

STOP & SIG-COVID: Two Studies, One REDCap



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The STOP and SIG-COVID Studies

- Both studies look at the early COVID-19 surge (03-05/2020) in MA and SARS-CoV-2 infection among healthcare workers (HCW)
- STOP aims to look at risk factors associated with HCW infection and phylogenetics to identify intra-hospital clusters (*PI Karen Jacobson, Infectious Diseases*)
- SIG-COVID is a point seroprevalence study looking at SARS-CoV-2 antibody prevalence among HCW (*PI Yachana Kataria, Pathology*)
- Both studies performed SARS-CoV-2 serology as a study activity

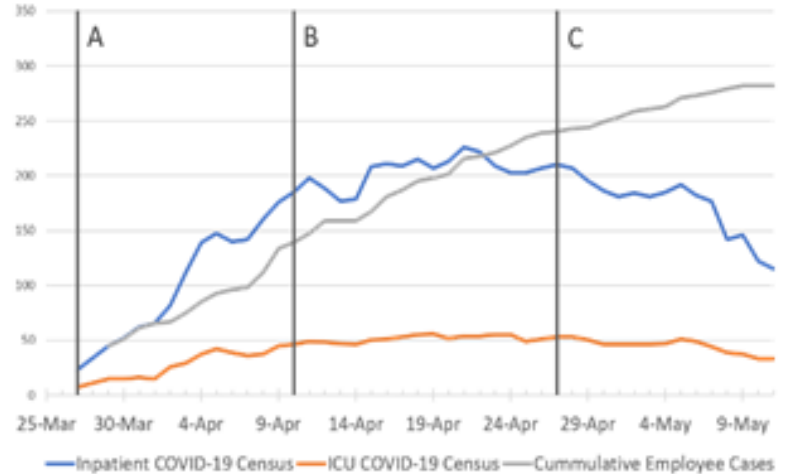
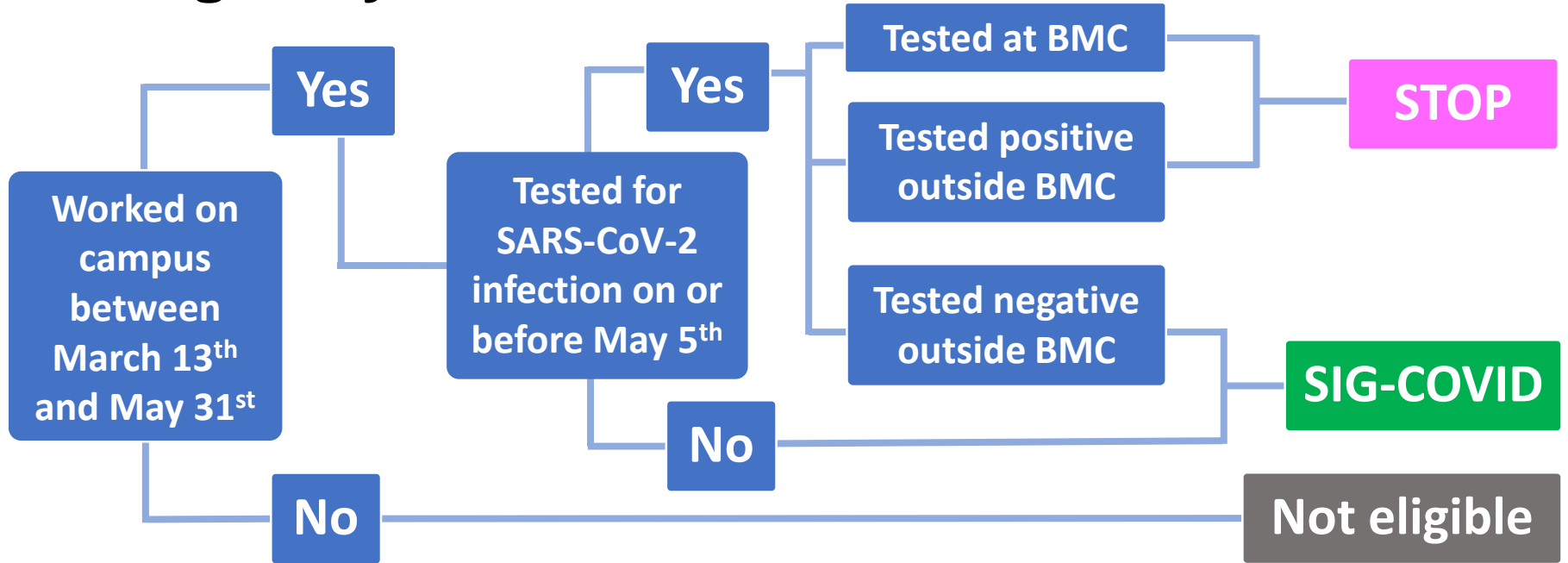


Figure 1. Boston Medical Center SARS-CoV-2 PCR positive COVID-19 Cases.

