MONTHLY INVESTIGATOR MEETING

9/19/2024

COLUMBIA | COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Agenda

- Introduction
- Overview of Projects (Background, Introduction, Methods, Results)
  - Renewals Submitted In Calendar Year 2022
  - QA/QI Interviews for Renewal Submissions
- Preventive Action Plans

Overview of Renewals Submitted in Calendar Year 2022

- Background:
  - Renewal submissions across Columbia University (CU) that are not submitted in a timely manner cause disruptions to the HRPO workflow processes because they are prioritized to avoid lapses in Institutional Review Board (IRB) approval.

Introduction

- The Columbia IRBs received 4,327 submissions in calendar year 2022 of Renewals and Annual Reports.
- This presentation focuses on data for the subset of 3,055 that are Renewals, because failure to obtain approval for them will result in a lapse in IRB approval.
- Although failure to obtain approval for an Annual Report will appear in Rascal as a lapse in IRB approval, it is not, from a regulatory perspective, because Annual Reports are only permitted for studies for which the regulatory requirement for continuing review is eliminated.

Introduction

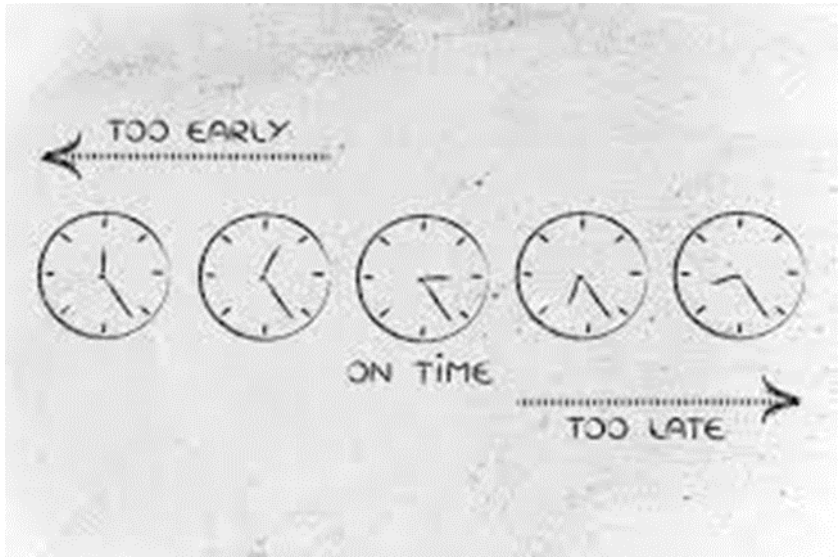
- Data for renewals processed by facilitative review were not included in this analysis.
- This presentation covers renewals for Columbia-only studies and for studies for which Columbia served as Reviewing IRB for other institutions.
- The purpose of this project was to identify the number and percentage of renewals submitted for each submission interval to IRBs 1-5 and to the Expedited, Admin, and Morningside committees during calendar year 2022.

Methods

- The status of submission groups for IRBs 1-5 renewals were designated by the following time intervals:
  - Early is greater than 90 calendar days before expiration,
  - On time is between 61 to 90 calendar days before expiration
  - Late is between 31 to 60 calendar days before expiration
  - Very late is between 1 to 30 calendar days before expiration
  - On day of expiration is 0 calendar days before expiration
  - After expiration is between 1 to 30 calendar days after expiration
  - Long after expiration is 31 calendar days or more after expiration.

