Integrating COVID-19 Prevention into Your Clinical Research

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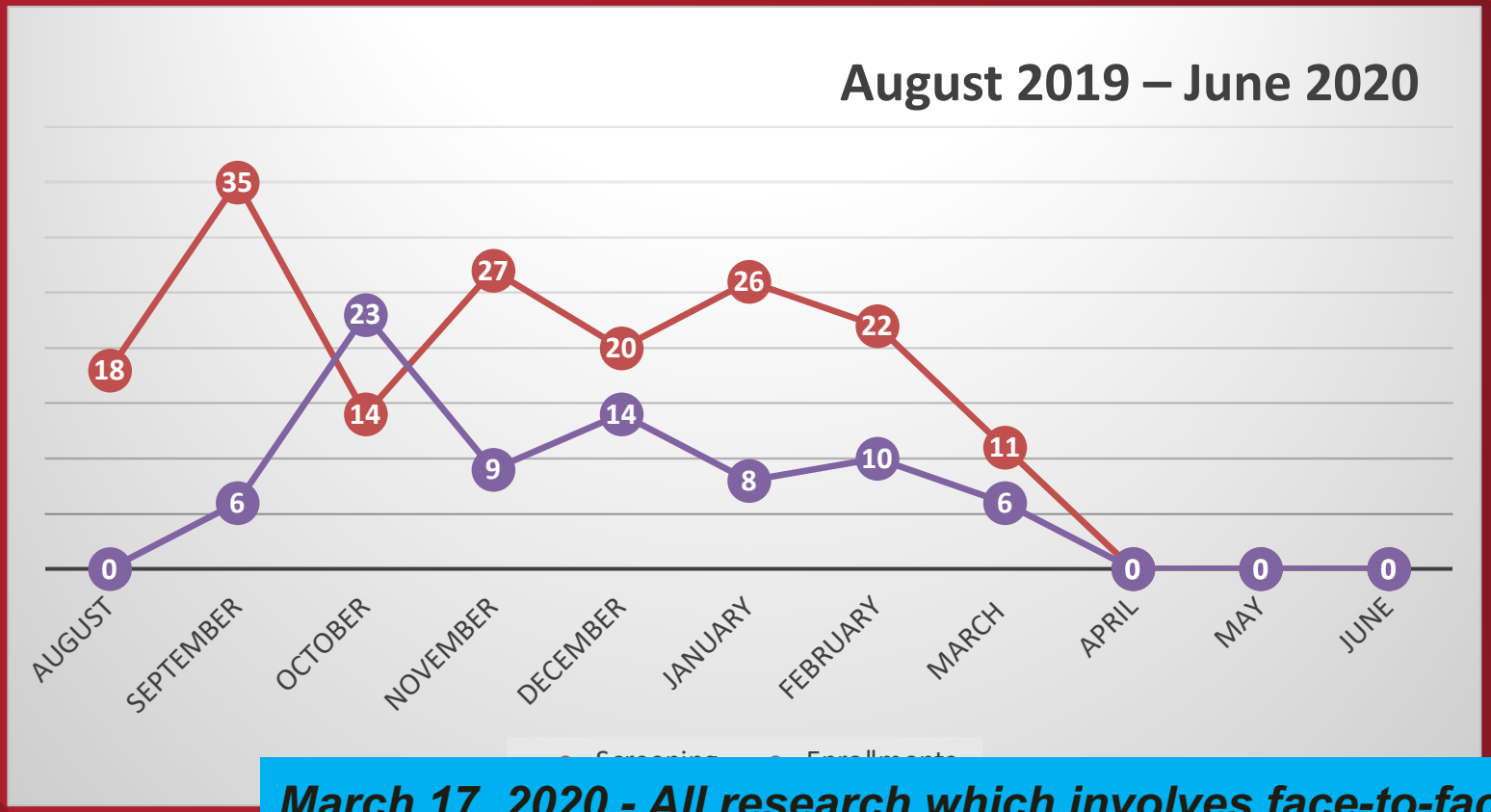
Objective

At the end of this presentation, the audience will be familiar with procedural adjustments to clinical research which can improve safety and decrease risk of transmission of COVID.