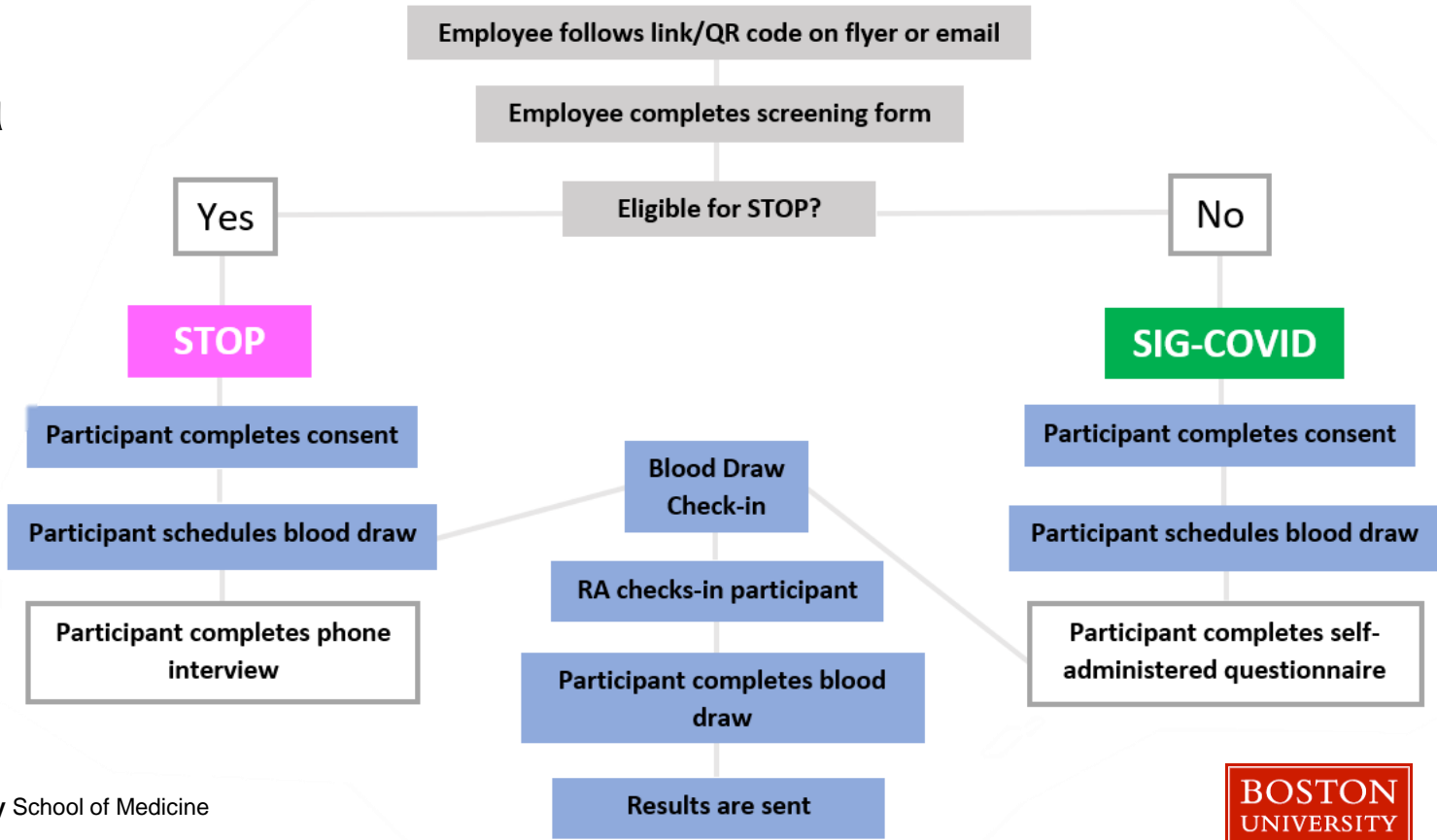
Eligibility Criteria



Why one REDCap project?

