REDCap Grand Rounds: From Users Like You 1.0

Data/Specimen Requests and Approval Workflow

The James

THE OHIO STATE UNIVERSITY
COMPREHENSIVE CANCER CENTER

Total Cancer Care Protocol

Total Cancer Care: *A lifetime partnership with patients of the James*

Lifetime consent

Identify & recontact patients

Access to medical information

Genomic testing

Commercialization

Collect, store and distribute biospecimens

Over 69,000 patients consented to TCC

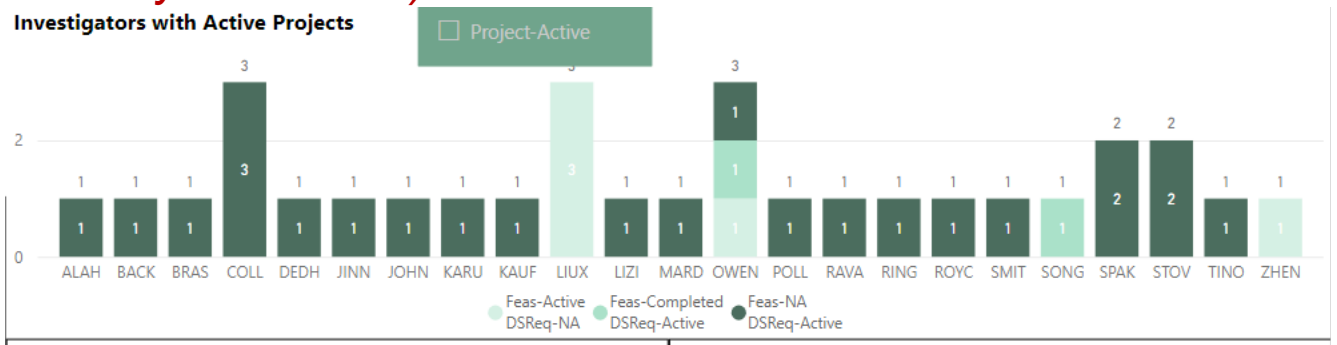
TCCP Data & Specimen Request Database
(background and requirements)

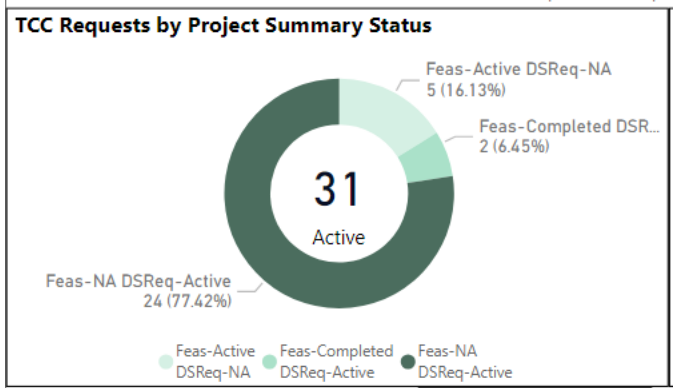
- Requests historically tracked in eRAMP (billing system)
- Our needs: *eliminate manual emails for process standards*
  - Capture additional details in the initial request
  - Link feasibility requests with data/specimen requests
  - Integrate with other REDCap databases
  - Automate some of the process…
    - Agreements
    - Approvals
    - Outcomes surveys
- Enhancements
  - Metrics/reporting (SQL)
    - Manually tracked/managed on spreadsheets → reports created in SQL to help manage the process
      - Due to the number of tables in this database, SQL became essential to pulling together the data
  - Dashboarding
    - Manually created graphs/metrics → automated updates to PowerBI dashboards (via SQL)
  - Visibility for the requesters/investigators

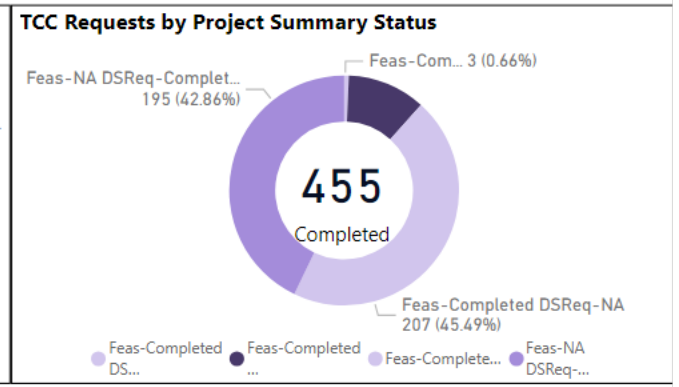
Know what you need to track

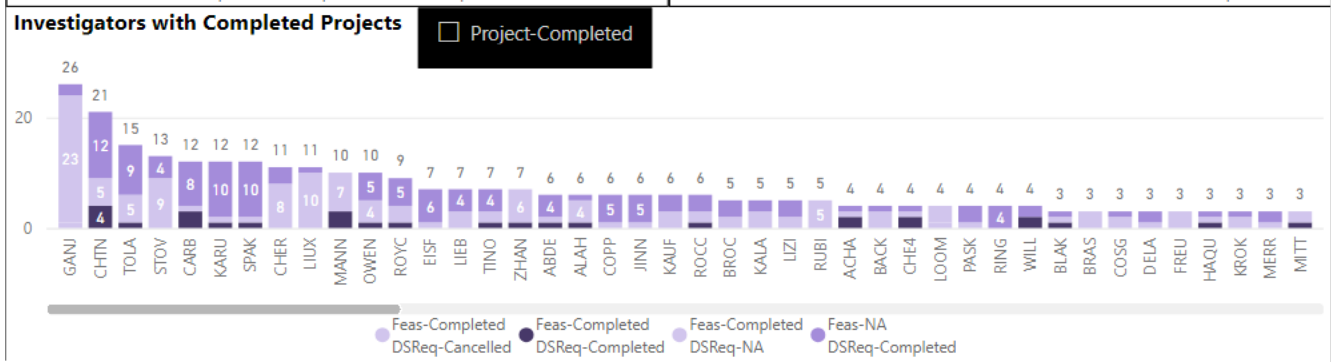
(discretely capture with additional fields instead of summary text boxes)

- Project counts
  - Feasibility, data/specimen, both
  - Deidentified, coded-limited, IRB approved
- Project Status
- Disease groups of interest
  - Breast, colorectal, thoracic, etc.
- Specimen types
  - Frozen tissue, blood DNA, plasma/serum, etc.
- Investigators/departments/programs
- TCC Patient counts
  - Screened
  - Final counts









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Comprehensive Cancer Center

Instruments, Events and Survey Settings

(33 instruments, 5 events, 28 enabled as surveys)

Initial Request

[initial_request_arm_1]

Request

completed by requester (https://go.osu.edu/osutcc)

Instrument name	Fields	View PDF	Enabled as survey
TCC Project Form	82		
Feasibility Form	33		
Data/Specimen Form	120		

Agreements

completed by investigator for data/specimen requests

TCC Investigator Agreement (De-identified)	11		
TCC Investigator Agreement (Identified)	11		
TCC Data Use Agreement	11		

Dashboard

viewable by requester/investigator

TCC Project Status Dashboards	13		
Admin	2		Enable

Project Survey

[project_survey_arm_1]

Project Outcomes Survey

completed by requester/investigator

Data/Specimen Survey	29		

Project Status

[project_status_arm_1]

Timeline Log

updated by TCC Admins

Project Timeline	5		Enable

Internal Review

[internal_review_arm_1]

Internal Review/Project Plan

completed by TCC Admins

Feasibility TCC Internal Review	3		Enable
Data/Specimen TCC Internal Review	9		Enable

Database set up as **longitudinal** to allow us to automate some of the process

Committee Approval

[committee_approval_arm_1]

Approvals

completed by committee members and disease group leader(s)

TCC Research Committee Approval	72		
PI/Director Review	62		
TCC Review Member #1	68		
TCC Review Member #2	68		
TCC Review Member #3	68		
TCC Review Member #4	68		
AL MDS Approval	68		
BMT Approval	68		
Breast Approval	68		
CLL Approval	68		
CNS Approval	68		
GI Approval	68		
GU Approval	68		
Gynecologic Approval	68		
HN Approval	68		
Lymphoma Approval	68		
Melanoma Approval	68		
MM Approval	68		
Sarcoma Approval	68		
Thoracic/Lung Approval	68		
Thyroid Approval	68		

Initial Request
(TCC Project Form, Feasibility Form and Data/Specimen Form)

- Split the request into three separate forms to field redundancy and link current data/specimen requests with past feasibility requests.
  - **TCC Project Form** – project level request data
    - *applicable to both feasibility and data/specimen request*
  - **Feasibility Form** – feasibility specific questions
  - **Data/Specimen Form** – detailed/discrete questions related to the data and/or specimens

NOTES
Field Type = Begin New Section
Piping Logic
Formatting with Rich Text Editor
No branching logic

Project Summary

(Summary of the data submitted on the project form)

TCC Request ID #500

Requestor: Jane Test

Title: Study the XYZ1 gene in colorectal cancer patients who are MSI-H vs wildtype.
Principal Investigator: Test, John
Co-Investigator(s): Jane Test and Jim Test

Objectives: Requesting tumor tissue and blood (germline) samples from 50 patients (25 from each group) who are MSI-H and MSI wildtype and do not have any sequencing data available. Requesting sequencing data from 50 additional patients (25 from each group) that do have sequencing data available.

We would like to study XYZ1 in both tumor and germline samples to see the correlation between tumors being classified as MSI-H vs wildtype.

Project/Patient Inclusion Criteria: stage 3 and 4
Project/Patient Exclusion Criteria: stage 0, 1 & 2

Site(s) of Interest: Digestive System
Malignancy Level: Malignant neoplasms
Histology Main Category(s): Carcinoma
Histology ICD-O Category(s):
Adenomas and adenocarcinomas

Feasibility & Data/Specimen

Feasibility Summary

Patient Count Minimum: 100
Specimens Inclusion Criteria: 30 mg frozen tumor
10 curls @ 5 microns FFPE tumor
1ug blood DNA
Specimens Exclusion Criteria: _____

Additional Requirements: Frozen Tissue, FFPE Tissue, DNA from blood
Molecular Data: WES - Tumor, WES - Germline

LOS Application Title: Study the XYZ1 gene in colorectal cancer patients who are MSI-H vs wildtype.

Aggregate Counts Provided:

Patients with tumor tissue: 35 patients with MSI-H & 48 patients with wildtype

Patients with sequencing available: 25 patients with MSI-H & 25 patients with wildtype

NOTES
Field Type = Descriptive Text
Piping Logic
Formatting with Rich Text Editor
Branching logic

Data/Specimen Only
branching logic = blank if no feasibility

Initial Request
(Project Summary & Feasibility Summary field creation)

Field Type: Begin New Section (with optional text)

Field Label — Use the Rich Text Editor

```
<center><h3><b><u>Project Summary</h3></b></u><h4>(Summary of the data submitted on the project form)</h4></center>
<h6>
<u><b>TCC Request ID #[initial_request_arm_1][tcc_request_id]</u></b>

<u><b>Requestor:</u></b> [initial_request_arm_1][requester_name]

<u><b>Title:</u></b> [initial_request_arm_1][project_study_title]
<u><b>Principal Investigator:</u></b> [initial_request_arm_1][pi_last_name], [initial_request_arm_1][pi_first_name]
<u><b>Co-Investigator(s):</u></b> [initial_request_arm_1][co_investigator]

<u><b>Objectives:</u></b> [initial_request_arm_1][project_objective]

<u><b>Project/Patient Inclusion Criteria:</u></b> [initial_request_arm_1][patient_inclusion]
<u><b>Project/Patient Exclusion Criteria:</u></b> [initial_request_arm_1][patient_exclusion]

<u><b>Site(s) of Interest:</u></b> [initial_request_arm_1][site_of_interest]
<u><b>Malignancy Level:</u></b> [initial_request_arm_1][malignancy_level]
<u><b>Histology Main Category(s):</u></b> [initial_request_arm_1][histo_main_cat]
<u><b>Histology ICD-O Category(s):</u></b>
&amp;nbsp;&amp;nbsp;&amp;nbsp;&amp;nbsp;[initial_request_arm_1][carcinoma_histo_cat]
&amp;nbsp;&amp;nbsp;&amp;nbsp;&amp;nbsp;[initial_request_arm_1][lymphleukmyeloma_histo_cat]
&amp;nbsp;&amp;nbsp;&amp;nbsp;&amp;nbsp;[initial_request_arm_1][reproneoplasm_histo_cat]
&amp;nbsp;&amp;nbsp;&amp;nbsp;&amp;nbsp;[initial_request_arm_1][sarcoma_histo_cat]
```

REMINDER
Include the [**event-name**] in front of the variable for **piping** to work correctly.

Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) — Codebook

Question Number (optional)
Displayed only on the survey page

Field Label — Use the Rich Text Editor

```
<center><h3><b><u>Feasibility Summary</h3></b></u></center><h6>
<u><b>Patient Count Minimum:</u></b> [initial_request][feas_patient_min]
<u><b>Specimens Inclusion Criteria:</u></b> [initial_request][feas_spec_inclusion]
<u><b>Specimens Exclusion Criteria:</u></b> [initial_request][feas_spec_exclusion]

<u><b>Additional Requirements:</u></b> [initial_request][feas_add_requirements]
<u><b>Molecular Data:</u></b> [initial_request][feas_molecular_data_types]

<u><b>LOS Application Title:</u></b> [initial_request_arm_1][los_application_title]

<u><b>Aggregate Counts Provided:</u></b>
[initial_request_arm_1][feas_aggregate_counts]
```

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

How to use [Smart Variables] [Piping] [Field Embedding]

Optional media to embed or attach:
Embed media (video, website, survey, etc.)
Provide media URL
e.g. https://youtube.com/watch?v=E1cCuWMupz0, http://example.com/movie.mp4, [survey-url:instrument_name], https://redcap.myinstitution.org/surveys/?s=M9HL8L8WWT

Choose method below for the following field: feasibility_pipping - *Feasibility Summary Patient C...*

Advanced Branching Logic Syntax — How to use [Branching Logic] [Smart Variables] [Special Functions]

Show the field ONLY if...

```
[purpose_of_request] = "Feasibility"
```

Clear logic

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

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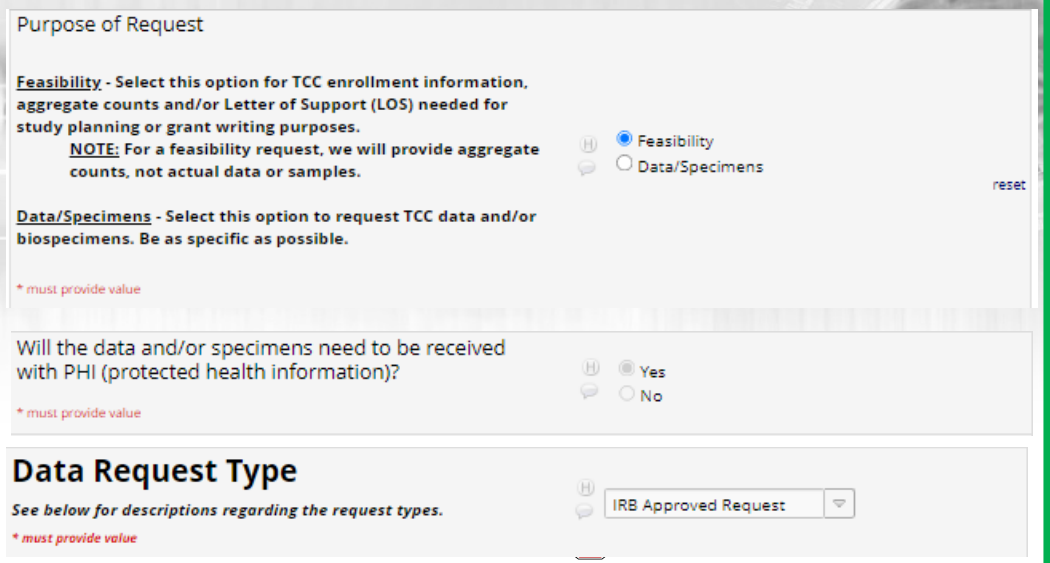
Initial Request
(TCC Project Form)

@HIDDEN-SURVEY

- Auto-numbering for records
  - Hands off and automated
- Project ID (visual cue that corresponds to a specific project)
  - Utilizing auto-numbering from REDCap
- Distinct Investigator Codes
  - Metrics/reporting
  - Filtering
  - Alerts & Notifications for committee approvals

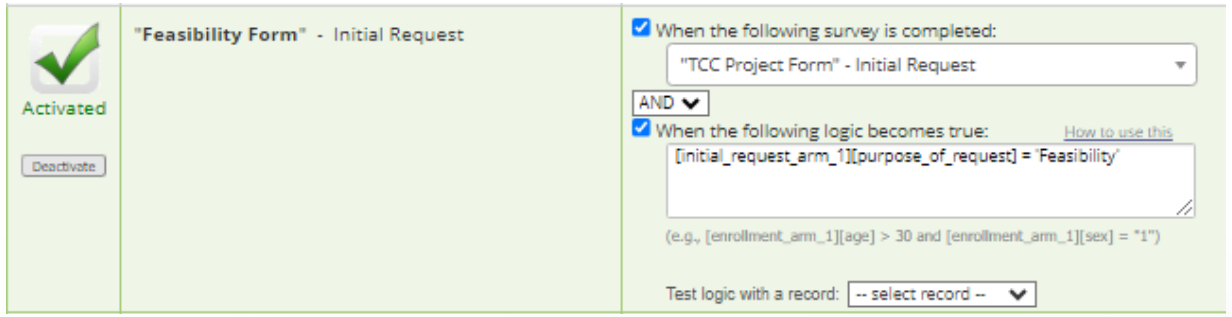
Part of the request completed by requester

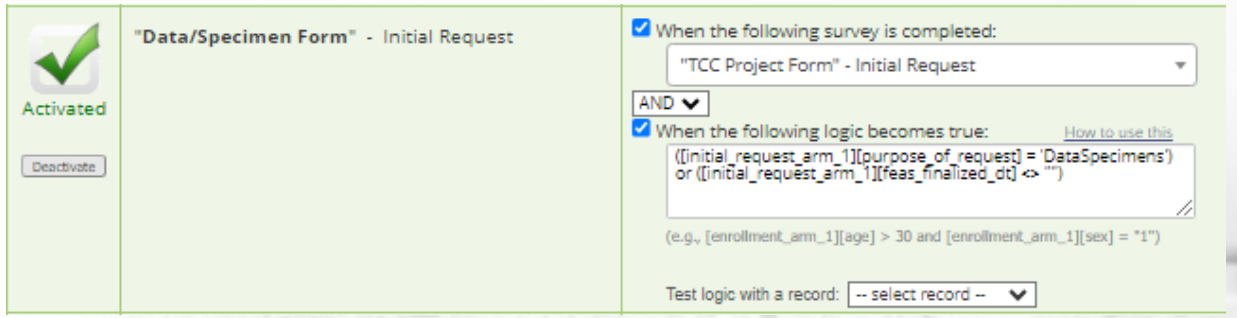
- Purpose of Request
  - Directs requester to next appropriate form based on the request
- PHI & Data Request Type
  - Directs requester/investigator to the appropriate agreements



Survey Queue: Initial Request
(instrument must be enabled as a survey)

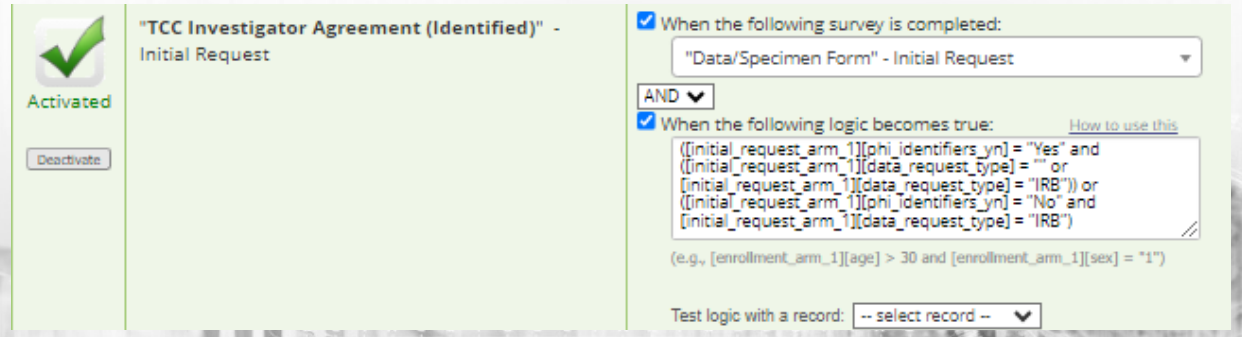
Request
completed by requester (https://go.osu.edu/osutcc)

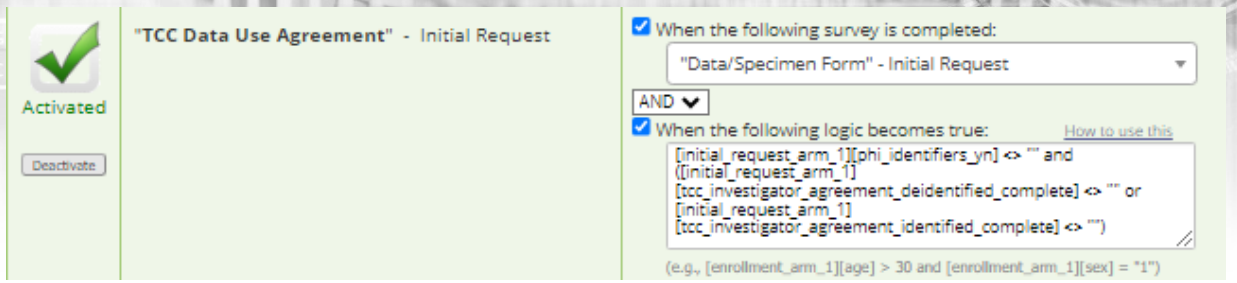




REMINDER
Include the [**event-name**] in front of the variable for **logic** to work correctly.

Agreements
completed by investigator for data/specimen requests

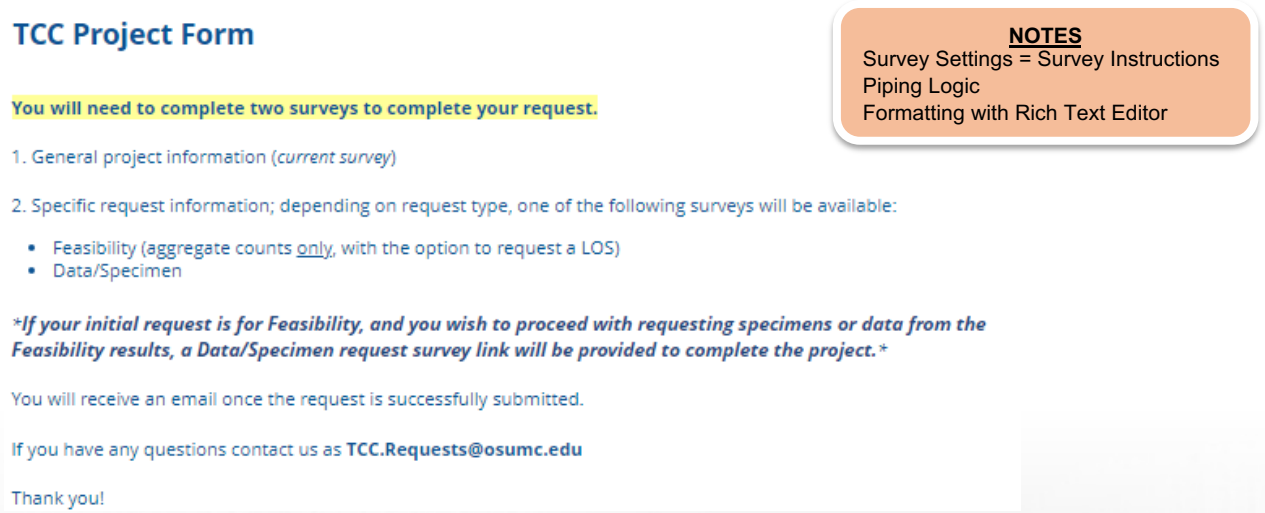




Survey Settings
(instrument must be enabled as a survey)

- Survey Instructions & Survey Completion Text
  - Font/formatting
  - Piping logic

- NOTE: The investigator can complete the agreements required for the request from the **survey queue** if the investigator is the one who completed the request.