Clinical Trial: Screening & Enrollment Visits



March 17, 2020 - All research which involves face-to-face contact that has no direct subject benefit should be halted

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Research Operations

- Research Updates
- Safeguarding Research Data
- COVID-19 Research Information
- FAQs – Ask a Question

Research Response to COVID-19

Posted by Jennifer Larsen | March 13, 2020

Ask a Research Question

COVID-19 has taught us to be ready for and respond quickly to twists and turns. The Vice Chancellor for Research Office has developed this blog to be the go to place for questions regarding how to get things done (research operations) or any concerns you have, whether you are a student, employee or faculty member. Our first goal is to keep our research personnel as well as research subjects safe.

As this has been an unprecedented time of personnel working remotely from each other, we have revised this site to include updates regarding how and where to best save and protect research data, as well.

Integrating COVID-19 Prevention Into Your Clinical Research

- What can we do to reduce exposure and prevent transmission of COVID?
- Do these changes work with current clinic processes and practices?
- Do these changes meet IRB requirements for sound, safe and ethical research?

COVID- 10 Protocol Example

COVID-19 Height, weight, waist circumference – All Visits Protocol

- Staff a … when they walk ir…
- Maske… y they will have p…
- Using l…
- Maske…
- Using l…
- Once t… …propriate cleane…
- Give th… it in the proper… struction if adjusti…
- Once t… …trash bin by participant

*Hand sanitizer will be used after touching of equipment each time.

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REDCap & COVID-19 Screening

Record ID **76**

Data Collection Instrument	6 Week COVID-19 Screening	6 Week Visit / Contact	3 Month (12 week) Contact	Request Supplements	6 Month (26 weeks) Visit	6 Month COVID-19 Screening	we Cont
Subject Id							
Symptoms Checklist (survey)		✓	✓		✓		
Baseline Symptoms Questionnaire (survey)							
SF12 (survey)					✓		
HAP (survey)					✓		
Blinding Assessment (survey)		✓	✓		✓		
Health Status (survey)		✓	✓		✓		
Covid 19 Screening Prior To Visit (survey)						✓	
lete all data on event:		✗	✗		✗		

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We have scheduled you for your Enrollment Visit on **Friday, January 29th @ 1:00 PM**. You may get an automated reminder to come 20 minutes prior to your scan time @ 1:40 PM. Please come at 1:00 PM in order for you to complete the check in process and other study tasks. You must complete the COVID-19 Screening prior to your visit. The survey link is at the bottom of this email. Please respond to this email if you would like a research coordinator to complete this over the phone. This survey will take a few minutes.

Arrival directions

Your visit is located at Nebraska Medicine Village Point (111 N 175th St. Omaha, Neb.) Use Entrance F.

Mask guidelines

If you do not have a mask Nebraska Medicine will provide one.
Information of about what to expect at your clinic visit at Nebraska Medicine can be found here:
https://www.nebraskamed.com/COVID/what-to-expect-at-your-next-appointment

Sincerely,
Kara M. Smith

Please take this survey.

You may open the survey in your web browser by clicking the link below:
COVID-19 Screening

Minimize Contact Time

- Electronic or virtual consent
- Questionnaires shifted to online/survey format for completion at home
- Mailing vs. in-person delivery of supplements

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ADULT CONSENT - CLINICAL BIOMEDICAL
Main Consent Form

Title of this Research Study
Evaluation of the Spry Belt for Improving Bone Quality

Invitation and Summary

You are invited to take part in this research study. Participation in this research study is voluntary. You do not have to take part.

Dr. Laura Bilek, the principal investigator of this study, has stock/ stock options / warrants for services provided to Bone Health Technologies, a spin-off company of Theranova, LLC, the sponsor of this study. The principal investigator (PI) is a clinical advisor for the company sponsoring this study.

Here is a summary of the purpose, methods, risk, benefits, and alternatives, to help you decide whether or not to take part in the research.

Have all your questioned been answered?

- ○ Yes
- ○ No

reset

First Name

* must provide value

Last Name

* must provide value

Date of Birth

* must provide value

Today M-D-Y

Which of the research coordinators is speaking to you on the phone?