- Overlap in study population of interest
 - all STOP participants were eligible for SIG-COVID
- Reduced research burden on BMC employees
- Enabled co-recruitment (e.g., shared flyers, posters, etc.)
- Enabled co-screening (i.e., self-administered screening on REDCap)
- Enabled collaboration between two study teams and necessary data/results sharing
 - All STOP participants were also SIG-COVID participants, so SIG-COVID had access to STOP questionnaire data
- Shared phlebotomy station during two-week period

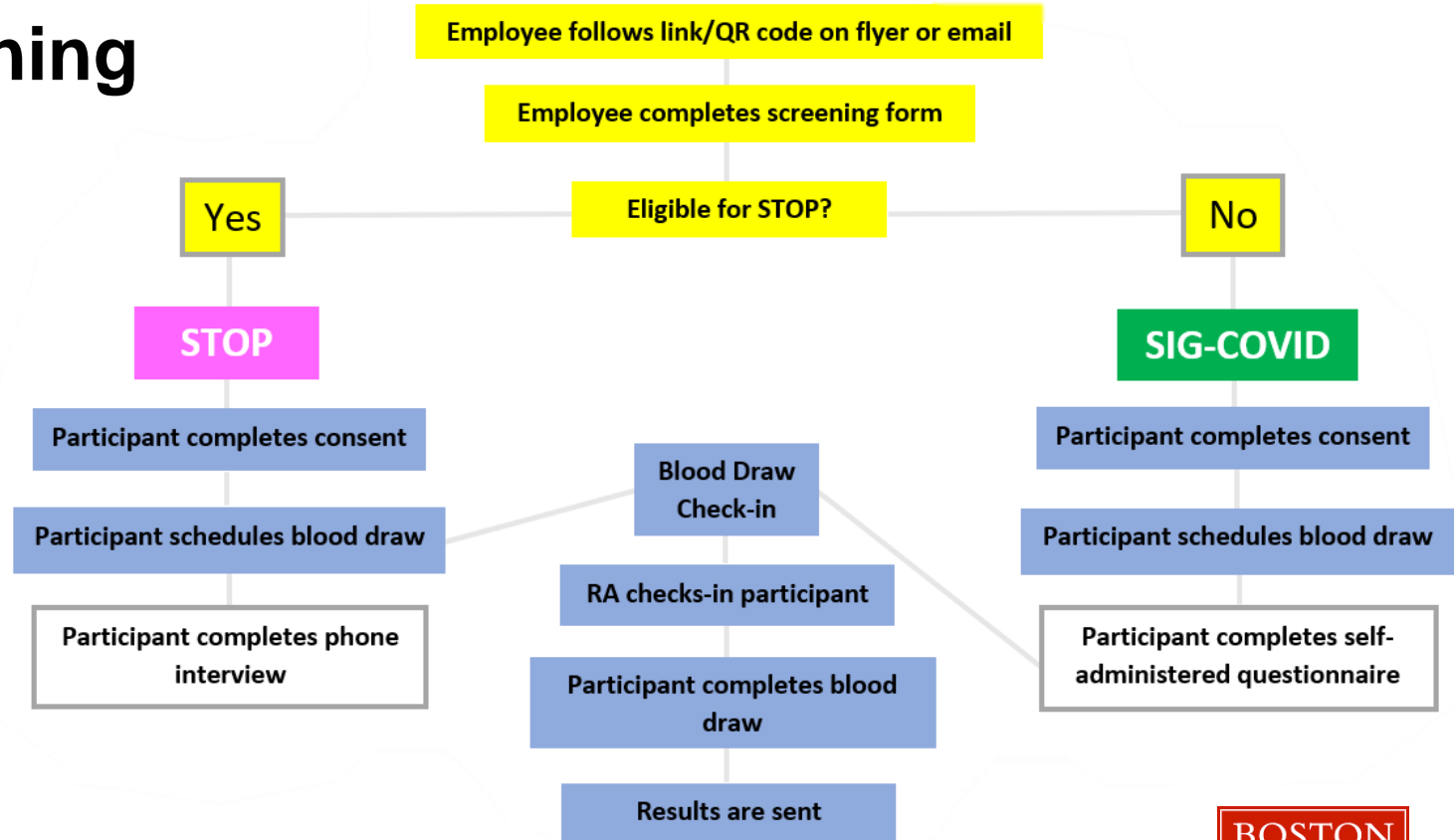
REDCap Flow



REDCap Functions Overview

- Screening
 - Calculated field
- Consent
 - Branching logic; Confirmation email with attached PDF
- Scheduling
 - Response limit; Confirmation email
- Check-in
 - REDCap report; Branching logic
- Release of results
 - Data import tool; Alerts and notifications

Screening



Screening

- Based on eligibility, participants were deemed eligible for either STOP, SIG-COVID, or neither study
- Calculated field was used to identify which study a participant was eligible for

Edit Field

Field Type: Calculated Field

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?