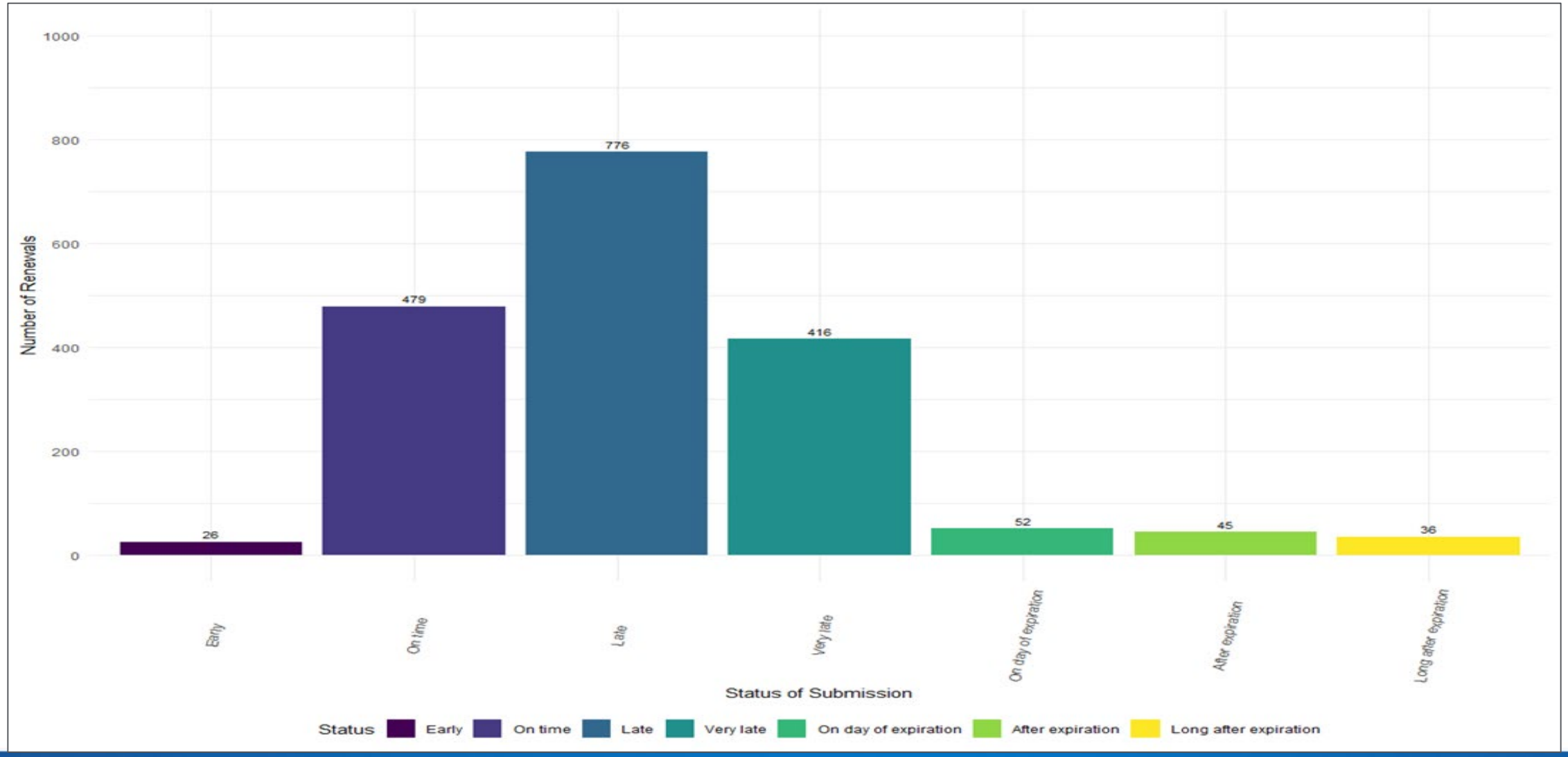
Methods

- The status of submission groups for the Expedited, Admin, and Morningside renewals were designated by the following time intervals:
  - Early is greater than 60 calendar days before expiration
  - On time is between 31 to 60 calendar days before expiration
  - Late is between 1 to 30 calendar days before expiration
  - On day of expiration is 0 calendar days before expiration
  - After expiration is between 1 to 30 calendar days after expiration
  - Long after expiration is 31 calendar days or more after expiration.