NOTES
Survey Settings = Survey Instructions
Piping Logic
Formatting with Rich Text Editor

NOTES
Survey Settings = Survey Completion Text
Piping Logic
Formatting with Rich Text Editor

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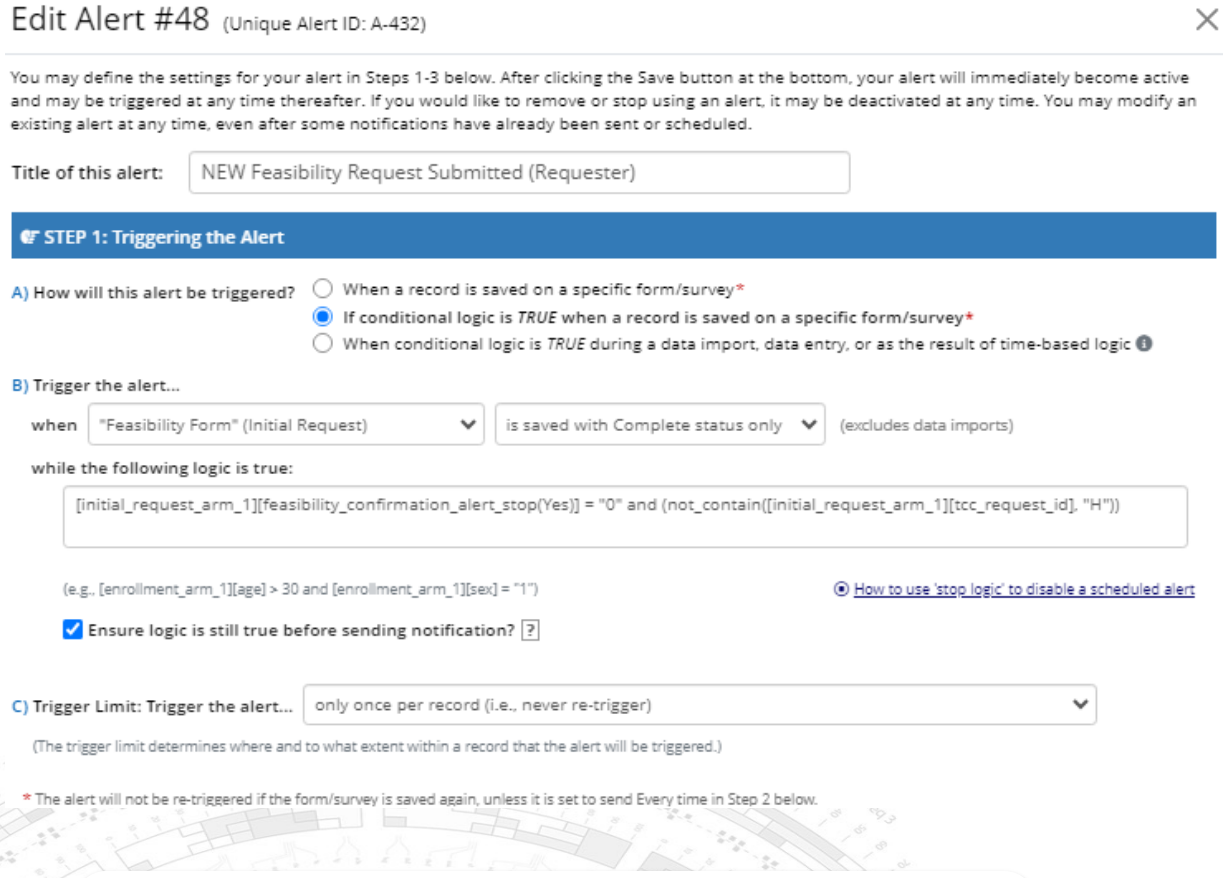
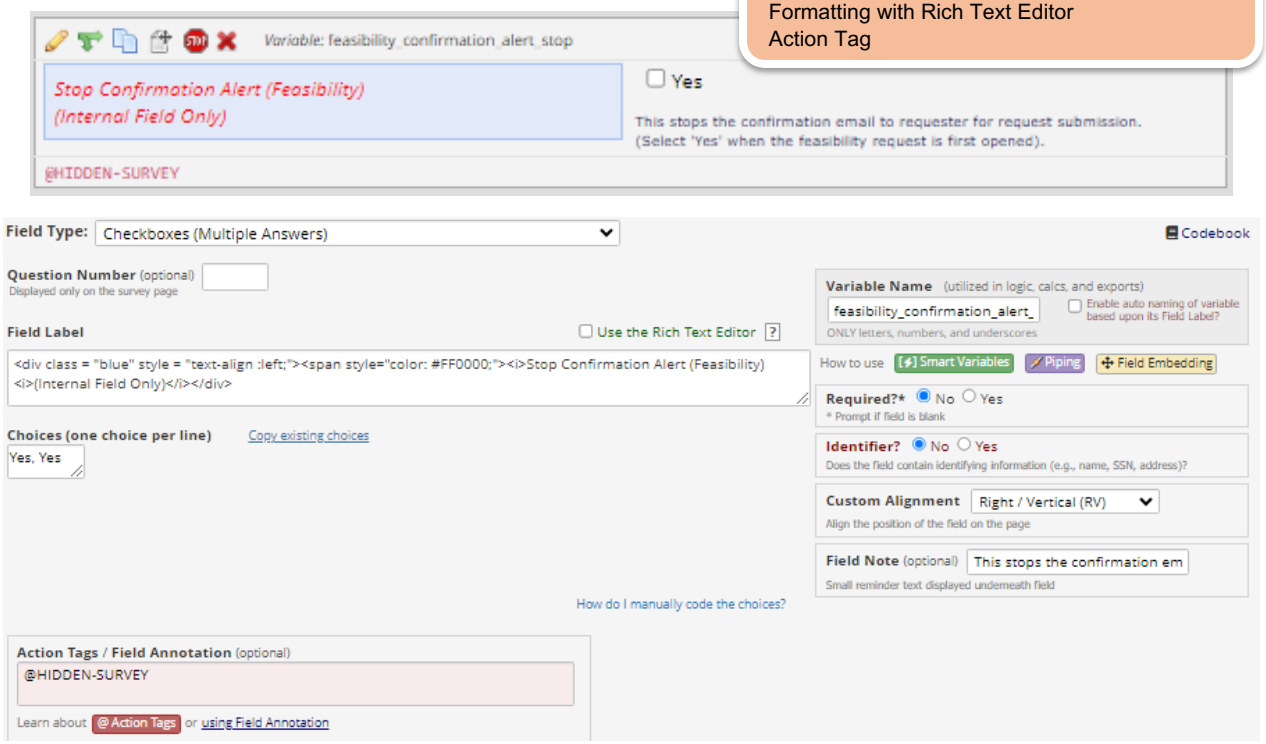
Alerts & Notifications
(Requester Alert: New Feasibility Request Summary)



NOTES
Field Type = Checkboxes or Radio Buttons
Formatting with Rich Text Editor
Action Tag



REMINDER
Adding fields to your project to initiate/inhibit Alerts & Notifications from triggering will help prevent unwanted notifications when working in a record and saving changes.

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Comprehensive Cancer Center

Alerts & Notifications

(Requester Alert: New Feasibility Request Summary)

STEP 2: Set the Alert Schedule

When to send the alert?

- (•) Send immediately
- ( ) Send on next [Day] at time [ ] H:M
- ( ) Send the alert [ ] days [ ] hours [ ] minutes
  [after] [the exact time that the alert was triggered]
- ( ) Send at exact date/time: [MM/DD/YYYY HH:MM]

Send it how many times?

- (•) Just once
- ( ) Every time the form/survey in Step 1B is [saved]
  (excludes data imports)
- ( ) Multiple times on a recurring basis:
  - Send every [0] [days] after initially being sent.
    Tip: A monthly recurrence can be approximated as 30.44 days.
  - Send up to [ ] times total (including the first time sent).
    Leave blank to continue sending forever.

Alert expiration: (optional)

[MM/DD/YYYY HH:MM]

This alert will be auto-deactivated at the specified date/time above. Note: This will cause any already-scheduled notifications not to be sent after the expiration time.

STEP 3: Message Settings

Email From: * must provide value
[Display name (optional)] [tcc.requests@osumc.edu]

Email To: * must provide value
[× [initial_request_arm_1][requester_email] "Requester's email" (Initial Request)]
Or manually enter emails: [jane@example.com; john@mysite.org]

Email CC:
[Select recipients]
Or manually enter emails: [jane@example.com; john@mysite.org]

Email BCC:
[× tcc.requests@osumc.edu]
Or manually enter emails: [jane@example.com; john@mysite.org]

Email to send email-failure errors:
[tcc.requests@osumc.edu]

Subject * must provide value
TCC Feasibility Request Submission Confirmation ([pi_last_name], [pi_first_name] Request ID #[tcc_request_id])

Message: * must provide value

[Paragraph] [B] [I] [U] [link] [code] [image] [attach] [align] [undo] [redo]

[requester_name],

Thank you for completing the TCC Feasibility Request Form for your project, "**[project_study_title]**". The request ID is **#[initial_request_arm_1][tcc_request_id]**.

To view the status of your request, visit ***[initial_request_arm_1][survey-link:tcc_project_dashboards:TCC Project Status Dashboard]***

Thank you,

Total Cancer Care Operations Team

[ ] Prevent piping of data for Identifier fields

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

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

Learn about Data Collection Strategies for Repeating Surveys

Example of a repeating survey using recurring alerts:
Please complete your daily survey: [survey-link:daily_repeating_survey][new-instance]