Study this person is eligible for:
1=STOP
2=SIG-COVID
0=ineligible

Calculation Equation [How do I format the equation?](#)
if([screen_agree]=1 and [on_campus_work]=1 and [tested]=1 and ([tested_where]=1 or [tested_where]=3 or ([tested_where]=2 and [positive]=1)),1, if([screen_agree]=1 and
[Clear calculation](#)

Test calculation with a record: -- select record --

Action Tags / Field Annotation (optional)
@HIDDEN-SURVEY
[Learn about @ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)
 Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use Smart Variables Piping

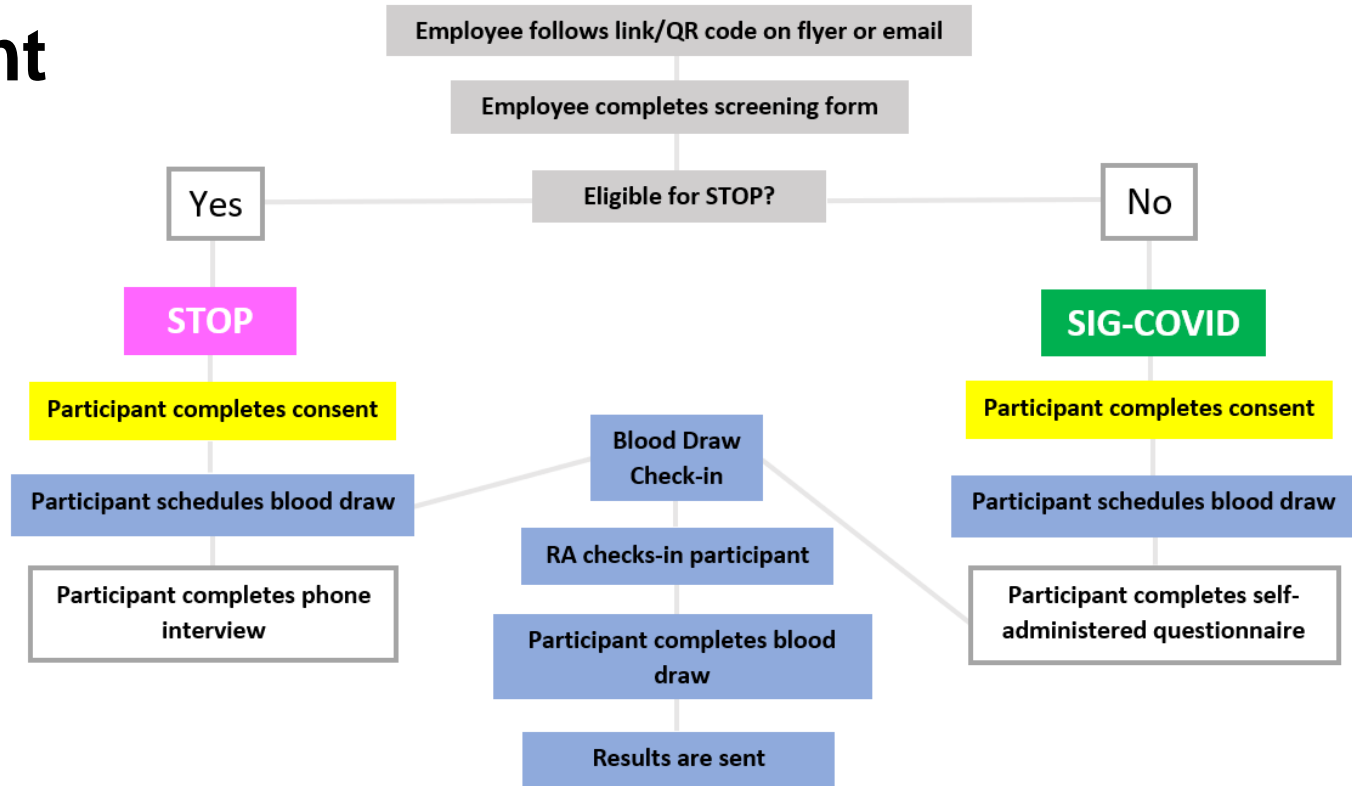
Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Consent



Consent

- 6 different versions built into the same REDCap form based on study and preferred language from screening form
 - Languages: English, Spanish, Haitian-Creole
- Used branching logic to route participants to one of the 6 versions
- E-signature provided
- Confirmation email sent with attached PDF of completed form

Choose method below for the following field: **stop_basic_info_english** - *Basic Information Title ...*

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#)

Show the field ONLY if...