Results

Figure 1. IRB 1-5 Renewals By Status of Submission in Calendar Year 2022



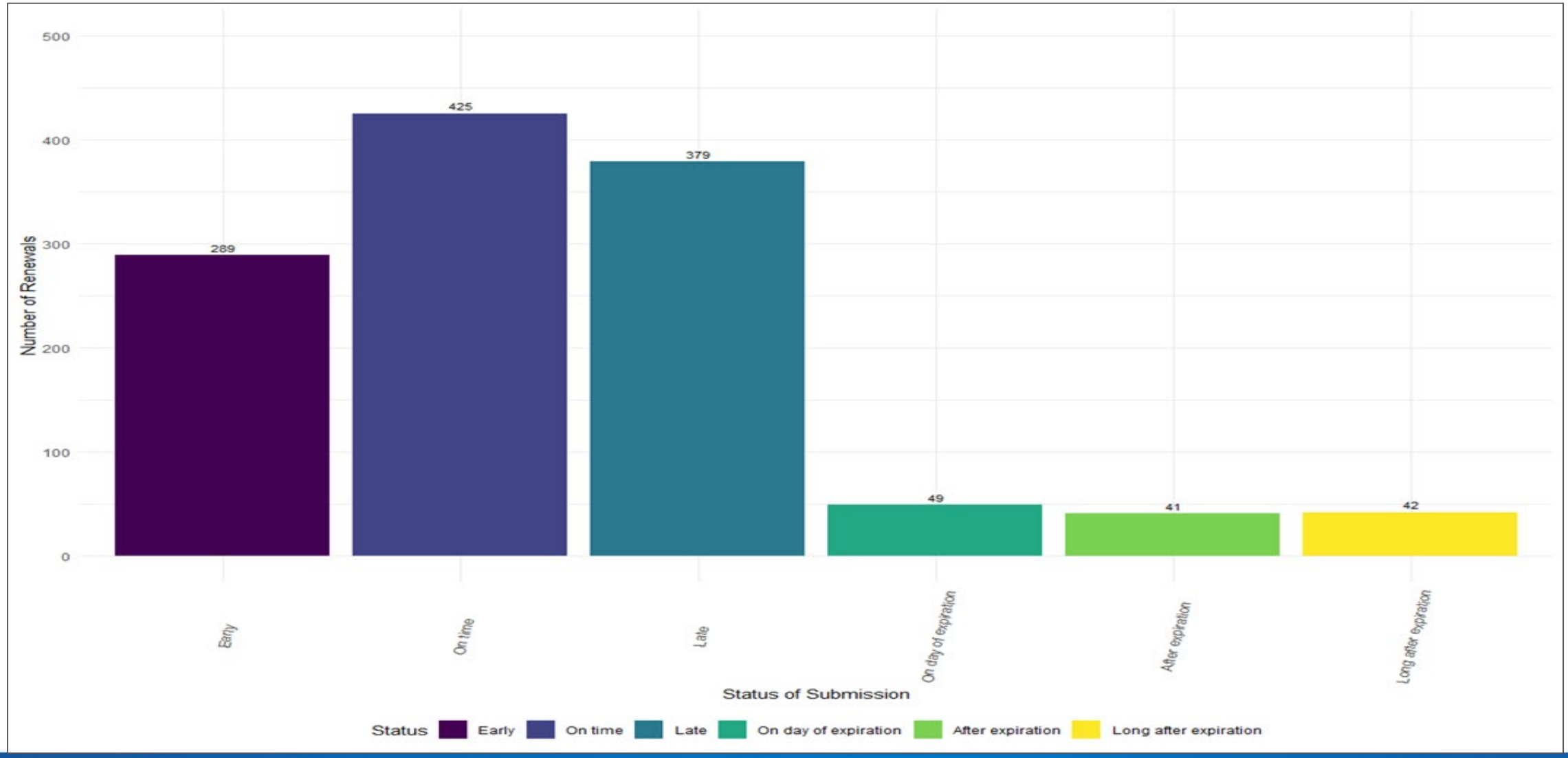
Results

Table 1. Descriptive Statistics for IRB 1-5 Renewals By Status of Submission in Calendar Year 2022

Status	Count	Percent	Total	Mean	Median	Standard Deviation	Minimum	Maximum
Early	26	1.42	1830	121.12	105.0	51.58	91	343
On time	479	26.17	1830	72.57	70.0	8.99	61	90
Late	776	42.40	1830	46.97	48.0	8.54	31	60
Very late	416	22.73	1830	20.10	21.0	8.17	1	30
On day of expiration	52	2.84	1830	0.00	0.0	0.00	0	0
After expiration	45	2.46	1830	-10.82	-8.0	7.90	-29	-1
Long after expiration	36	1.97	1830	-322.69	-113.5	605.94	-2867	-33

Results

Figure 2. Expedited, Admin, And Morningside Renewals By Status Of Submission In Calendar Year 2022



Results

Table 2. Descriptive Statistics for Expedited, Admin, And Morningside Renewals By Status Of Submission In Calendar Year 2022

Status	Count	Percent	Total	Mean	Median	Standard Deviation	Minimum	Maximum
Early	289	23.59	1225	79.08	77	21.92	61	345
On time	425	34.69	1225	46.28	47	9.12	31	60
Late	379	30.94	1225	18.41	20	8.56	1	30
On day of expiration	49	4.00	1225	0.00	0	0.00	0	0
After expiration	41	3.35	1225	-10.44	-6	9.14	-29	-1
Long after expiration	42	3.43	1225	-311.14	-187	362.41	-1520	-33

Overview of QA/QI Interviews for Renewal Submissions

- Background:
  - Quality assurance and quality improvement (QA/QI) interviews were conducted in early 2024 as a response to the portion of renewals that were submitted late to IRBs 1-5 and the Expedited, Administrative, or Morningside teams during calendar year 2022.

Introduction

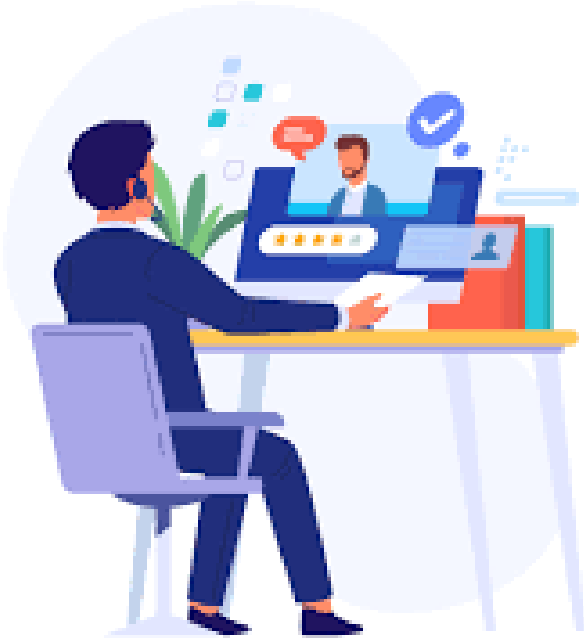
- QA/QI interviews were performed to gain a better understanding of why renewals are submitted late within Rascal.
- These interviews were also implemented to comprehend how the current process can be improved to allow for efficient renewal submissions within Rascal and minimize the number of renewal submissions that are submitted late.
- This presentation provides a synopsis of the QA/QI interviews that were held for 7 Principal Investigators (PIs) and 9 research staff (RS) with varying titles across CU during January and February 2024 regarding the current Rascal renewal submission process and how it can be improved.