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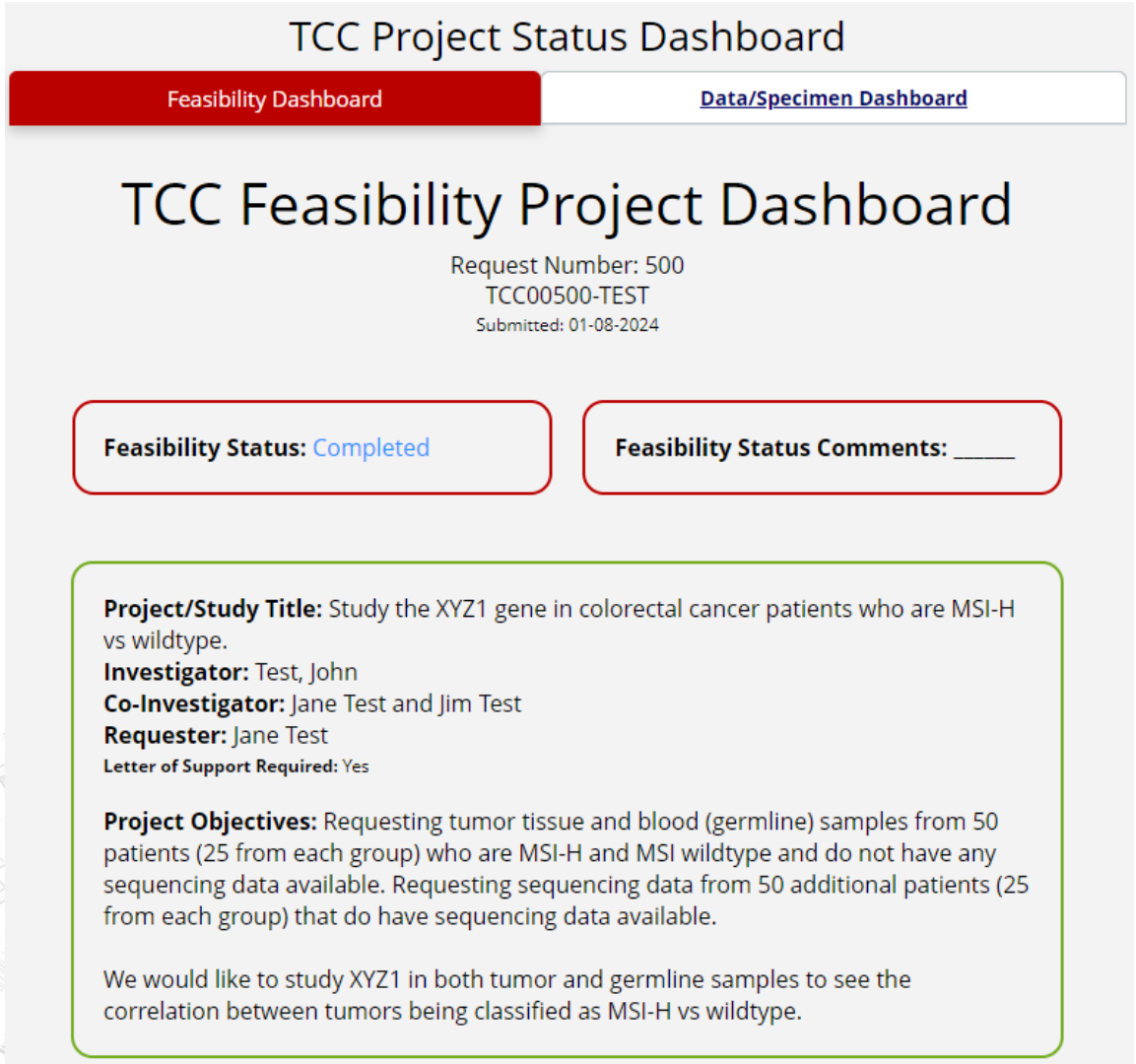
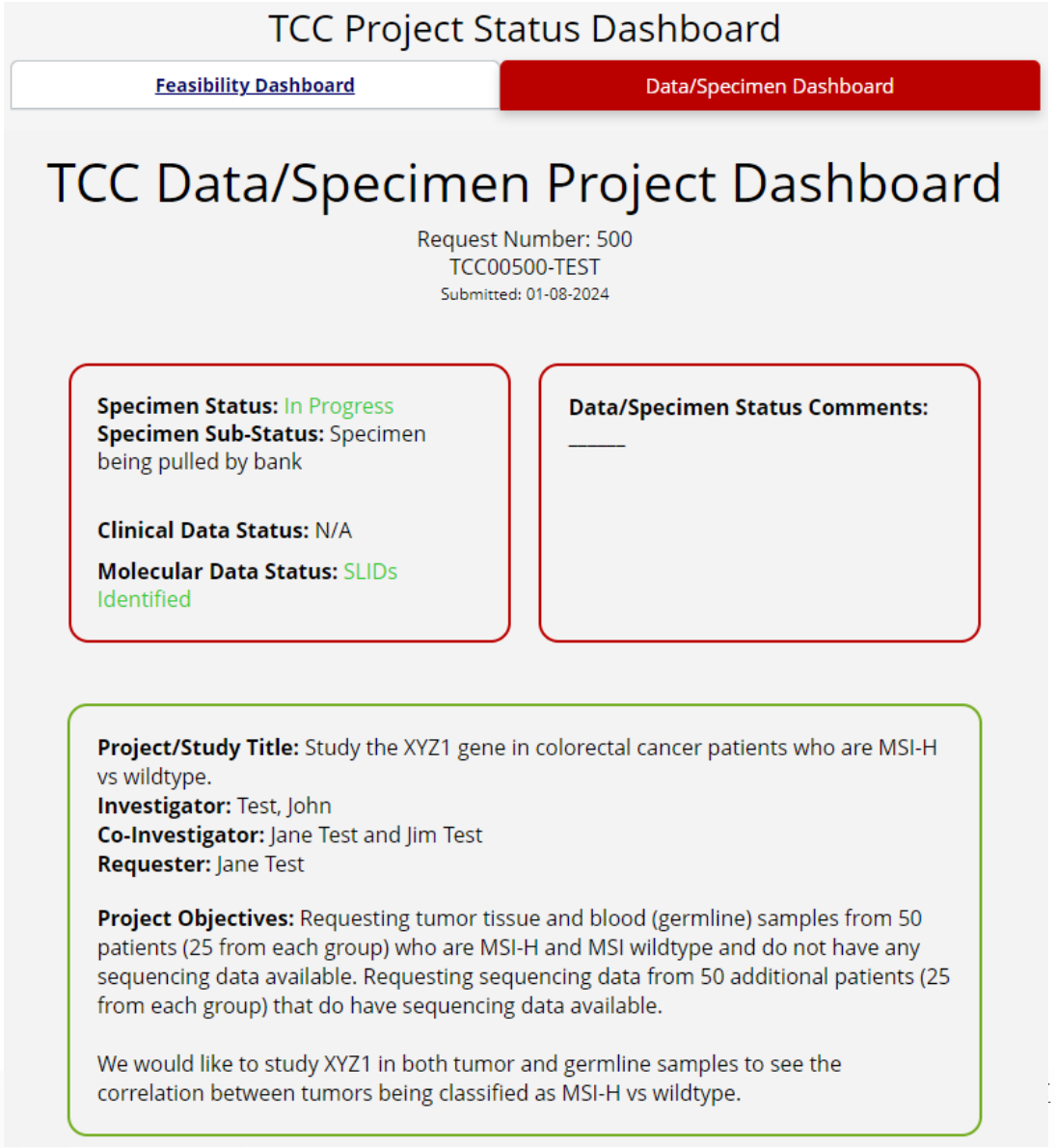
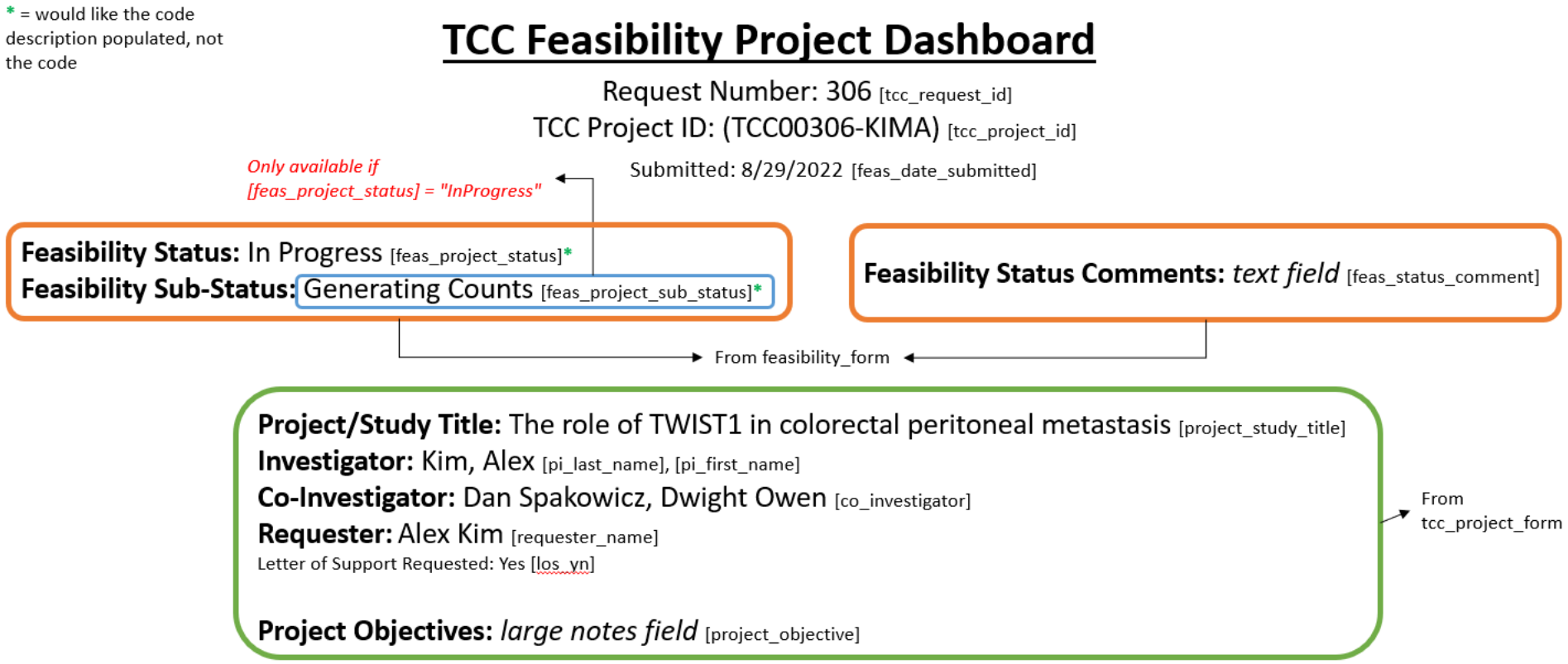
TCC Project Status Dashboard
(REDCap Extension)



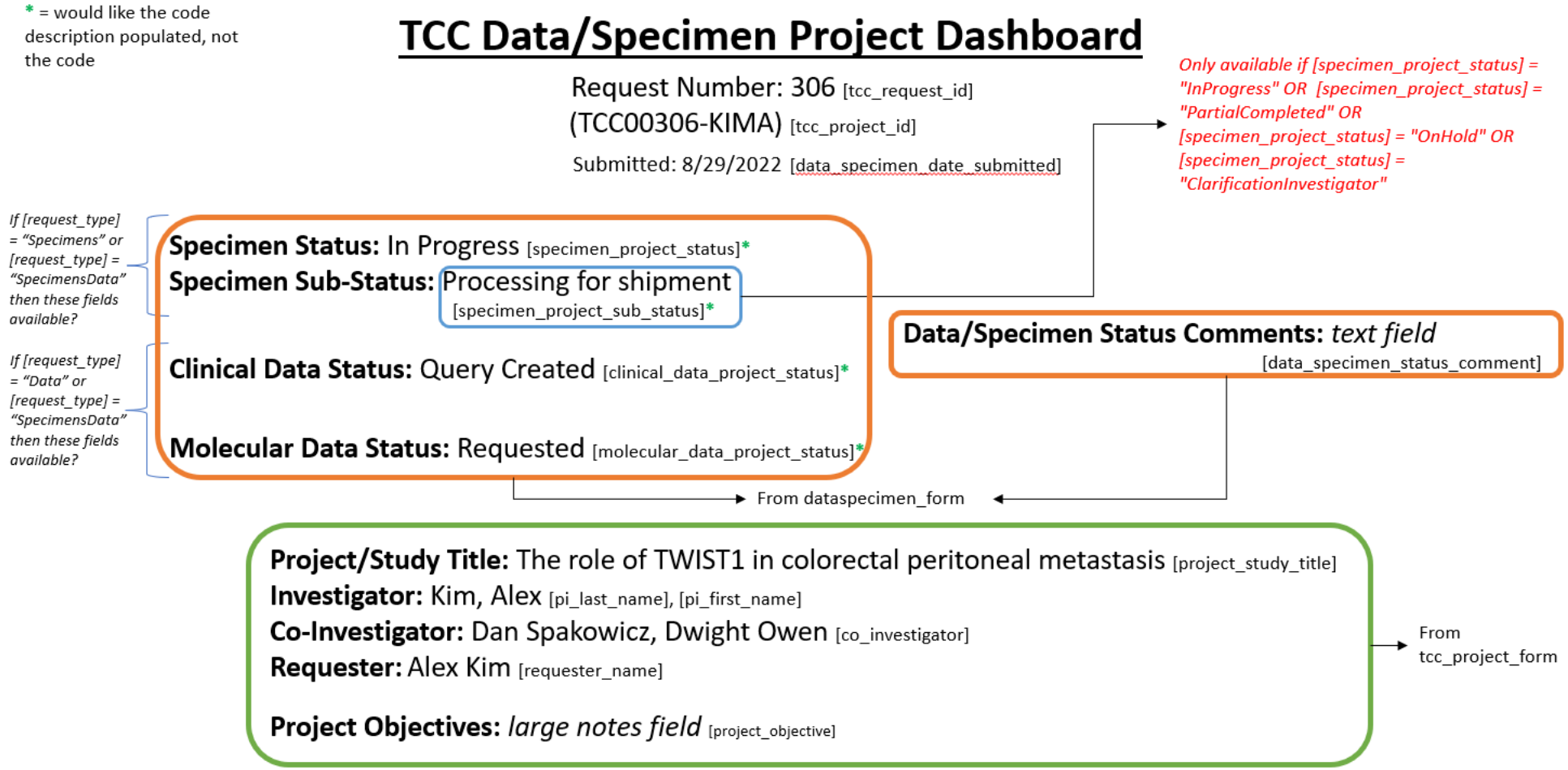


TCC Project Status Dashboard
(REDCap Extension request)



Dashboard visible when [feasibility_form_complete] = “2”

TCC Project Status Dashboard
(REDCap Extension request)