[assigned_study]='1' and [language]='1'

[Clear logic](#)

Test logic with a record: -- select record -- ▾

Choose method below for the following field: **sigcovid_basic_info_english** - *Please read below ...*

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#)

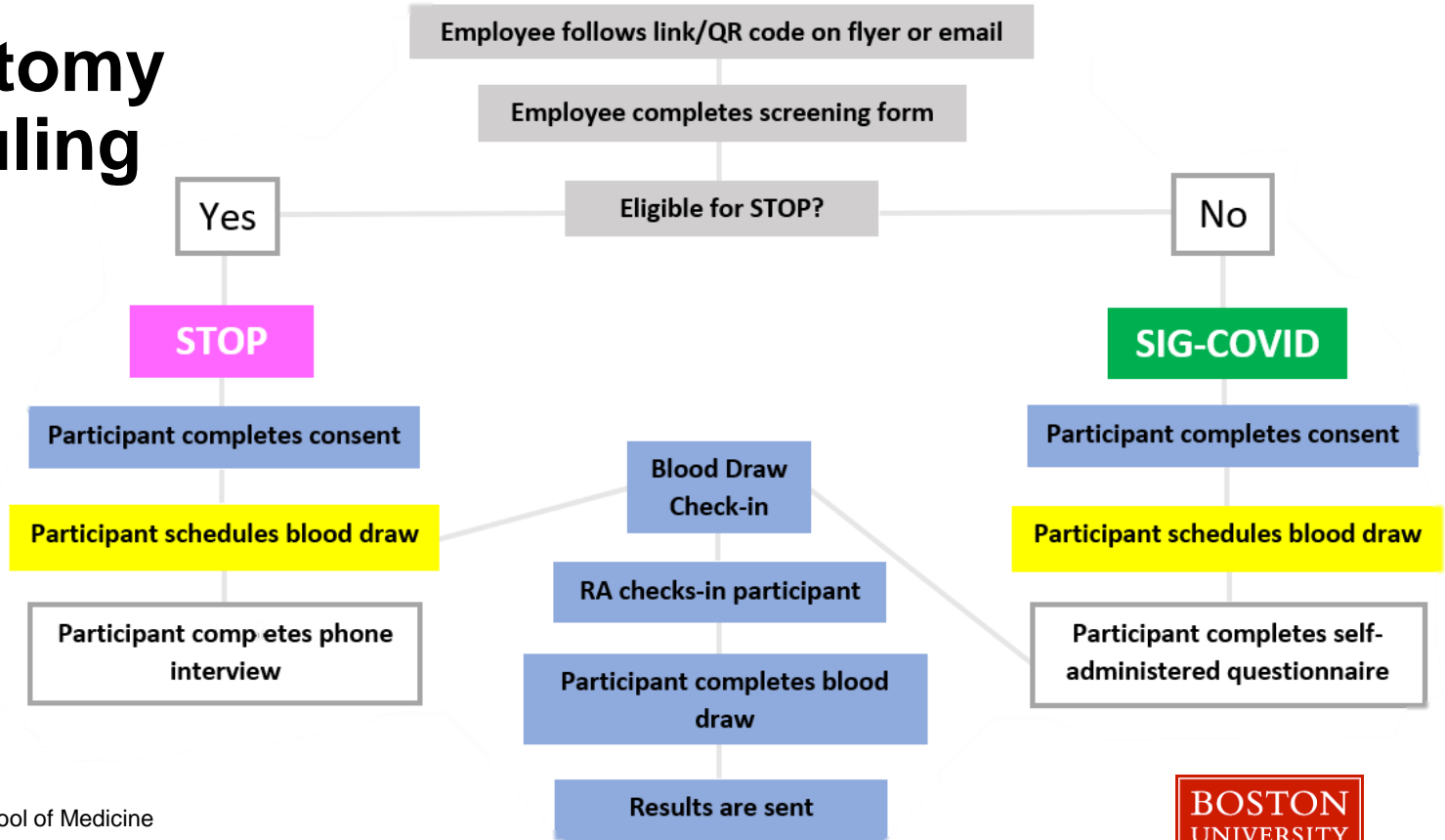
Show the field ONLY if...