Methods

- The PIs and RS were selected based on the following criteria:
  - Being a PI or RS member for the most renewals that were submitted either on time or late and were either assigned to IRBs 1-5 or the Expedited, Administrative, or Morningside teams during calendar year 2022.
- 7 PIs and 9 RS members were interviewed

Methods

- Interviews were held virtually and were conducted during January and February 2024.
- All of the interviewees were asked the same interview questions.



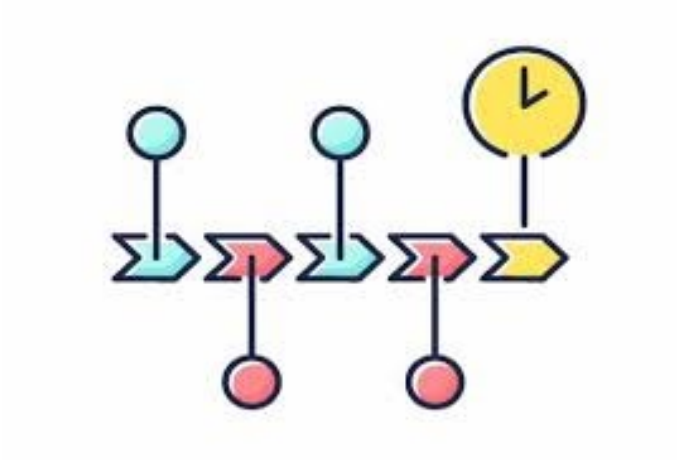
Results

- At what point do you generally start the renewal process?
  - Most of the PIs did not know when the renewal process starts for their studies.

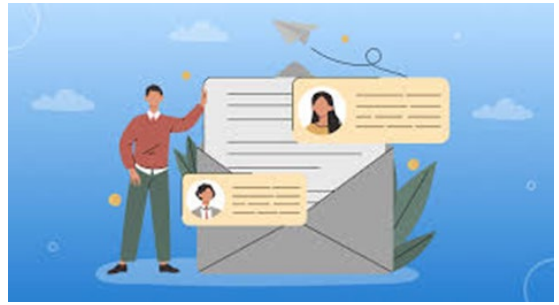
- In your experience, is there anything about the renewal submission process that is particularly helpful to you?
  - For PIs:
    - Rascal-generated emails
    - Timelines are clear
    - Information that is being requested is clear
  - For RS:
    - Using Rascal to check statuses to keep track of timelines
    - All the pages within the renewal submission, except the subjects page, being copied from the previous approved event.

Results

- In your experience, what are challenges that you have faced in regard to the renewal submission process?
  - For PIs:
    - Projecting how many subjects are going to be accrued in the following year.
    - Keeping track of the Rascal-generated emails.
    - Completing renewals for studies where not much has changed.
    - Volume of renewals that need to be submitted.
  - For RS:
    - Working with modifications that are submitted before the renewal
    - Not having documents stamped when a renewal is approved
    - Not knowing the status of the renewal submission
    - Renewal being returned for something that could have been clarified in an email
    - Differentiating between a renewal and an annual report.



Results



- What recommendations do you have for the HRPO/IRBs for improving the renewal submission process?
  - For PIs:
    - Providing renewal for more than one year for protocols that are minimal risk
    - Two emails should be sent to the PIs and research staff as reminders of the expiration of the renewal
    - Having more transparency on timing of the renewal process.
  - For RS:
    - Renewal documents being stamped at the time of approval
    - Instructions with screenshots should be provided to researchers to access study trainings
    - HRPO staff should reach out to the submitter directly as opposed to returning a renewal
    - Being able to add personnel to the renewal
    - Rascal sending automated email reminders more than 60 days before the renewal expires.

Results

- Can you share any best practices or tips that have worked well for you and could help other study teams in the renewal submission process?
  - For PIs:
    - Having great regulatory and research coordinators and retaining them.
    - Starting the renewal submission process early.
    - Having a generalized time frame for the process.
  - For RS:
    - Keeping the expiration date of the renewal in mind
    - Reviewing the renewals before submitting them
    - Working with the IRB Managers
    - Submitting the renewal as soon as possible to avoid delays caused by approving the renewal
    - Starting renewals 90 days before they expire to allow yourself time to request the required information and contact the HRPO staff if you have any questions

Preventive Action Plans

- Re-training of staff on stamping of documents and reasons for returns
- Development of Renewal and Annual Report FAQs
  - https://research.columbia.edu/maintaining-irb-approval#!#RenewalsandARs
- Revisions to Annual Report and Renewal Rascal Workshops to incorporate feedback from interviews
  - Reminder: This workshop is scheduled for Mon, Oct 28, 2024 3:00 PM - 4:00 PM
- Further information on differences between Renewals and Annual Reports was included in the HRPO December Newsletter