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Internal Review

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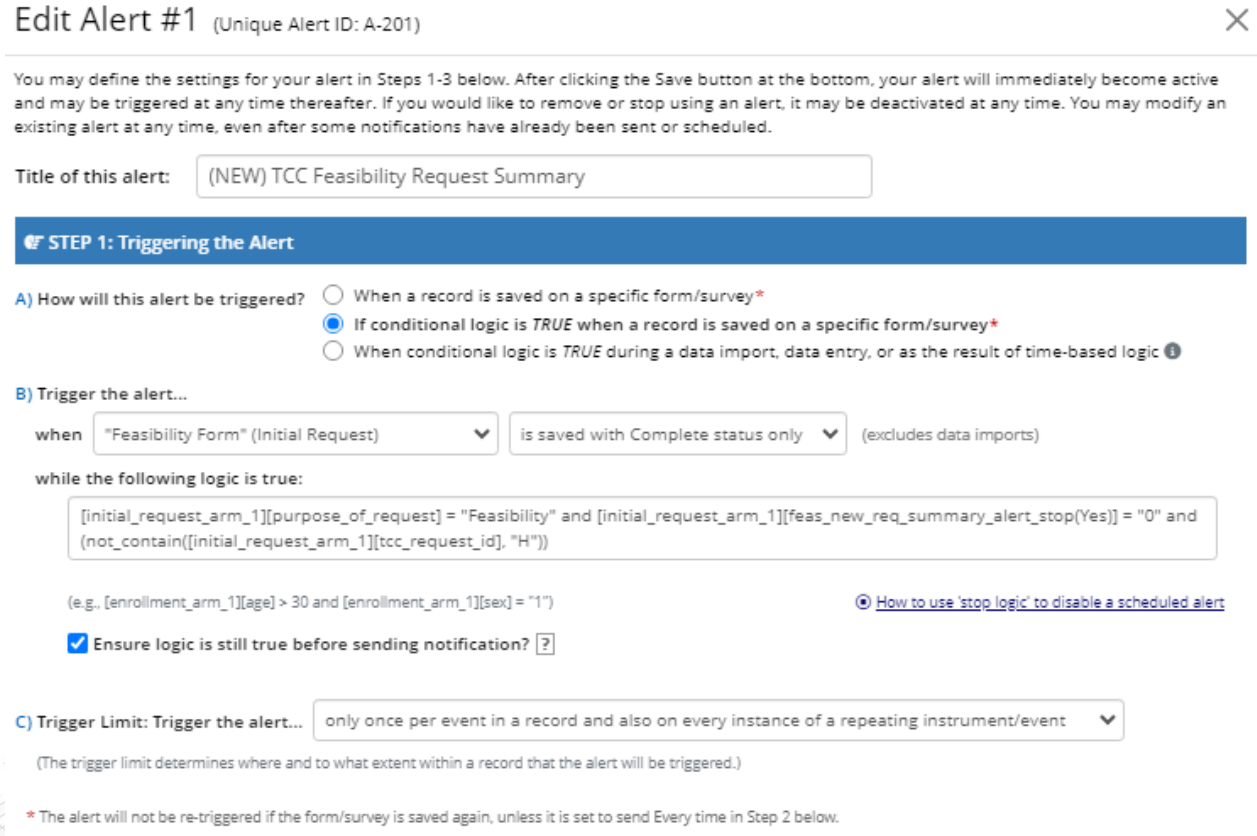
Alerts & Notifications
(Internal Alert: New Feasibility Request Summary)



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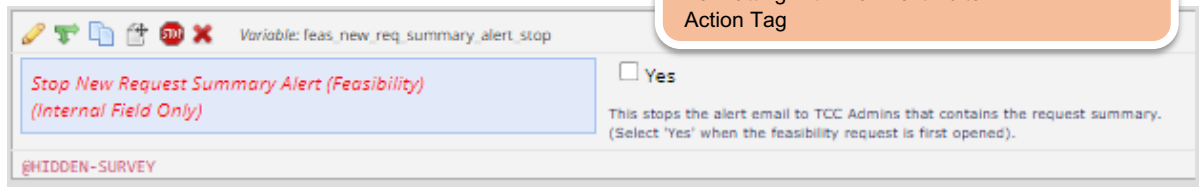
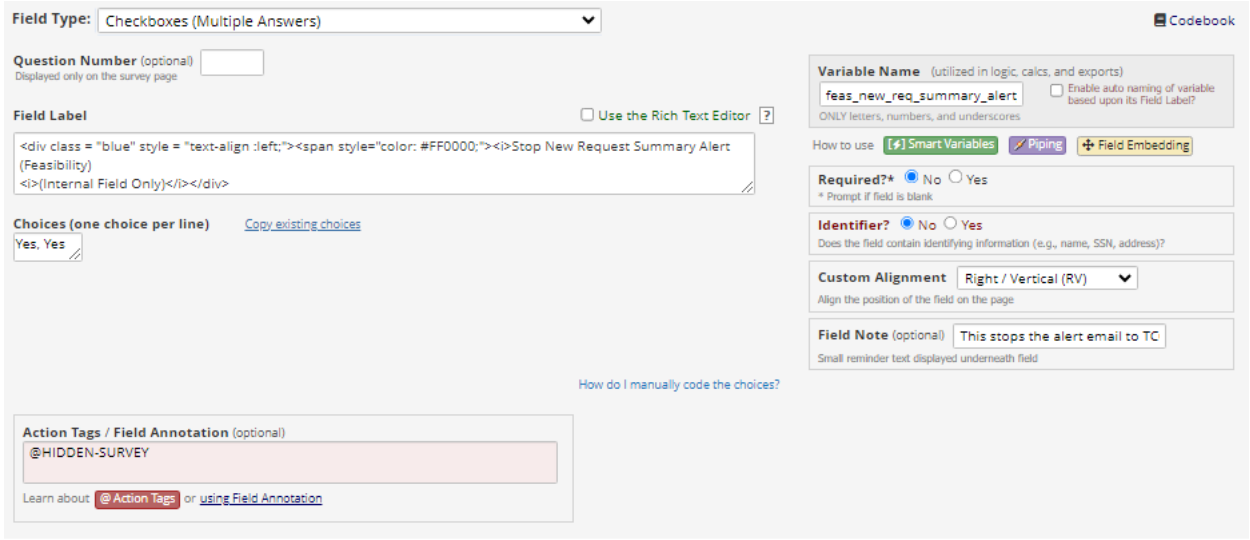
Action Tag





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STEP 3: Message Settings

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[Display name (optional)] [tcc.requests@osumc.edu]

Email To: * must provide value

[× tcc.requests@osumc.edu]

+ Show more options

Or manually enter emails: [jane@example.com; john@mysite.org]

Subject * must provide value

[NEW TCC Feasibility Request for [pi_last_name], [pi_first_name] (request #[tcc_request_id])]

Message: * must provide value

[Paragraph] [B] [I] [U] [link] [code] [image] [attach] [align] [undo] [redo]
[bullets] [numbers] [outdent] [indent] [table] [A] [highlight] [search] [source] [clear] [fullscreen]

TCC Feasibility Request Summary for [pi_last_name], [pi_first_name] submitted on [feas_date_submitted]

REDCap request #[tcc_request_id]

Letter of Support: [initial_request][los_yn]

LOS Due Date: [los_due_date]

Date of Feasibility Request: [initial_request][feas_date_submitted]

Title: [initial_request][project_study_title]

Principal Investigator: [pi_last_name], [pi_first_name]

Co-Investigators: [initial_request][co_investigator]

Requester: [initial_request][requester_name]

Department: [initial_request][requester_department]

Site(s) of Interest: [initial_request][site_of_interest]

Additional Site Specifications: [site_specifications]

Malignancy Level Requested: [initial_request][malignancy_level]

Histology Main Category(s) of Interest: [initial_request][histo_main_cat]

Histology ICD-O Category(s):

    Carcinoma = [carcinoma_histo_cat]

    Lymphoma/Leukemia/Myeloma = [lymphleukmyeloma_histo_cat]

    Reproductive Cell/Tissue Neoplasms = [reproneoplasm_histo_cat]

    Sarcoma/Soft Tissue Tumors = [sarcoma_histo_cat]

Additional Histology Specifications: [histo_specifications]

[☑] Prevent piping of data for Identifier fields

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

Instruments, Events and Survey Settings

(33 instruments, 5 events, 28 enabled as surveys)

Initial Request

[initial_request_arm_1]

Request

completed by requester (https://go.osu.edu/osutcc)

Instrument name	Fields	View PDF	Enabled as survey
TCC Project Form	82		
Feasibility Form	33		
Data/Specimen Form	120		

Agreements

completed by investigator for data/specimen requests

TCC Investigator Agreement (De-identified)	11		
TCC Investigator Agreement (Identified)	11		
TCC Data Use Agreement	11		

Dashboard

viewable by requester/investigator

TCC Project Status Dashboards	13		
Admin	2		Enable

Project Survey

[project_survey_arm_1]

Project Outcomes Survey

completed by requester/investigator

Data/Specimen Survey	29		

Project Status

[project_status_arm_1]

Timeline Log

updated by TCC Admins

Project Timeline	5		Enable

Internal Review

[internal_review_arm_1]

Internal Review/Project Plan

completed by TCC Admins

Feasibility TCC Internal Review	3		Enable
Data/Specimen TCC Internal Review	9		Enable

Database set up as **longitudinal** to allow us to automate some of the process

Committee Approval

[committee_approval_arm_1]

Approvals

completed by committee members and disease group leader(s)

TCC Research Committee Approval	72		
PI/Director Review	62		
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HN Approval	68		
Lymphoma Approval	68		
Melanoma Approval	68		
MM Approval	68		
Sarcoma Approval	68		
Thoracic/Lung Approval	68		
Thyroid Approval	68		

Committee Approval Process

- Fields from initial request and internal review arms are piped to create the project plan (yellow screen shot).
- TCC Admin selects the disease chairs needed for approval
- Send and then stop the alert & notification

NOTES
Field Type = Begin New Section
Piping Logic
Formatting with Rich Text Editor
No branching logic

TCC Project ID
[initial_request][tcc_project_id]

Date of Request: [initial_request_arm_1][data_specimen_date_submitted]
Requestor: [initial_request_arm_1][requester_name]
Principal Investigator: [initial_request_arm_1][pi_last_name], [initial_request_arm_1][pi_first_name]
Co-Investigator(s): [initial_request_arm_1][co_investigator]

Title: [initial_request_arm_1][project_study_title]

Objectives: [initial_request_arm_1][project_objective]

Site(s) of Interest: [initial_request_arm_1][site_of_interest]
Malignancy Level: [initial_request_arm_1][malignancy_level]
Histology Main Category(s): [initial_request_arm_1][histo_main_cat]
Histology ICD-O Category(s):
[initial_request_arm_1][carcinoma_histo_cat]
[initial_request_arm_1][lymphleukmyeloma_histo_cat]
[initial_request_arm_1][reproneoplasm_histo_cat]
[initial_request_arm_1][sarcoma_histo_cat]

Request Type: [initial_request_arm_1][request_type]
Patient Counts:
[internal_review_arm_1][patient_counts]
Specimens Requested: (will not deplete unless noted below)
[internal_review_arm_1][specimen_summary]
Clinical Data Requested (if applicable):
[internal_review_arm_1][clinical_data_identified]
Molecular Data Requested (if applicable):
[internal_review_arm_1][molecular_data_req]

TCC Notes: [internal_review_arm_1][data_specimen_tcc_review_notes]

Variable: disease_chair_approve_list

Disease chair approval needed:

- Acute Leukemia + MDS
- BMT
- Breast
- CLL
- CNS
- Gastrointestinal (GI)
- Genitourinary (GU)
- Gynecologic/Oncology
- Head and Neck
- Lymphoma
- Melanoma
- Multiple Myeloma
- Sarcoma
- Thoracic/Lung
- Thyroid/NET +

NOTES
Field Type = Checkboxes or Radio Buttons
Formatting with Rich Text Editor
Action Tag

Variable: send_vote_request

Send Vote Request Alert

Yes

This sends the email to the reviewers to begin the voting process.
(Select 'Yes' when the data/specimen project is ready to be reviewed).

Add Field | Add Matrix of Fields | Import from Field Bank

Variable: stop_vote_request

Stop Vote Request Alert

Yes

This stops the alert email to the reviewers for this request.
(Select 'Yes' after the vote requests go out).

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HN Approval	68		
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Melanoma Approval	68		
MM Approval	68		
Sarcoma Approval	68		
Thoracic/Lung Approval	68		
Thyroid Approval	68		

Committee Approval Process
(Alerts & Notifications)

- TCC PI, director and standing committee members receive approval email request for all projects, except projects they are involved in.
  - investigator codes allow us to stop the alerts.

- Approval process set up to handle the initial project as well as two supplemental requests.

