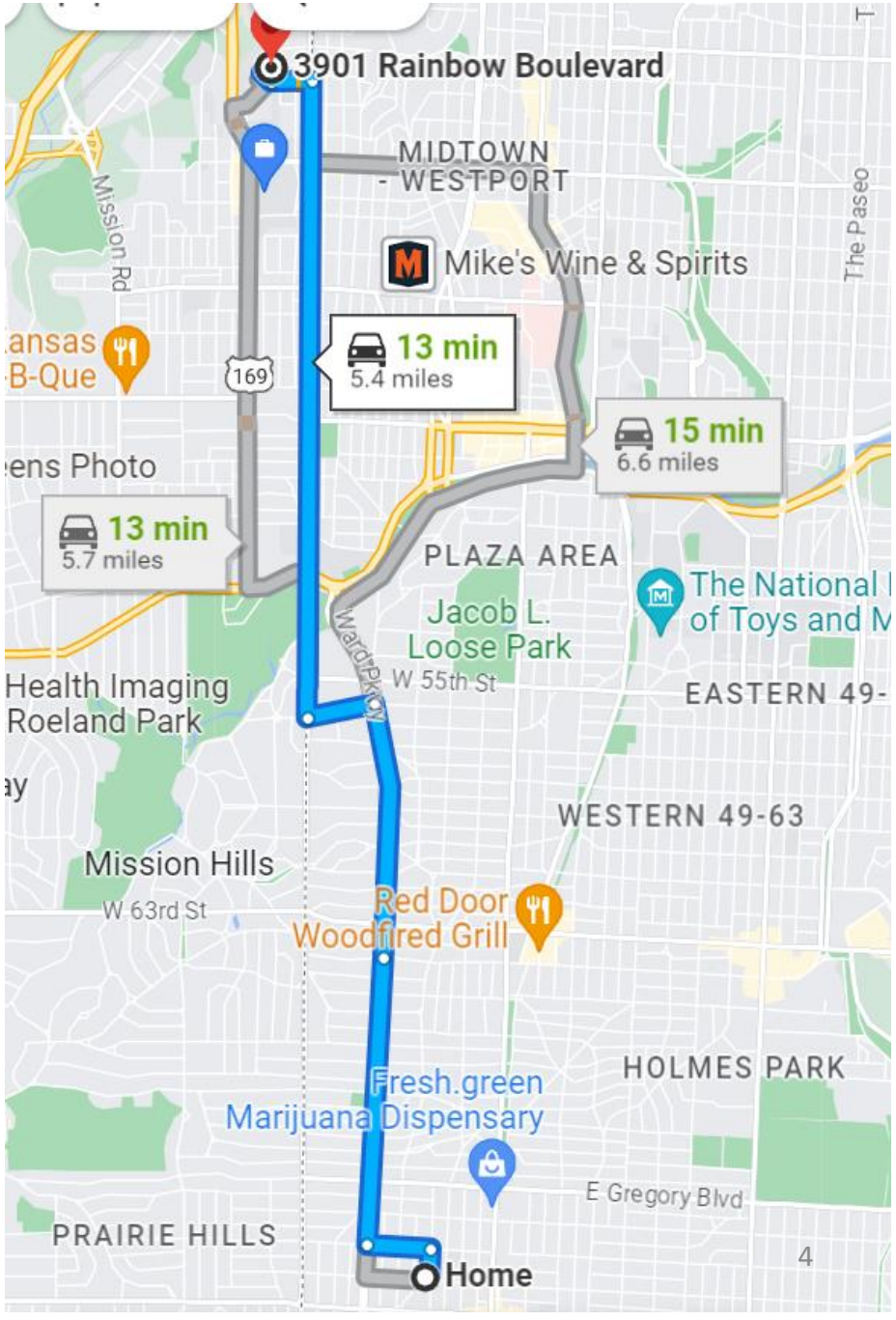
New route 1: Rainbow

- Two lanes
- Faster speed
- Direct



New route 2: Stateline

- Straight
- Direct
- One lane (slower?)



I want to see if there is a better route than Plaza

Arm	Route
1	Plaza (Control)
2	Rainbow
3	Stateline

Assumptions

Arm	Route	Data Source	Average Driving Time (μ_j)
1	Plaza (Control)	Google maps	15 minutes
2	Rainbow	Google maps	13 minutes
3	Stateline	Google maps	13 minutes

$\sigma \sim 1.2$ minutes (preliminary data)

Fixed Design (Strawman)

- 1:1:1 Allocation
- One analysis
- Compare two new arms to control
- Type I error 2.5%, 1-sided, Bonferroni (2.5%/2=1.25%)
- 90% power -> 11/group (n=33)
- Will take about 6.5 weeks to implement (1 driver, 5 times/week)

Can we do better? Adaptive Design Choices?

- Prior?
- Randomization? Response Adaptive Randomization
- What's the optimal allocation control?
- Interim analyses? How many?
- Success and futility rule?
- Can we do better in the average number of drives, time, better route?

Goal

- Design, conduct, and analyze this study.
- Write-up for a journal (*Journal of Statistics and Data Science Education*), all of us co-authors
- Need a Principal Investigator (PI)
  - Leads the project, manages timelines, and works with Co-Investigators
  - Works with notes taker to have good notes
  - Responsible for leading the final write-up
- Need milestone co-I (co-Investigators)
- Who's in?

Milestones/Products

1) Design (FACTS)
2) Protocol
3) Statistical Analysis Plan
4) Data Capturing (RedCAP and a Shiny App for Randomization)
5) Analysis
6) Paper (PI)

Milestone 1: Design

- Each of you, with a partner, come up with a new design
  - Pair a rookie user with a veteran user of FACTS
  - FACTS, Core Design, Continuous
- Calculate operating characteristics under various virtual subject responses (VSR)
- Accrual (drive all workdays)
- Endpoint (Driving time immediate)
- When you have your design in FACTS:
  - Put it in Shared Drive
  - Have done by September 15
  - Each will present brief overview, then we vote which one to build off of

Virtual Subject Responses (VSR): Average Driving Time

Arm	Route	Null	Expected	One Best
1	Plaza (Control)	15 minutes	15 minutes	15 minutes
2	Rainbow	15 minutes	13 minutes	13 minutes
3	Stateline	15 minutes	13 minutes	14 minutes

$\sigma \sim 1.2$ minutes