Preventive Action Plans – Rascal Changes

- Pop-up notifications in Rascal:
  - Proposal #1: Researchers to receive a pop-up notification in Rascal when a modification is submitted within 30/60 days of a Renewal with notification of expiration date and recommendation to submit the modification within the Renewal
    - **Estimated completion: November 2024**
  - Proposal #2: Pop-up notification to HRPO staff prior to logging in an event alerting them to documents that may have been missed as needing to be stamped during HRPO review process
    - **Estimated completion: December 2024**
- Ancillary Reviews Status Box

Preventive Action Plans – Rascal Changes

- Personnel Change Module:
  - Phase 1: Rascal warning prior to submitting if any research personnel listed in the IRB protocol have not completed all required trainings
    - **Completed as of March 2024**
  - Phase 2: Separate modification event type solely for adding and removing personnel. These events can be automatically approved in Rascal as long as all training requirements from personnel have been met
    - **Estimated Completion: Testing to begin late September/early October with anticipated rollout by end of 2024**

Interviews – Common Questions & Misinformation

- Request by researchers for more than one year be provided for studies that are minimal risk
  - **Clarification:** "An IRB must conduct continuing review of research at intervals appropriate to the degree of risk, **but not less than once per year** (45 CFR 46.109(e))."
- Request by researchers for multiple Rascal-generated emails be sent to the PIs and research staff as reminders of the expiration of the renewal
  - **Clarification:** This is already happening at 90, 60, 30 days before expiration and upon expiration. Confirmed with the Rascal team that these are received by: PI, Initiator, and Coordinator(s).
- Researchers communicated a challenge with the renewal submission process is not knowing the status of the renewal submission
  - **Clarification:** several statuses in Rascal are provided – submitted, logged in, returned, distributed, assigned to meeting, pending. These can be found in the "History" page.

Interviews – Common Questions & Misinformation (continued)

- A PI also stated another challenge with the renewal submission process is if there is an expedited modification and the renewal requires an IRB meeting then the renewal submission becomes delayed.
  - **Clarification:** An expedited modification would not delay a renewal submission. However, if a renewal that would otherwise be eligible for expedited review procedures includes a substantive modification requiring review at a convened meeting, then the renewal review/approval can take longer as it would now require review at a convened meeting.
- Researchers commented on Renewals being returned for something that could have been clarified:
  - **Clarification:** this is something that HRPO staff are actively working on; please note that many times, staff request clarifications via correspondence, however no response is received. Please monitor your correspondence notifications.

Interviews – Common Questions & Misinformation (continued)

- Some of the PI's did not know when the renewal process starts for their renewals
  - **Clarification:** Determination letters remind researchers "Renewal applications should be submitted 60 days (30 days for studies assigned to IRB Exp) before the expiration date of this study through Rascal…" Thus, the renewal application should be started prior to that in order to have the renewal application ready for submission within the 60 (or 30) days prior to expiration.

Rascal Screenshots (Renewal)

Legacy Protoc

Study Summary

Event	Creation Date	Initiator	Identifier/Summary	Status	IRB Ap
Closure	12/06/2016	Yaritza Collazo (yr111)	IRB#3 Testing	Distributed	
Modification (Y02M01)	12/18/2015	Yaritza Collazo (yr111)	IRB#3 Testing	Withdrawn	
LAPSE OCCURRED 12/17/2016 TO 09/16/2024					
Renewal (Y02M00)	11/16/2015	Yaritza Collazo (yr111)	IRB#3 Testing	Expired	12/18/20
Protocol (Y01M00)	08/03/2015	Yaritza Collazo (yr111)	IRB#4 Testing: Docs & Stamping	Approved	08/03/20

Suspend Protocol to all study-related activities
Suspend Protocol to new enrollment
Pause of In-Person Procedures for COVID-19
Modified Procedures for COVID-19