Initial project approval

Logic Editor

Use the text box below to compose your logic, calculation, action tags, etc. If you need more space, click the Fullscreen Mode button to enlarge the text box. When you are finished, click the 'Update' button to minimize the Editor window. Learn how to use Smart Variables Special Functions @ Action Tags or open the Codebook

```
([committee_approval_arm_1][send_vote_request(Yes)] = "1")

AND ([initial_request_arm_1][distinct_investigator_list] <> "SPAK")

AND (not_contain([initial_request_arm_1][distinct_coinvestigator_list], "SPAK"))

AND
([committee_approval_arm_1][stop_vote_request(Yes)] = "0"
OR [committee_approval_arm_1][member_1_request_approval] = "")
```

From:	tcc.requests@osumc.edu
To:	daniel.spakowicz@osumc.edu
Subject	TCC Request Ready for Review (TCC00500-TEST)
Message:	Hello Dr. Spakowicz, We have a **TCC Data and Specimens** request from **Test, John** that is ready for your vote on fulfilling this request. Project Title: **Study the XYZ1 gene in colorectal cancer patients who are MSI-H vs wildtype.** Co-Investigators (if applicable) for the request include: **Jane Test and Jim Test** You may open the survey in your web browser by clicking the link below: **TCC Review Member #1** If the link does not work, try copying the link below into your web browser: **https://redcap.osumc.edu/redcap/surveys/?s=KcmUjzheWC4XY7Dj** Please provide us with your vote for or against fulfilling this request. If you have any questions that you would like the investigator to clarify please provide them in the designated comment field. Thank you, Total Cancer Care Operations Team

Supplemental request approval

Logic Editor

Use the text box below to compose your logic, calculation, action tags, etc. If you need more space, click the Fullscreen Mode button to enlarge the text box. When you are finished, click the 'Update' button to minimize the Editor window. Learn how to use Smart Variables Special Functions @ Action Tags or open the Codebook

```
(([committee_approval_arm_1][sup_1_vote_trigger(Send)] = "1")
    AND (([committee_approval_arm_1][sup_1_vote_trigger(Stop)] = "0")
        OR ([committee_approval_arm_1][member_1_request_approval_sup_1] = "")))

OR
(([committee_approval_arm_1][sup_2_vote_trigger(Send)] = "1")
    AND (([committee_approval_arm_1][sup_2_vote_trigger(Stop)] = "0")
        OR ([committee_approval_arm_1][member_1_request_approval_sup_2] = "")))

AND [initial_request_arm_1][distinct_investigator_list] <> "SPAK"

AND ([not_contain([initial_request_arm_1][distinct_coinvestigator_list], "SPAK")])
```

Paragraph

Hello Dr. Spakowicz,

We have a **TCC [initial_request_arm_1][request_type]** request from **[initial_request_arm_1][pi_last_name], [initial_request_arm_1][pi_first_name]** that is ready for your vote on fulfilling this request.

Project Title: **[initial_requst_arm_1][project_study_title]**

Co-Investigators (if applicable) for the request include:

[initial_request_arm_1][co_investigator]

You may open the survey in your web browser by clicking the link below:

[committee_approval_arm_1][survey-link:tcc_review_member_1]

If the link does not work, try copying the link below into your web browser:

[committee_approval_arm_1][survey-url:tcc_review_member_1]

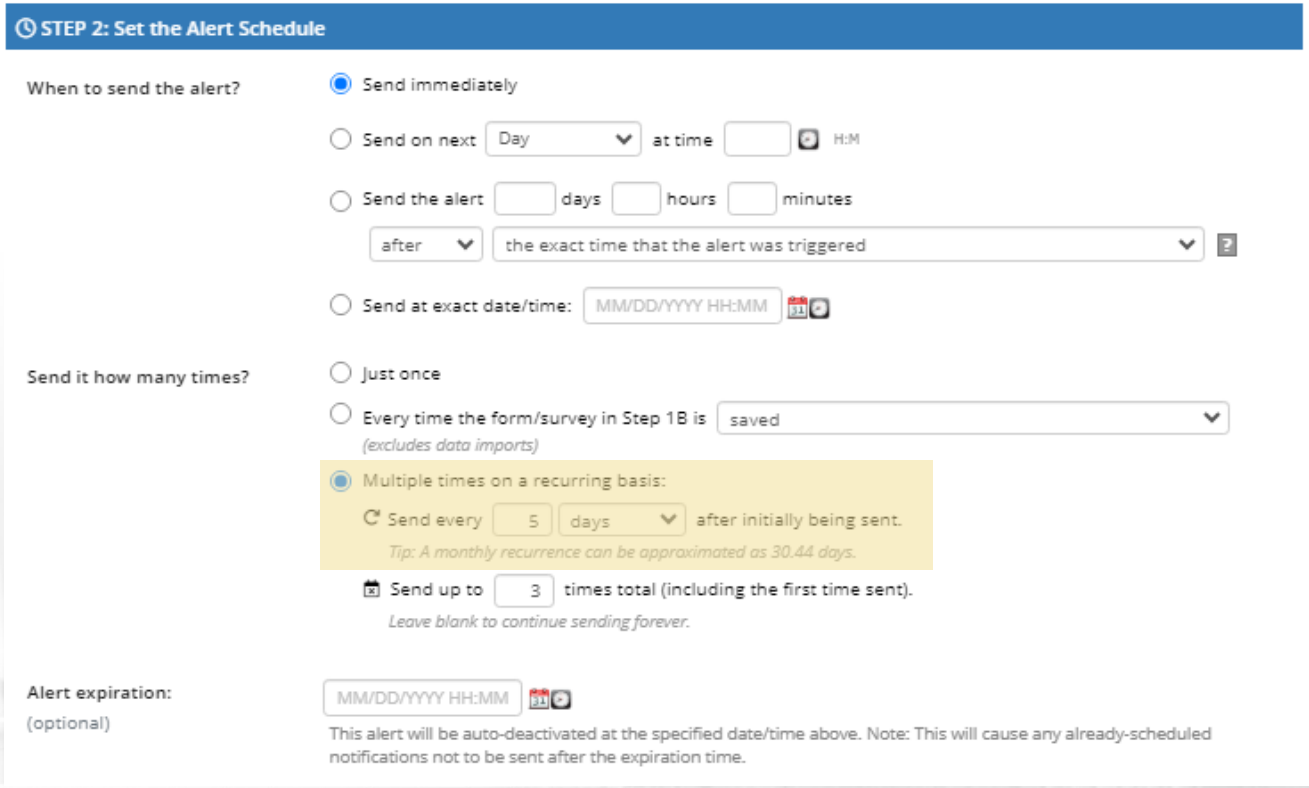
Please provide us with your vote for or against fulfilling this request. If you have any questions that you would like the investigator to clarify please provide them in the designated comment field.

Thank you,

Total Cancer Care Operations Team

Committee Approval Process
(Alerts & Notifications)

- 2 additional reminders are set up following the first email if a vote has not been cast.



Committee Approval Process

- Each approval group has their own designated form for the initial request as well supplemental.
  - 1 PI and director
  - 4 Standing members
  - 15 Disease groups
- Forms and variable names were created to allow for changes in members and disease group leaders.

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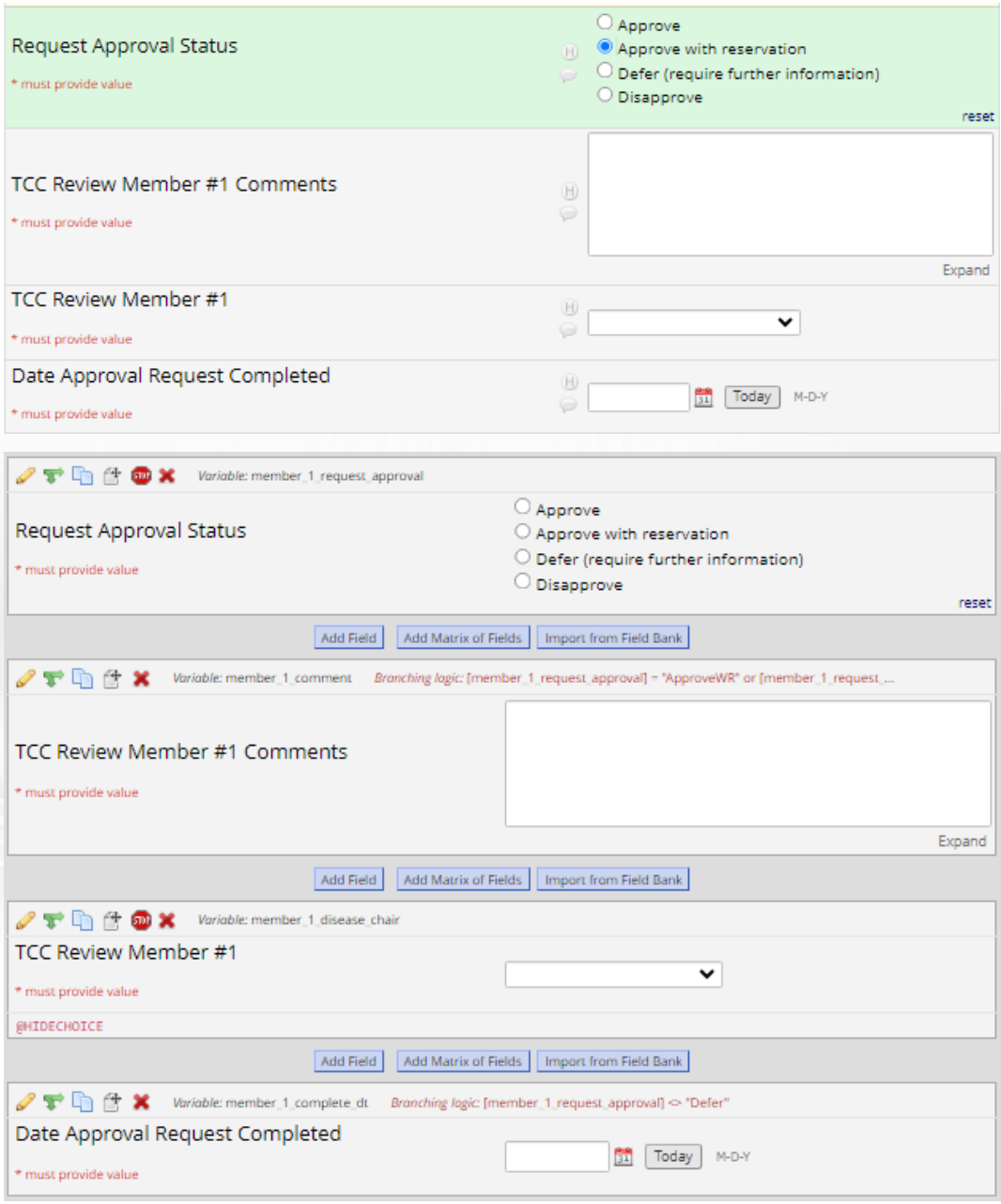
Gynecologic Approval	68		
HN Approval	68		
Lymphoma Approval	68		
Melanoma Approval	68		
MM Approval	68		
Sarcoma Approval	68		
Thoracic/Lung Approval	68		
Thyroid Approval	68		

Committee Approval Process

- Approval section:
  - Status and member name are always required
  - Comment only required if approval status is not “Approve” (*branching logic*).
  - Date only required if approval status is not “Defer” (*branching logic*).
  - Section duplicated for each of the three approval types
    - Branching logic applied to entire sections so they are only visible when needed



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Committee Approval Process

- Comments from committee members section:
  - Branching logic is applied to each field so they are only visible when applicable to the request.
  - Section duplicated for each of the three approval types

Without branching logic

Comments from other committee members (if applicable)

TCC Review Member 2 Approval Status:
——

TCC Review Member 2 Comment:
——

TCC Review Member 3 Approval Status:
——

TCC Review Member 3 Comment:
——

TCC Review Member 4 Approval Status:
——

TCC Review Member 4 Comment:
——

Acute Leukemia + MDS Approval Status:
——

Acute Leukemia + MDS Comment:
——

BMT Approval Status:
——

BMT Comment:
——

Breast Approval Status:
——

Breast Comment:
——

CLL Approval Status:
——

CLL Comment:
——

CNS Approval Status:
——

CNS Comment:
——

GI Approval Status:
——

GI Comment:
——

With branching logic

Comments from other committee members (if applicable)