[assigned_study]='2' and [language]='1'

[Clear logic](#)

Test logic with a record: -- select record -- ▾

Phlebotomy Scheduling



Phlebotomy Scheduling

- Drop-down to select a two-hour time slot
- Used response limit to set maximum number of blood draws scheduled for each two-hour period
- Confirmation email sent from REDCap with selected time

Current instrument: **Scheduling** Preview instrument

Add Field Add Matrix of Fields

Variable: time_option

Select slot option
* must provide value

Add Field Add Matrix

- Monday, July 13, 2020 6-8am
- Monday, July 13, 2020 8-10am
- Monday, July 13, 2020 10am-12pm
- Monday, July 13, 2020 12-2pm
- Monday, July 13, 2020 2-4pm
- Monday, July 13, 2020 4-6pm
- Tuesday, July 14, 2020 6-8am
- Tuesday, July 14, 2020 8-10am

Send confirmation email (optional)?
(Email the respondent when they complete the survey) Yes

Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. [How to use Piping here](#)

From: covid19study@bmc.org

Subject: Blood draw time

Compose Preview Send test email

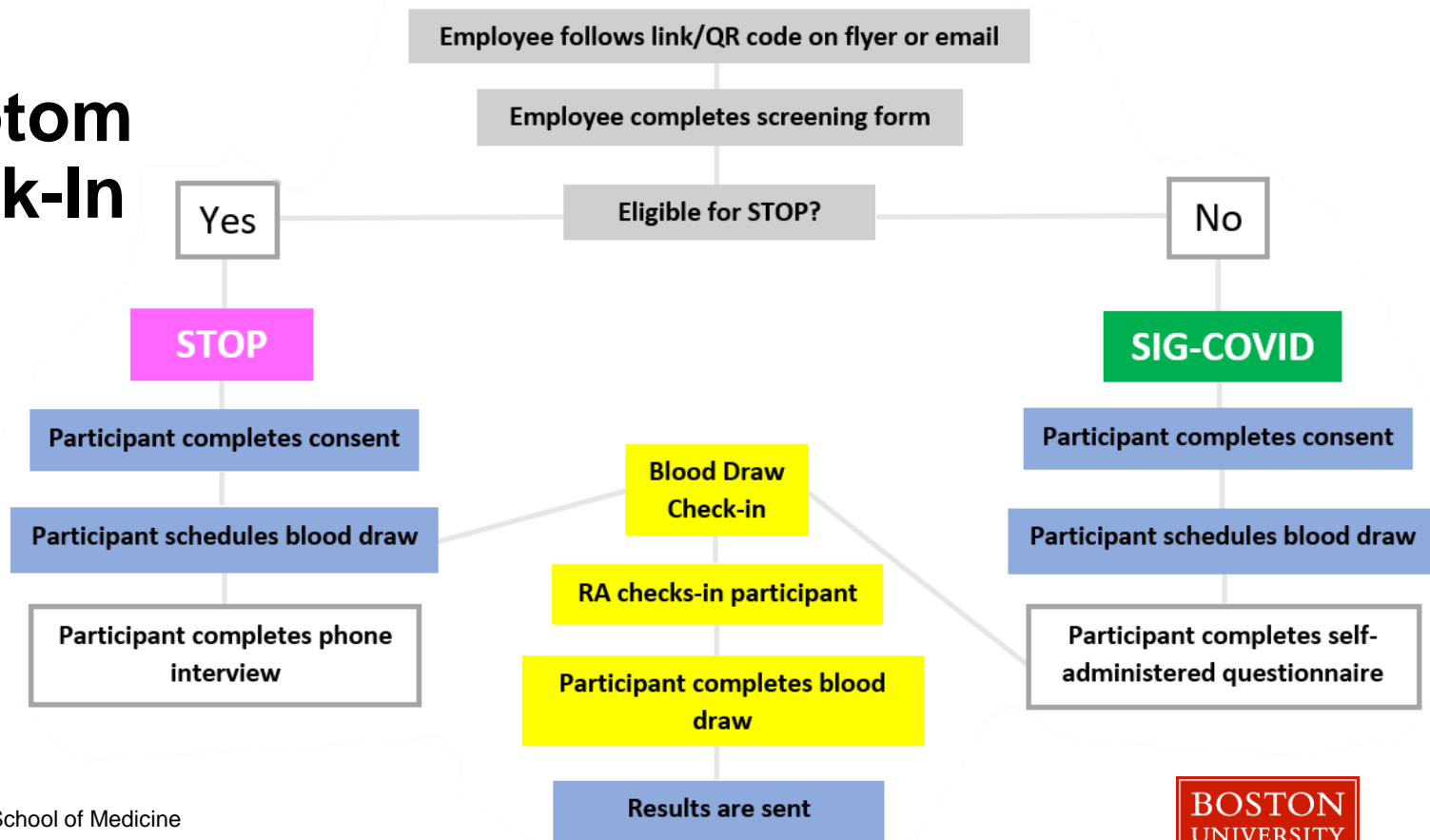
Hello [name_first],
You have chosen [time_option] for your study blood draw. The blood draw will take place in Shapiro 5C. Please arrive within that 2 hour block. You will be checked in by a research assistant and called in by the next available phlebotomist.