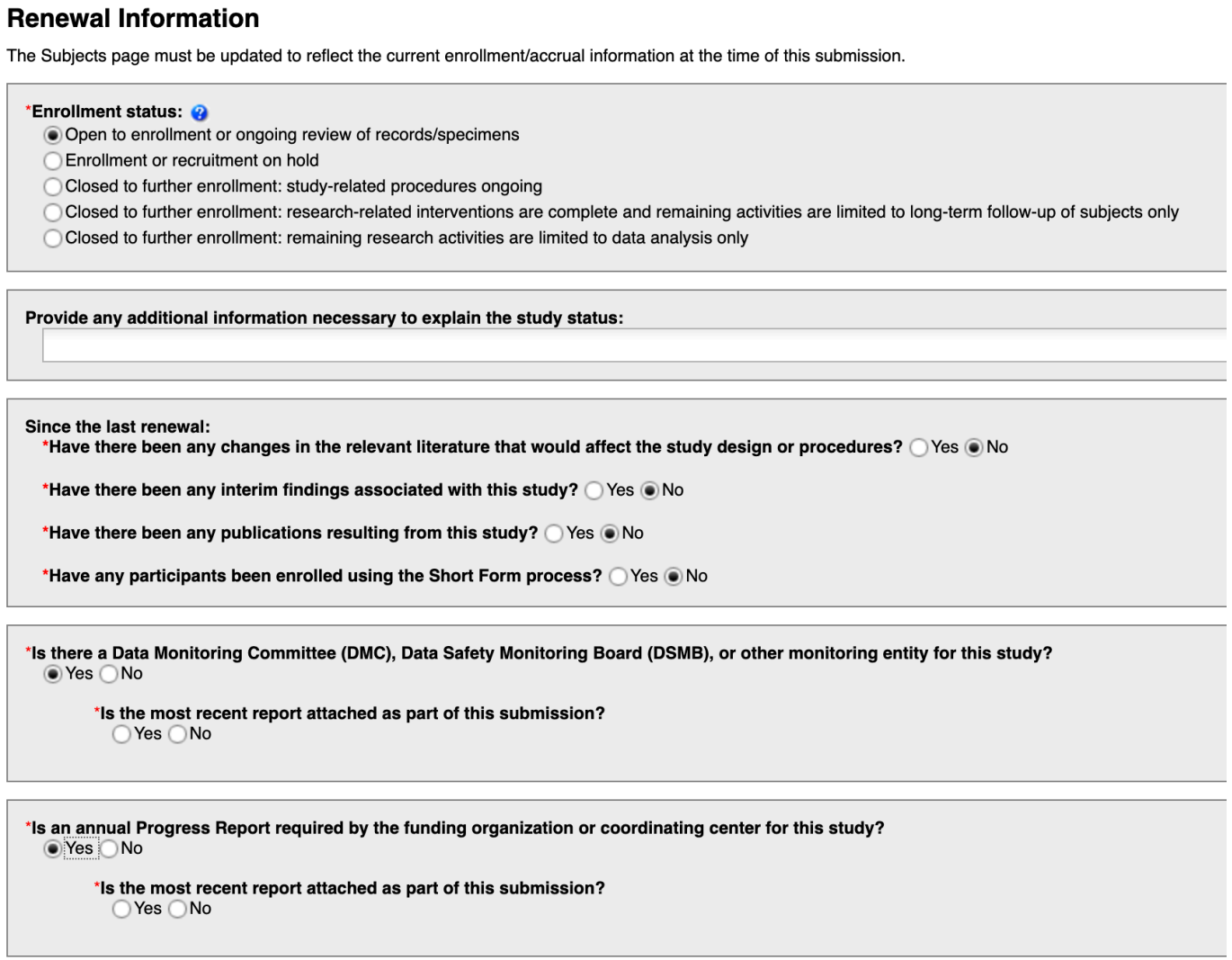
User	Suspend Type
No data to d	

- Create Modification
- Create Renewal
- Create Unanticipated Problem Report
- Create Closure Report
- Create Admin Closure Report

Protocol Content
- General Information
- Renewal Information
- Attributes
- Background
- Exempt and Expedited
- Funding
- Locations
- Personnel
  - Departmental Approvers
- Privacy & Data Security
- Procedures
  - Biological Specimens
  - Devices
  - Drugs/Biologics
  - Future Use
  - Imaging/Radiation
- Recruitment And Consent
- Research Aims & Abstracts
- Risks, Benefits & Monitoring
- Subjects
  - Child Involvement

Attachments
- Hazmats
- HIPAA Forms
- Documents

Rascal Screenshots (Renewal)



Renewal Information

The Subjects page must be updated to reflect the current enrollment/accrual information at the time of this submission.

*Enrollment status:

- (•) Open to enrollment or ongoing review of records/specimens
- ( ) Enrollment or recruitment on hold
- ( ) Closed to further enrollment: study-related procedures ongoing
- ( ) Closed to further enrollment: research-related interventions are complete and remaining activities are limited to long-term follow-up of subjects only
- ( ) Closed to further enrollment: remaining research activities are limited to data analysis only

Provide any additional information necessary to explain the study status:

Since the last renewal:

*Have there been any changes in the relevant literature that would affect the study design or procedures? ( ) Yes (•) No

*Have there been any interim findings associated with this study? ( ) Yes (•) No

*Have there been any publications resulting from this study? ( ) Yes (•) No

*Have any participants been enrolled using the Short Form process? ( ) Yes (•) No