TCC Review Member 2 Approval Status:
——

TCC Review Member 2 Comment:
——

TCC Review Member 3 Approval Status:
——

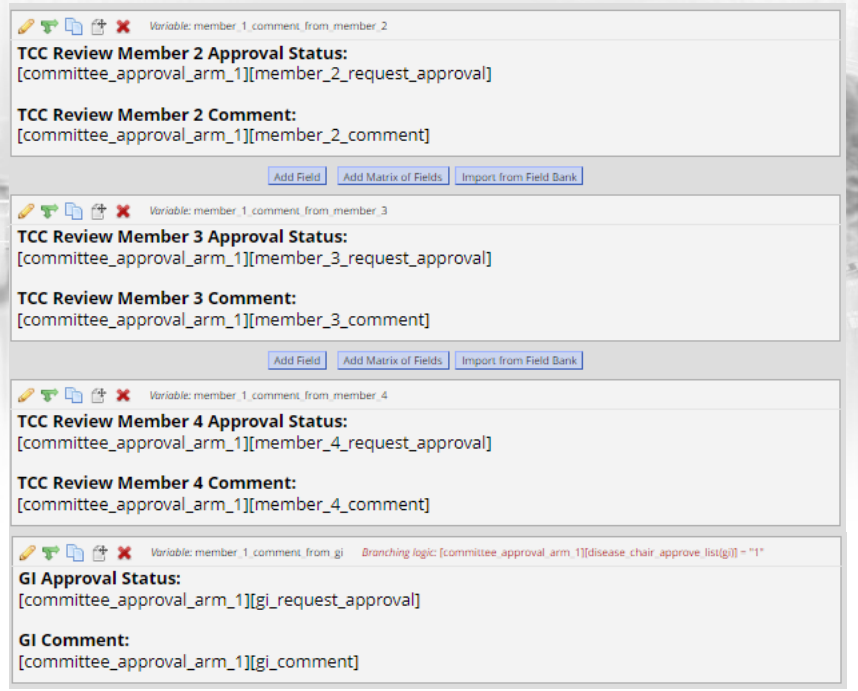
TCC Review Member 3 Comment:
——

TCC Review Member 4 Approval Status:
——

TCC Review Member 4 Comment:
——

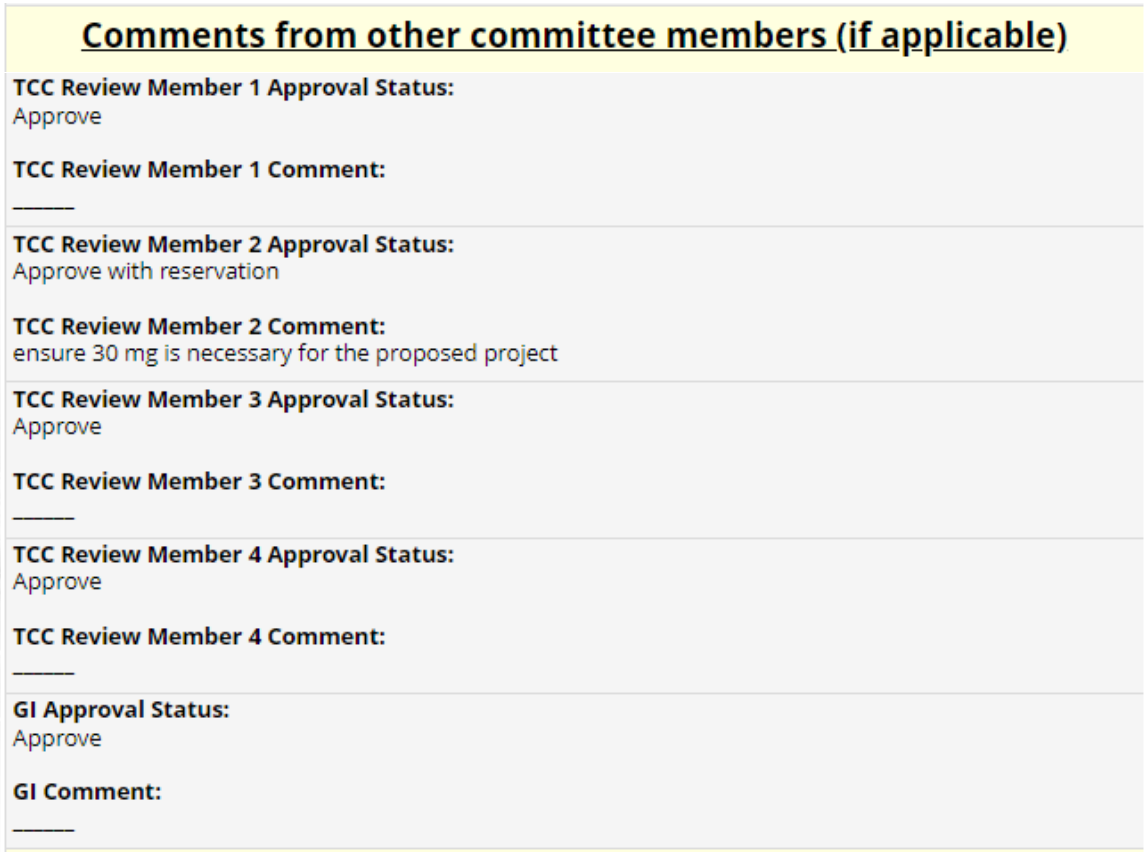
GI Approval Status:
——

GI Comment:
——



Committee Approval Process

- The main TCC Research Committee Approval form also has the summary of approvals and comments to review the progress of the requests through the approval process.



Comments from other committee members (if applicable)

TCC Review Member 1 Approval Status:
Approve

TCC Review Member 1 Comment:
_____

TCC Review Member 2 Approval Status:
Approve with reservation

TCC Review Member 2 Comment:
ensure 30 mg is necessary for the proposed project

TCC Review Member 3 Approval Status:
Approve

TCC Review Member 3 Comment:
_____

TCC Review Member 4 Approval Status:
Approve

TCC Review Member 4 Comment:
_____

GI Approval Status:
Approve

GI Comment:
_____

- Forms are locked once the approval process has completed.
  - Must have user rights to lock/unlock forms.

Instruments, Events and Survey Settings

(33 instruments, 5 events, 28 enabled as surveys)

Initial Request

[initial_request_arm_1]

Request

completed by requester (https://go.osu.edu/osutcc)

Instrument name	Fields	View PDF	Enabled as survey
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completed by investigator for data/specimen requests

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Dashboard

viewable by requester/investigator

TCC Project Status Dashboards	13		
Admin	2		Enable

Project Survey

[project_survey_arm_1]

Project Outcomes Survey

completed by requester/investigator

Data/Specimen Survey	29		

Project Status

[project_status_arm_1]

Timeline Log

updated by TCC Admins

Project Timeline	5		Enable

Internal Review

[internal_review_arm_1]

Internal Review/Project Plan

completed by TCC Admins

Feasibility TCC Internal Review	3		Enable
Data/Specimen TCC Internal Review	9		Enable

Database set up as **longitudinal** to allow us to automate some of the process

Committee Approval

[committee_approval_arm_1]

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completed by committee members and disease group leader(s)

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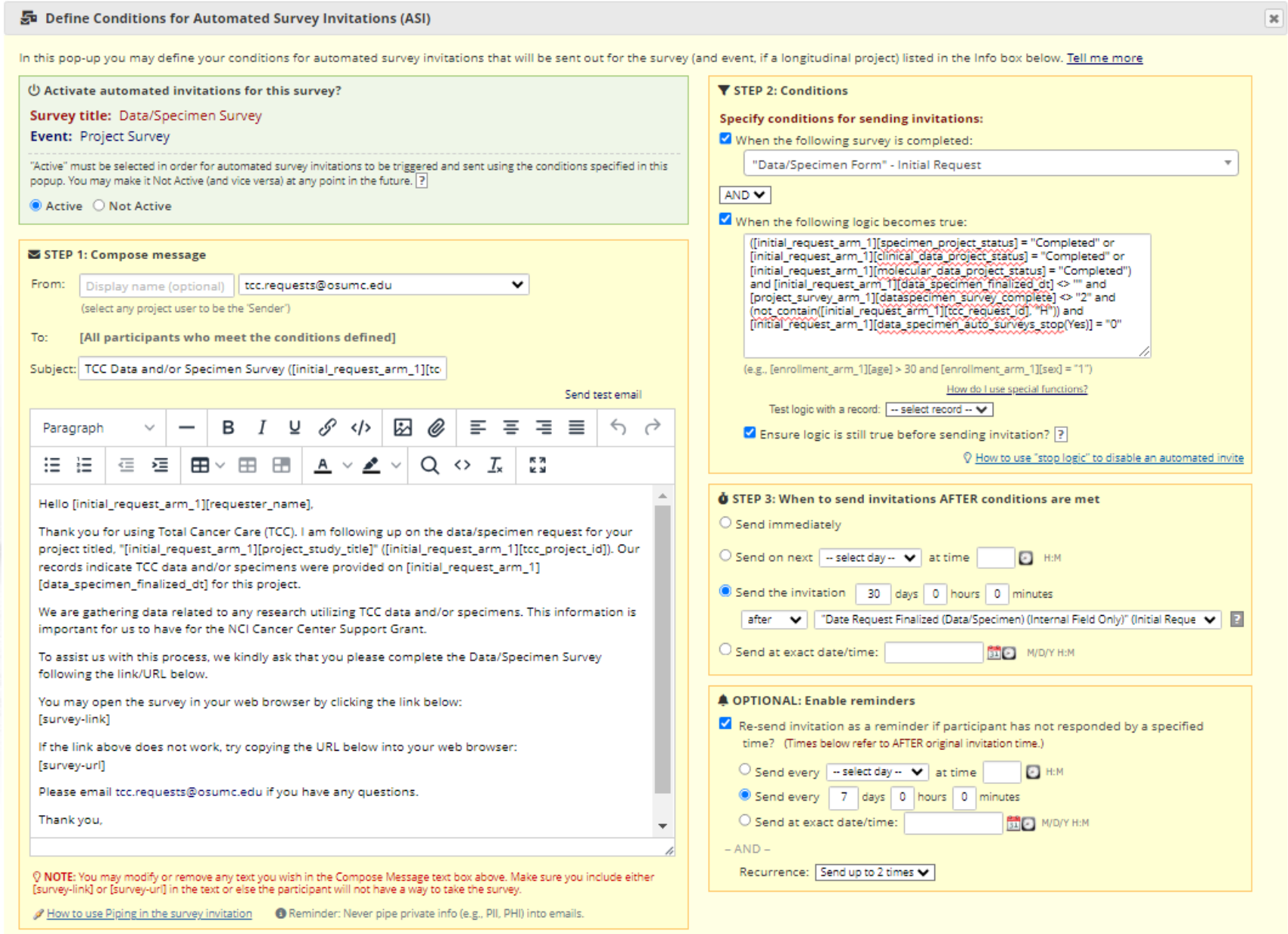
Melanoma Approval	68		
MM Approval	68		
Sarcoma Approval	68		
Thoracic/Lung Approval	68		
Thyroid Approval	68		

Data/Specimen Survey
(Automated Survey Invitations)

- This survey gets automatically sent to the requester after the designated # of days in the **Automated Survey Invitations** (ASI) configuration.



Define Conditions for Automated Survey Invitations (ASI)

In this pop-up you may define your conditions for automated survey invitations that will be sent out for the survey (and event, if a longitudinal project) listed in the Info box below. Tell me more

Activate automated invitations for this survey?

Survey title: Data/Specimen Survey
Event: Project Survey

"Active" must be selected in order for automated survey invitations to be triggered and sent using the conditions specified in this popup. You may make it Not Active (and vice versa) at any point in the future.

Active / Not Active

STEP 1: Compose message

From: Display name (optional) tcc.requests@osumc.edu
(select any project user to be the 'Sender')

To: [All participants who meet the conditions defined]

Subject: TCC Data and/or Specimen Survey ([initial_request_arm_1][tc

Send test email

Paragraph

Hello [initial_request_arm_1][requester_name],

Thank you for using Total Cancer Care (TCC). I am following up on the data/specimen request for your project titled, "[initial_request_arm_1][project_study_title]" ([initial_request_arm_1][tcc_project_id]). Our records indicate TCC data and/or specimens were provided on [initial_request_arm_1][data_specimen_finalized_dt] for this project.

We are gathering data related to any research utilizing TCC data and/or specimens. This information is important for us to have for the NCI Cancer Center Support Grant.

To assist us with this process, we kindly ask that you please complete the Data/Specimen Survey following the link/URL below.

You may open the survey in your web browser by clicking the link below:
[survey-link]

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

Please email tcc.requests@osumc.edu if you have any questions.

Thank you,

NOTE: You may modify or remove any text you wish in the Compose Message text box above. Make sure you include either [survey-link] or [survey-url] in the text or else the participant will not have a way to take the survey.

How to use Piping in the survey invitation — Reminder: Never pipe private info (e.g., PII, PHI) into emails.

STEP 2: Conditions

Specify conditions for sending invitations:

When the following survey is completed:
"Data/Specimen Form" - Initial Request

AND

When the following logic becomes true:

```
([initial_request_arm_1][specimen_project_status] = "Completed" or
[initial_request_arm_1][clinical_data_project_status] = "Completed" or
[initial_request_arm_1][molecular_data_project_status] = "Completed")
and [initial_request_arm_1][data_specimen_finalized_dt] <> "" and
[project_survey_arm_1][dataspecimen_survey_complete] <> "2" and
(not_contain([initial_request_arm_1][tcc_request_id], "H")) and
[initial_request_arm_1][data_specimen_auto_surveys_stop(Yes)] = "0"
```

(e.g., [enrollment_arm_1][age] > 30 and [enrollment_arm_1][sex] = "1")

How do I use special functions?

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

Ensure logic is still true before sending invitation?

How to use "stop logic" to disable an automated invite

STEP 3: When to send invitations AFTER conditions are met

Send immediately

Send on next -- select day -- at time H:M

Send the invitation 30 days 0 hours 0 minutes
after "Date Request Finalized (Data/Specimen) (Internal Field Only)" (Initial Reque

Send at exact date/time: M/D/Y H:M

OPTIONAL: Enable reminders

Re-send invitation as a reminder if participant has not responded by a specified time? (Times below refer to AFTER original invitation time.)