* must provide value

- ○ Kara Smith
- ○ Melissa Cole

reset

Date

* must provide value

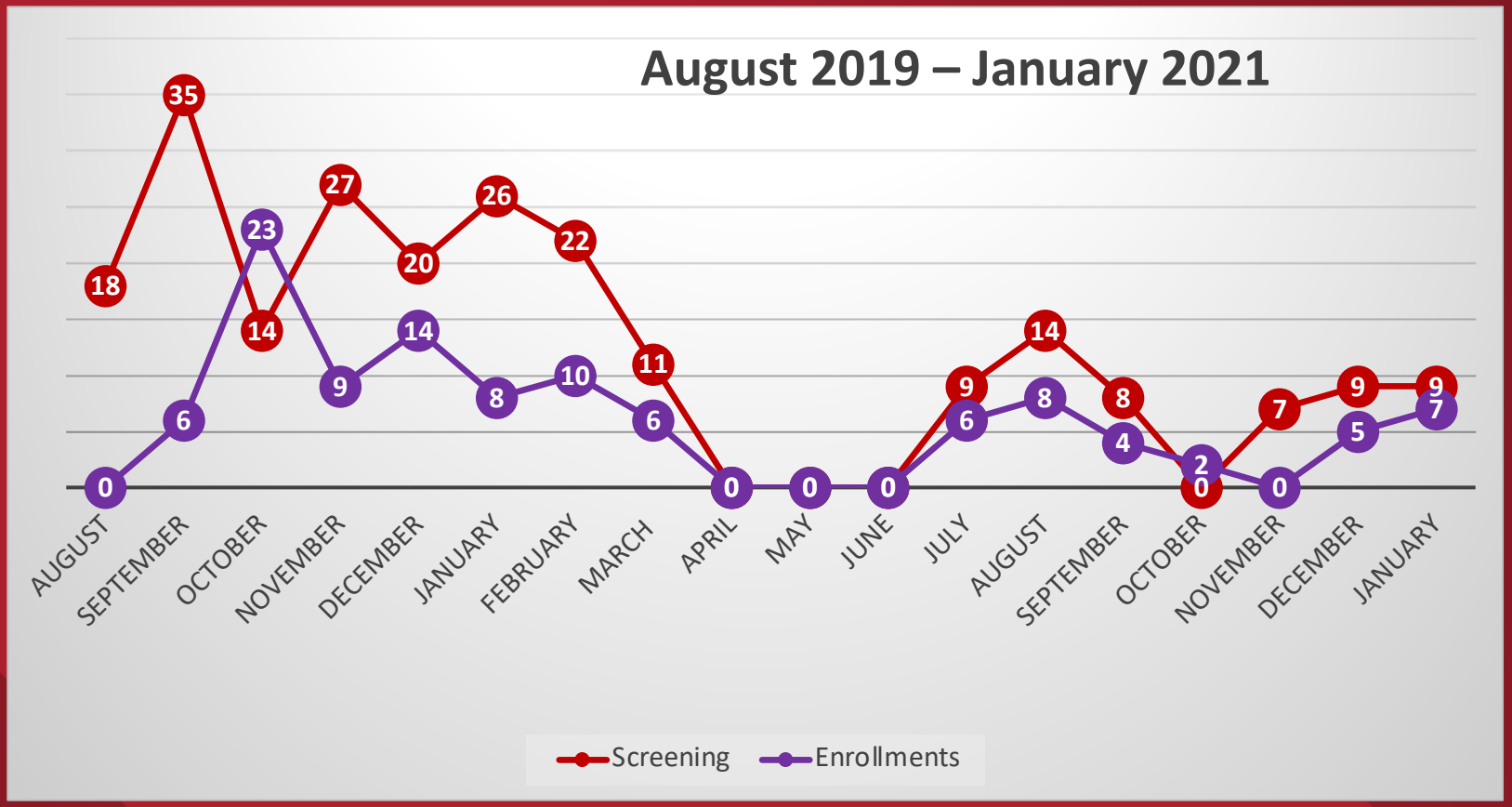
Today M-D-Y

Please click on the link on the right to add your signature

* must provide value

Add signature

Resume In Person Visit July 2020



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Integrating COVID-19 Prevention Into Your Clinical Research - Takeaways

- Planning, planning, planning
  - Able to schedule visits the first day we received the go ahead
- Communication, guidance to administrators, subjects and sponsors
  - Building trust
- We discovered ways to be efficient and streamlined in our study visits. We will implement in future studies to improve efficiency even after risk of COVID is controlled.
  - All questionnaires online vs at visits
  - Mailing supplements to the subjects directly from the pharmacy