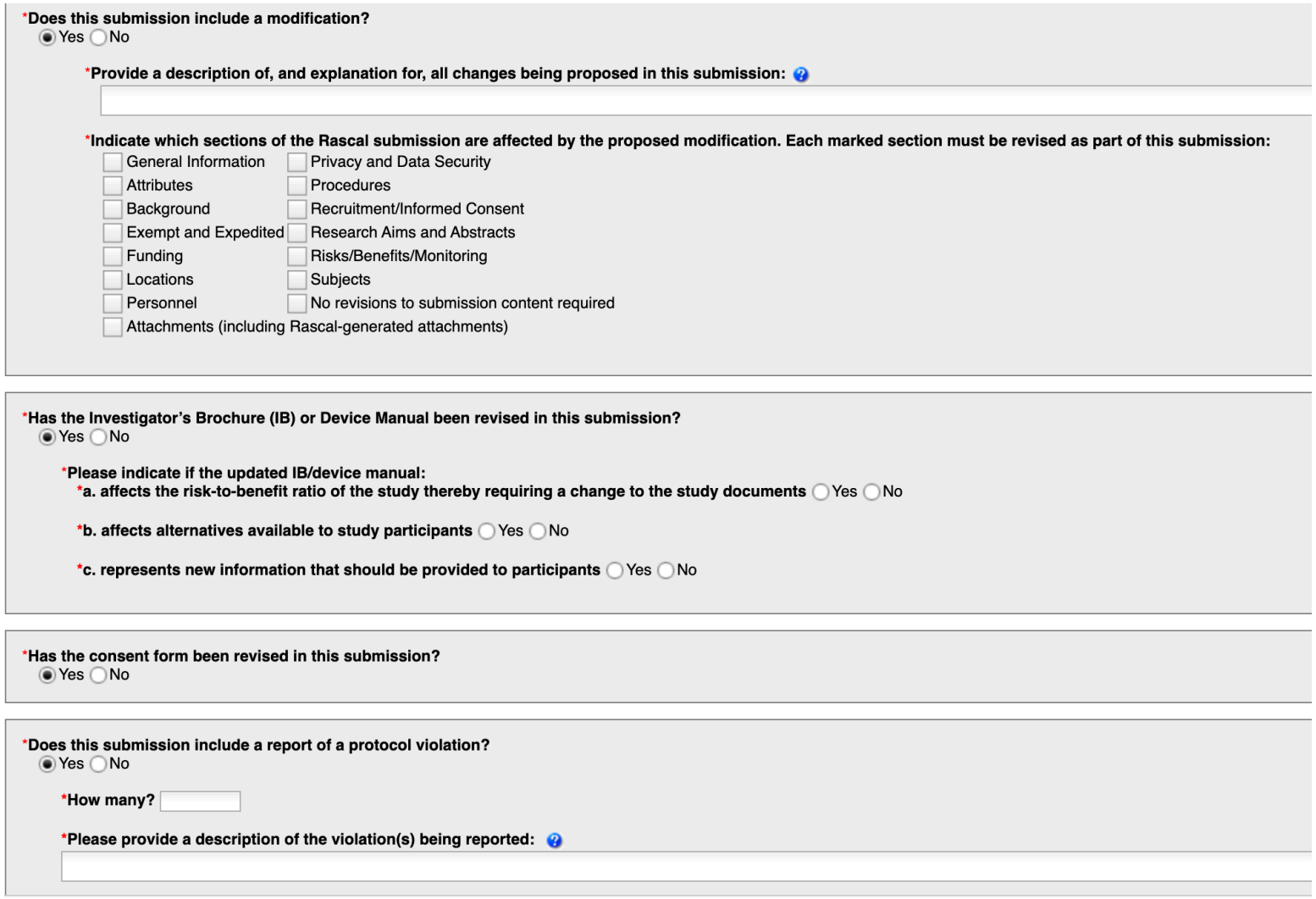
*Is there a Data Monitoring Committee (DMC), Data Safety Monitoring Board (DSMB), or other monitoring entity for this study?
(•) Yes ( ) No

*Is the most recent report attached as part of this submission?
( ) Yes ( ) No

*Is an annual Progress Report required by the funding organization or coordinating center for this study?
(•) Yes ( ) No

*Is the most recent report attached as part of this submission?
( ) Yes ( ) No

Rascal Screenshots (Renewal)



Rascal Screenshots (Renewal)

Subjects

Unless otherwise noted, the information entered in this section should reflect the number of subjects enrolled or accrued under the purview of Columbia researchers, whether at Columbia or elsewhere. Definitions for Subjects, Enrollment, and Accrual can be found in the Help Text.

*Target enrollment:	10
*Number enrolled to date:	8
*Number enrolled since the last renewal or, if there has not been a renewal, since the initial approval:	2
*Number anticipated to be enrolled in the next approval period:	10

*Does this study involve screening/assessment procedures to determine subject eligibility?

(•) Yes ( ) No

*Target accrual:	8
*Number accrued to date:	4
*Number accrued since the last renewal or, if this is the first renewal, since the initial approval:	2
*Number anticipated to be accrued in the next approval period:	1

Rascal Screenshots (Renewal)

*Of the number of subjects enrolled, or the number accrued for interventional studies with a screening process:

*How many remain on the study? 2

*How many are off study? 1

(Note: The total number 'off study' will be automatically calculated based on your answers to each item below.)