Attachment: Choose File No file chosen Expand

Include PDF of completed survey as attachment

WARNING: Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PHI).

Phlebotomy Check-In



Phlebotomy Check-in

- RA searched for participant by last name using REDCap report
- Specimen ID used as secondary identifier to distinguish between the two studies (e.g. STOP-001 or SIGC-001)
- Name and chosen time slot piped into form
- Color of study name text matched color of requisition forms

The screenshot displays a REDCap form interface with three sections, each with 'Add Field' and 'Add Matrix of Fields' buttons at the top.

- Section 1:** Variable: id. Field: Specimen ID.
- Section 2:** Variable: blood_draw_checkin_2. Field: Date. Includes a 'Now' button and 'M-D-Y H:M' format indicator.
- Section 3:** Variable: blood_draw_stop. Branching logic: [assigned_study]=1. Content: 'This participant is enrolled in: STOP'. Fields: Name: [name_first] [name_last], Time Slot: [time_option].
- Section 4:** Variable: blood_draw_sigcovid. Branching logic: [assigned_study]=2 and [language]=1. Content: 'This participant is enrolled in: SIG-COVID'. Fields: Name: [name_first] [name_last], Date of Birth: [dob], Consent for purple top?: [sigcovid_dna], Time slot: [time_option].

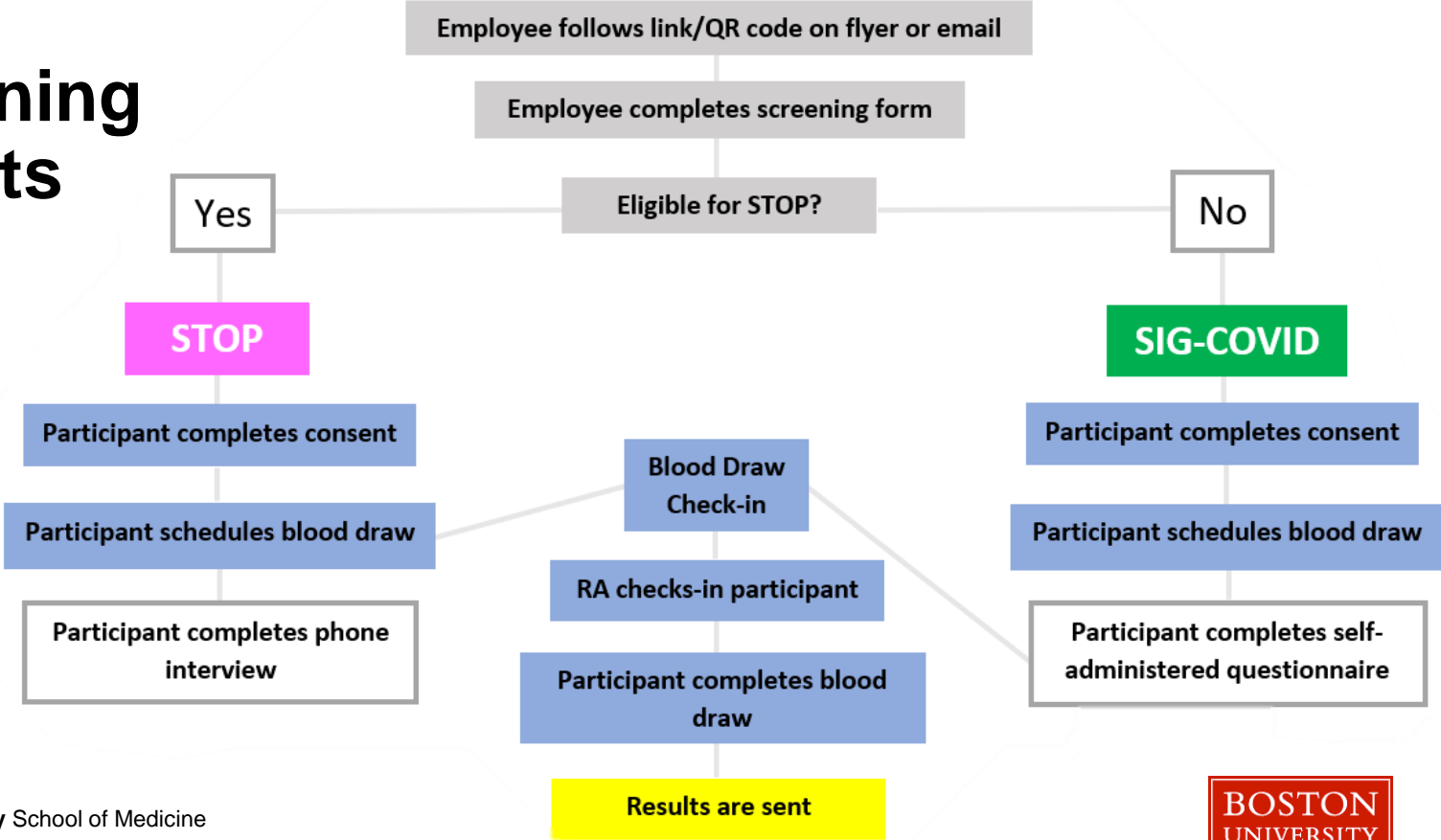
Phlebotomy Check-in

- Branching logic used to alert RA to any incomplete forms
- Participants were instructed to complete forms before returning for blood draw
- When all required forms were complete, the RA would see a message that participant is eligible for blood draw (top)

The screenshot displays a branching logic interface with four messages, each with its own variable and branching logic:

- Message 1 (Green):** "This participant is eligible to receive their blood draw." Variable: `blood_draw_eligible`. Branching logic: `((assigned_study)=1 and [brief_screening_agreement_complete]=2 ...)`
- Message 2 (Red):** "This participant is not yet eligible to receive their blood draw. The screening form is incomplete." Variable: `blood_draw_no_screen`. Branching logic: `[brief_screening_agreement_complete] != 2`
- Message 3 (Red):** "This participant is not yet eligible to receive their blood draw. The consent form is incomplete." Variable: `blood_draw_no_consent`. Branching logic: `[consent_form_complete] != 2`
- Message 4 (Red):** "This participant is not yet eligible to receive their blood draw. The Symptom Screen and Medical History Survey is incomplete." Variable: `blood_draw_no_survey`. Branching logic: `[assigned_study]=2 and ([symptom_screen_and_medical_history_sur...`