Send every -- select day -- at time H:M

Send every 7 days 0 hours 0 minutes

Send at exact date/time: M/D/Y H:M

– AND –

Recurrence: Send up to 2 times

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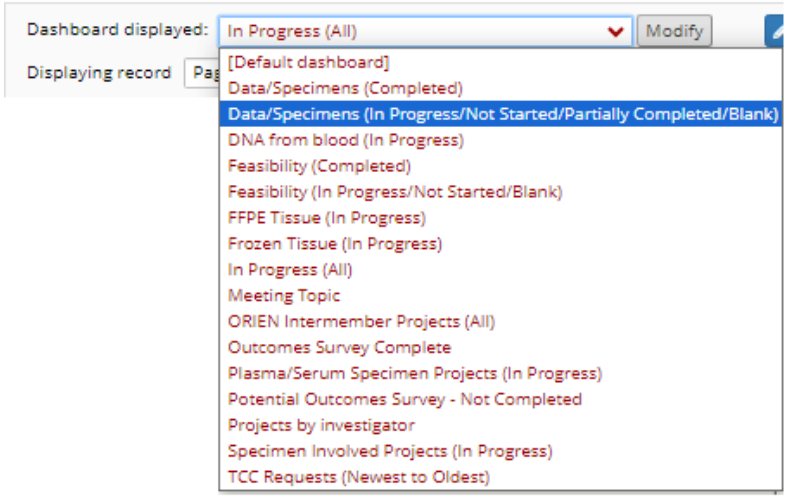
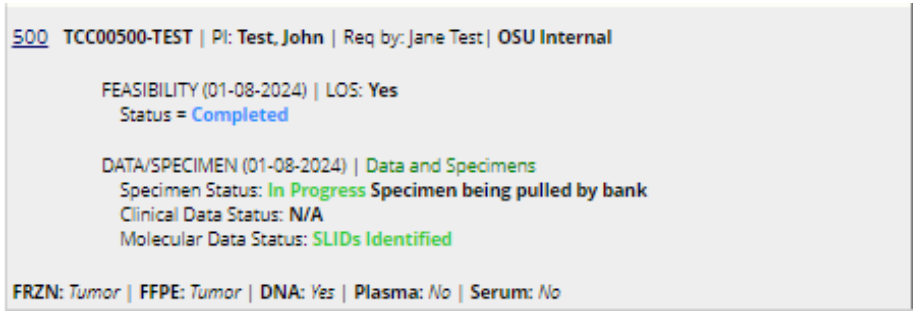
Record Status Dashboard



Custom Record Label



Custom Record Label: [meeting_topic] [tcc_project_id] | PI: [pi_last_name], [pi_first_name] | Req by: [requester_name]| [project_type]

 FEASIBILITY ([feas_date_submitted]) | LOS: [los_yn] Status = [feas_project_status] [feas_project_sub_status]
 DATA/SPECIMEN ([data_specimen_date_submitted]) | [request_type] Specimen Status: [specimen_project_status] [specimen_project_sub_status]
 Clinical Data Status: [clinical_data_project_status]
Molecular Data Status: [molecular_data_project_status]</br>
FRZN: [tissue_type_frozen] | FFPE: [tissue_type_ffpe] | DNA: [dna_blood] | Plasma: [plasma] | Serum: [serum]</br>

Field Choices:

NotStarted, Not Started
PendingCommitteeApproval, Pending Committee Approval
InProgress, In Progress
ClarificationInvestigator, Clarification Needed from Investigator
OnHold, On Hold
PartialCompleted, Partially Completed
Completed, Completed
CancelledTCC, Cancelled - TCC Admin
CancelledPI, Cancelled - PI/Requester
UnableToFill, Unable To Fill
Duplicate, Duplicate
NA, N/A

RGB Color Codes Chart
(https://www.rapidtables.com/web/color/RGB_Color.html)

Color	Color Name	Hex Code #RRGGBB	Decimal Code R,G,B
	dark slate gray	#2F4F4F	(47,79,79)
	teal	#008080	(0,128,128)
	dark cyan	#008B8B	(0,139,139)
	aqua	#00FFFF	(0,255,255)
	cyan	#00FFFF	(0,255,255)
	light cyan	#E0FFFF	(224,255,255)
	dark turquoise	#00CED1	(0,206,209)

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REDCap Reports

Data Exports, Reports, and Stats

VIDEO: How to use Data Exports, Reports, and Stats

+ Create New Report | My Reports & Exports | Other Export Options | View Report: Request by PI

Number of results returned: 1
Total number of records queried: 1,990
('records' = total available data across all designated events)
Report execution time: 0.2 seconds

Stats & Charts | Export Data | Print Page | Edit Report

Live filters: Test, John | [Distinct Co-Investigator List (Inter | Reset

Request by PI

TCC Request ID tcc_request_id	Event Name redcap_event_name	Repeat Instrument redcap_repeat_instrument	Repeat Instance redcap_repeat_instance	TCC Project ID (Internal Field Only) tcc_project_id	Distinct Investigator List (Internal Field Only) distinct_investigator_list	Distinct Co-Investigator List (Internal Field Only) distinct_coinvestigator_list	TCC Project File Name (Internal Field Only) tcc_project_file_name	Requester's Name requester_name	Requester's email requester_email	Requester's phone number requester_phone_number	Project/Study Title project_study_title	Project ObjectivesBriefly describe the objectives/hypothesis of the project. project_objective
500 **TCC00500-TEST** | PI: **Test, John** | Req by: Jane Test| **OSU Internal** FEASIBILITY (01-08-2024) | LOS: **Yes** Status = **Completed** DATA/SPECIMEN (01-08-2024) | Data and Specimens Specimen Status: **In Progress** **Specimen being pulled by bank** Clinical Data Status: **N/A** Molecular Data Status: **SLIDs Identified** **FRZN:** *Tumor* | **FFPE:** *Tumor* | **DNA:** *Yes* | **Plasma:** *No* | **Serum:** *No*	Initial Request			TCC00500-TEST (TCC00500-TEST)	Test, John (TEST)	Test, Jane | Test, Jim (TES2-TES3)		Jane Test	brittney.sharick@osumc.edu		Study the XYZ1 gene in colorectal cancer patients who are MSI-H vs wildtype.	Requesting tumor tissue and blood (germline) samples from 50 patients (25 from each group) who are MSI-H and MSI wildtype and do not have any sequencing data available. Requesting sequencing data from 50 additional patients (25 from each group) that do have sequencing data available. We would like to study XYZ1 in both tumor and germline samples to see the correlation between tumors being classified as MSI-H vs wildtype.

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REDCap Reports

P1694 -- TCCP Data & Specimen Request (DSR) PID 2313

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the Define My Events page.

Choose action for record

Legend for status icons:

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved)
- Partial Survey Response
- Completed Survey Response
- Many statuses (all same)

TCC Request ID **500** **TCC00500-TEST** | PI: **Test, John** | Req by: Jane Test | **OSU Internal**

FEASIBILITY (01-08-2024) | LOS: **Yes**
Status = **Completed**

DATA/SPECIMEN (01-08-2024) | Data and Specimens
Specimen Status: **In Progress** **Specimen being pulled by bank**
Clinical Data Status: **N/A**
Molecular Data Status: **SLIDs Identified**

FRZN: *Tumor* | **FFPE:** *Tumor* | **DNA:** *Yes* | **Plasma:** *No* | **Serum:** *No*

We utilize the status icon color to monitor the project.

Data Collection Instrument	Initial Request initial_request	Project Status project_status	Internal Review internal_review	Project Survey project_survey	Committee Approval committee_approval
TCC Project Form (survey)	●				
Feasibility Form (survey)	●				
Data/Specimen Form (survey)	●				
TCC Investigator Agreement (De-identified) (survey)	○				
TCC Investigator Agreement (Identified) (survey)	●				
TCC Data Use Agreement (survey)	●				
Feasibility TCC Internal Review			●		
Data/Specimen TCC Internal Review			●		
TCC Research Committee Approval (survey)					●
PI/Director Review (survey)					●
TCC Review Member #1 (survey)					●
TCC Review Member #2 (survey)					●
TCC Review Member #3 (survey)					●
TCC Review Member #4 (survey)					●
AL MDS Approval (survey)					○
BMT Approval (survey)					○
Breast Approval (survey)					○
CLL Approval (survey)					○
CNS Approval (survey)					○
GI Approval (survey)					●
GU Approval (survey)					○
Gynecologic Approval (survey)					○
HN Approval (survey)					○
Lymphoma Approval (survey)					○
Melanoma Approval (survey)					○
MM Approval (survey)					○
Sarcoma Approval (survey)					○
Thoracic/Lung Approval (survey)					○
Thyroid Approval (survey)					○
Data/Specimen Survey (survey)				●	

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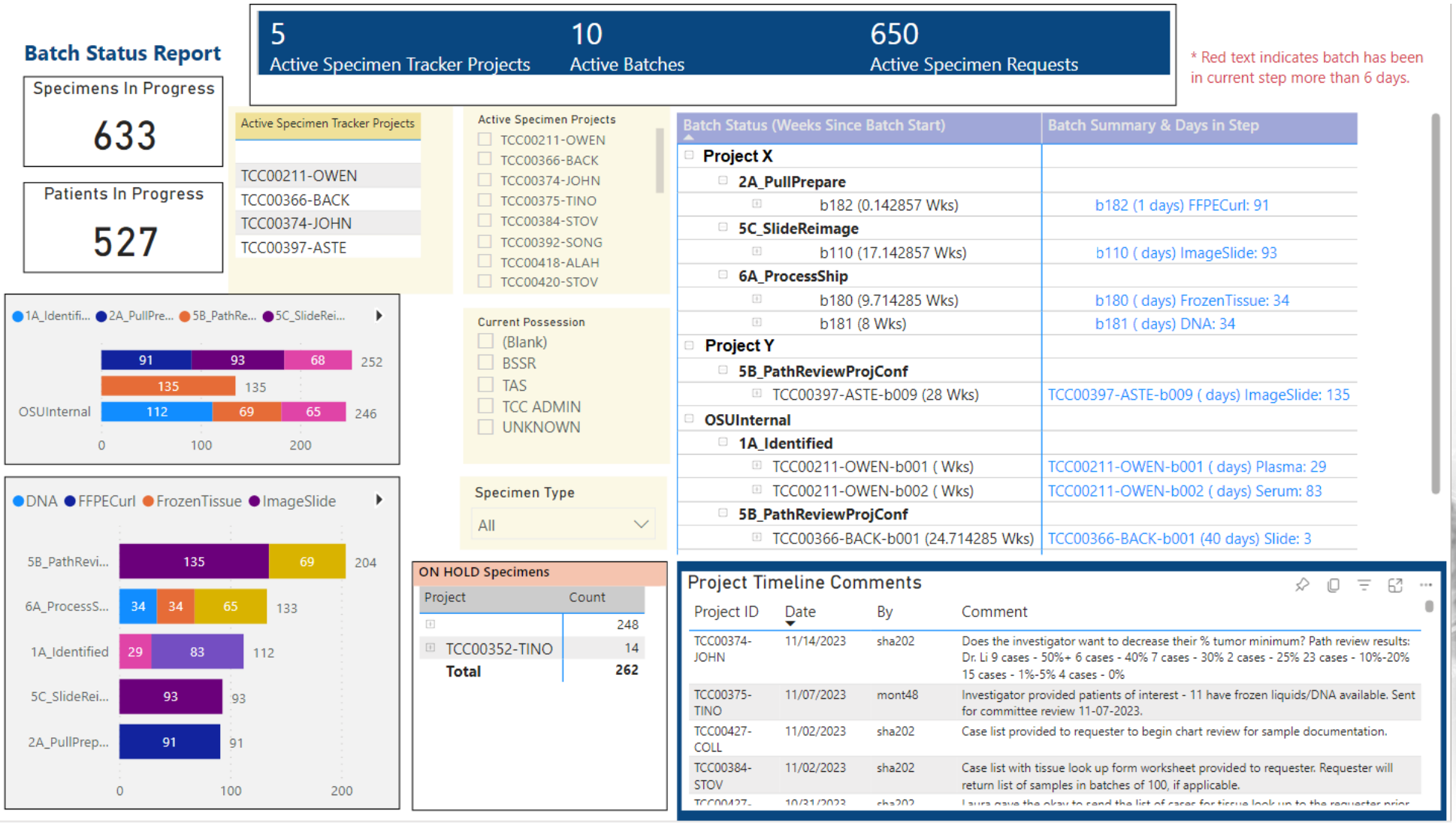
Dashboarding
(PowerBI)

- Pulling together multiple REDCap databases (in SQL) + SQL reports to create detailed dashboards.



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Questions?

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