*How many completed the study? 1

*Have any withdrawn of their own initiative?
Yes No

*Have any been removed by PI?
Yes No

*Have any been lost to follow-up?
Yes No

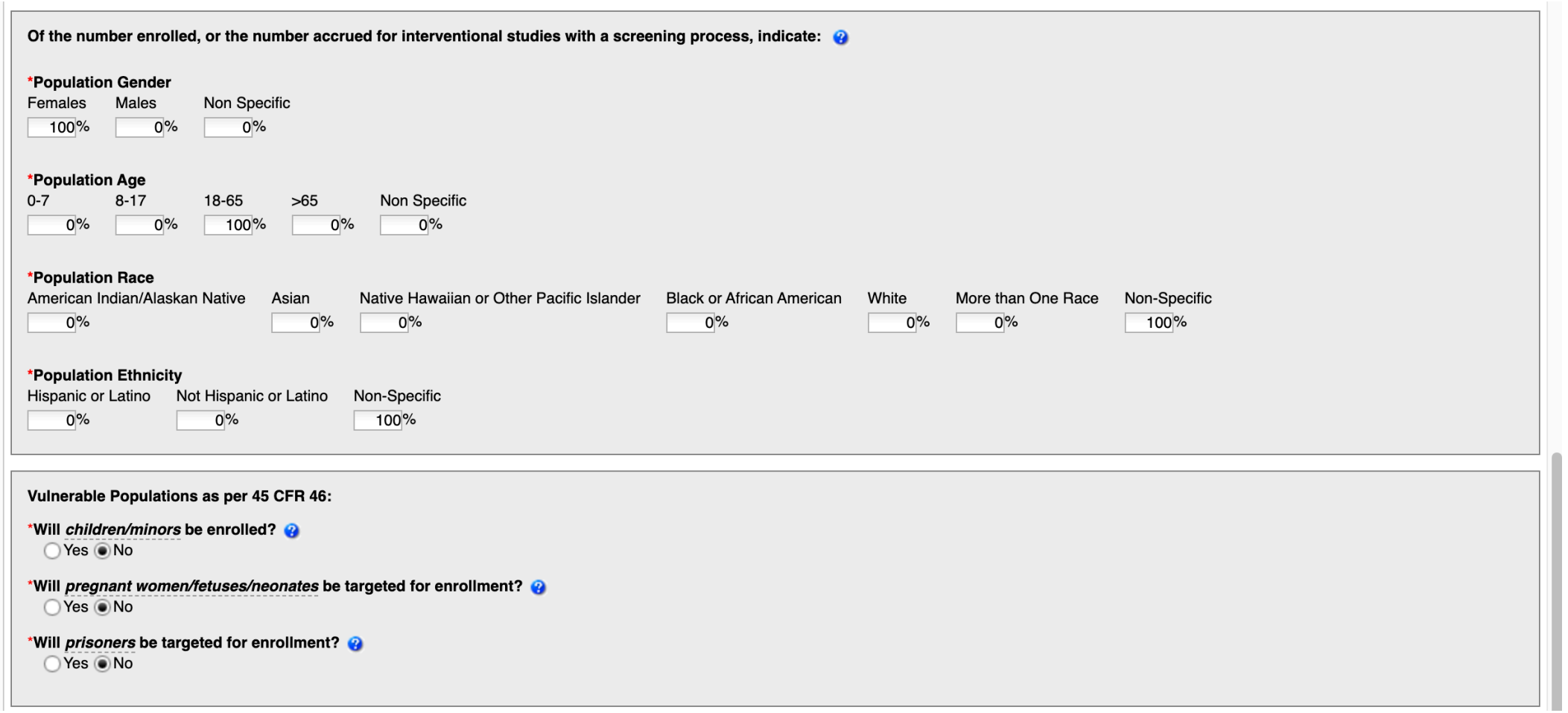
*Have any died while on study?
Yes No

*Have any subject complaints been received?
Yes No

*Is this a multi-center study?
(Note: This question and the answer displayed below are on the Attributes page and may not be changed here. Display only.)
Yes

*Target number of eligible subjects to be included at all sites: 10

Rascal Screenshots (Renewal)



Of the number enrolled, or the number accrued for interventional studies with a screening process, indicate:

***Population Gender**

Females	Males	Non Specific
100%	0%	0%

***Population Age**

0-7	8-17	18-65	>65	Non Specific
0%	0%	100%	0%	0%

***Population Race**

American Indian/Alaskan Native	Asian	Native Hawaiian or Other Pacific Islander	Black or African American	White	More than One Race	Non-Specific
0%	0%	0%	0%	0%	0%	100%

***Population Ethnicity**

Hispanic or Latino	Not Hispanic or Latino	Non-Specific
0%	0%	100%

Vulnerable Populations as per 45 CFR 46:

***Will *children/minors* be enrolled?**
Yes (○) No (◉)

***Will *pregnant women/fetuses/neonates* be targeted for enrollment?**
Yes (○) No (◉)

***Will *prisoners* be targeted for enrollment?**
Yes (○) No (◉)