Returning Results



Returning Results

- Uploading Results
 - Results data imported using Data Import tool
 - Lab data was uploaded to a serology results form, then the interpretation field was piped into a survey which participants could access
 - Survey included information on the test and how to interpret results

The screenshot displays a survey interface with four main sections, each with a yellow background and a grey header bar containing 'Add Field' and 'Add Matrix of Fields' buttons. The first section is titled 'Your Result' and contains a grey box with the text '[name_first] [name_last]' and 'Result Interpretation: [interpretation]'. The second section asks 'What is the SARS-CoV-2 IgG assay?' and contains a grey box with the text 'The test is designed to detect antibodies in a blood sample that would indicate that you may have current or prior COVID-19 infection.' The third section asks 'What does it mean if I have a negative test result?' and is currently empty.

Returning Results

- Dissemination of Results (STOP)
 - Alert created to automatically send results link if serology results were uploaded and questionnaire was complete

Title of this alert:

STEP 1: Triggering the Alert

How will this alert be triggered?

When a record is saved on a specific form/survey*

When a record is saved on a specific form/survey with conditional logic*

Using conditional logic during a data import or data entry

Trigger the alert...

when (excludes data imports)

while the following logic is true:

```
[assigned_study] = '1' and [interpretation_stop] <> "" and [stop_esp_nosuccess] = ""
```

STEP 3: Message Settings

Email From:

* must provide value

Email To:

* must provide value

+ [Show more options](#)

Or manually enter emails:

Subject:

* must provide value

Message:

* must provide value

Paragraph

B

I

A

A

Prevent piping of data for Identifier fields

Please use the link below to view your results to your COVID-19 antibody test:
[survey-link:stop_return_of_results]

If the link above does not work, try copying the link below into your web browser:
[survey-url:stop_return_of_results]

If you would like to have a PDF copy of the results, please hit submit at the end of the survey page and you will have the option to download a PDF copy

In the subject or message, you may use Piping and Smart Variables

Example: Hi [first_name]! Please complete this survey: [survey-link:followup_survey]

Thank you!

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