# Geriatric Oncology Data Control Project

By: Lauren Mitchell

# Introduction

# About GeriOnc

- Independent Group
- Local IIT's
  - 28 studies
    - 5 in SSU
    - 11 Active
    - 12 CTA
- Team of ~40
- 2022 = centralization
  - 2022/2023 = Regulatory
  - 2023/Present = Data Control

# Data Control Project

**Purpose:** To ensure research data is being handled in compliance with all standards, regulations, and policies to safeguard research information.

This project will also serve to optimize data quality, reduce risk, and enhance data practices.

**Scope:** This project applies to all research studies under the purview of the Geriatric Oncology Research Group.

- The primary focus will be on the studies that are currently active
  - Including those currently in SSU
- The secondary focus will be on the studies that are closed to accrual

# Data Control Project

**Who:**

GeriOnc Director, Supriya Mohile MD

GeriOnc Clinical Research Regulatory Manager, Lauren Mitchell

GeriOnc Local Studies Information Analyst, Jenna Cacciatore

REDCap Administrator, Kim Kaukeinen

**When:** 2023-2026

# Data Control Project

**Why:**

- Improper data collection practices
- Data entry errors
- Little to no verification or validation processes
- Series of continuing non-compliance
- Incomplete and inaccurate data analysis

# Examples

- User Rights
  - Personnel were added to EDC and performed data entry who were not officially delegated to the study
- Study Measures
  - Measures that required pre-approval or licensing for use were not obtained
  - Study measures that were licensed were illegitimately adapted for study-specific use
  - Source documents & REDCap instruments were not built identical to the measure
    - Missing questions
    - Incorrect spelling
    - Improper coding logic to accommodate specific questions

# Examples

- Limited use of verification process(s)
  - Incorrect data entry practices & erroneous instrument designs led to incorrect data analysis
  - Study results and Publications in jeopardy

# Data Control Project

- All items and/or processes that come out of the data control project will be applied to all current and future GeriOnc research studies. They will serve to:
  - Centralize
  - Validate
  - Streamline consistency
  - Increase efficiency
  - Save time & effort
  - Decrease errors
  - Produce reliable results

# Phase I: Library

# Refresher

- Within each EDC system, research data is arranged on case report forms (CRFs) and these CRF's represent an instrument used to collect specific information
- CRFs should be built with consistency and accuracy. Faulty CRF's can lead to the integrity of the data can be comprised; increased risk in data entries errors can occur leading to invalidated or incorrect data being processed during data analysis
- Additionally, CRFs should be constructed to only collect research data that is
  - (1) required to be collected
  - (2) approved to be collected
  - (3) intended to be collected; all of which should support the research study
- CRF's should be designed simply and user-friendly

# The CRF Library

- This library will be an extensive collection of well-built, verified, and tested, CRF's designed to accurately reflect the original source and capture research data needed to run accurate and appropriate data analysis

- All local GeriOnc IIT's utilize REDCap as the study EDC. Therefore, the library is in REDCap

- It is managed by:
  - GeriOnc Director
  - GeriOnc Clinical Research Regulatory Manager
  - GeriOnc Local Studies Info Analyst
  - REDCap Administrator

# The CRF Library

CRF instrument built by Data Control Team

↓

Reviewed by GeriOnc Director

↓

1st Test by GeriOnc Research Staff

↓

2nd Test by Statisticians

↓

Released For Use on Research Studies

Some CRF's may be adapted while other's are permanent based on:

- Licensing
- Copyright privileges
- Validation
- Scoring

# The Source Document Library

- Source documents will be made to identically match each specific REDCap CRF

- Some source documents may be adapted while other's are permanent based on:
  - Licensing, copyright privileges, validation, and scoring

# Phase 2: Active Study Audits

# Information

- **All active studies in GeriOnc have and/or will undergo a fully comprehensive data audit by:**
  - GeriOnc Clinical Research Regulatory Manager
  - GeriOnc Local Studies Info Analyst

- **We Review:**
  - Team logistics
  - Complion & OnCore
  - The protocol
  - All consent forms/information sheets
  - Source documentation
  - The EDC
  - Storage/Retention of research data and research records
  - Data quality/validity
  - Data usability

# Data Audit: Resources

**Resource #1: Logistics**

- The logistics of the team is assessed on a study-by-study basis
- This checklist helps:
  - Assess the education and understanding of data practices across all members of the research team
  - Provides the auditors with a clear view of what is/is not occurring on the study in relation to data control

| | | | |
|---|---|---|---|
| Protocol#: | | PI: | |
| Audit Date(s): | | Study Team: | |
| Auditors: | | | |

| Logistics | | | |
|---|---|---|---|
| Item | Y | N | Comments |
| Does the PI and the study team have GDP training? | | | |
| Does the team use both electronic and ink signatures? | | | |
| Is the study team trained on the fundamentals of data integrity - never disclose their username or passwords to other employees? | | | |
| Does the study team understand the importance of ALCOA+C? | | | |
| Does the study team know that it is improper to back date or forward date a record? | | | |
| Do study team members know to use single-line cross outs accompanied by an initial and date when recording changes to a record? | | | |
| Are there policies and procedures in place to guide employees in reporting a data integrity breach? | | | |
| Does the study team use scribes? | | | |
| Does the study team have a process to perform secondary review of original paper records? | | | |
| Does the study team have a process to perform a check on the accuracy of data? | | | |
| Does the study team have a process in place for the secondary review of data? | | | |
| Does the study undergo internal audits that include checking data integrity? | | | |
| Is there a policy governing how long electronic records are kept? (Paper, electronic, and data sets?) | | | |

# Data Audit: Resources

| Data Control | | | |
|---|---|---|---|
| Item | Y | N | Comments |
| Is REDCap a system that is password protected? | | | |
| Does REDCap have an inactivity logout? | | | |
| Does REDCap have access roles? What types of access roles are in the system? | | | |
| Can each role have a defined access? | | | |
| Does REDCap have measures to prevent:<br>• Changes to the date & time of entries<br>• Renaming of entries<br>• Deleting of entries | | | |
| Is original data still readable when a correction has been applied? | | | |
| Are there audit trials available in place recording the identity of operators entering, changing, confirming, or deleting data? | | | |
| Does the system identify and record the person releasing or certifying the batches? | | | |
| Does REDCap allow for an electronic signature? | | | |
| Do electronic signatures contain an automatically generated timestamp? | | | |
| Are your electronic signatures permanently linked to their respective record? | | | |
| Are audit trails convertible to a generally intelligible form? | | | |
| Does REDCap automatically generate a timestamp when data is entered? | | | |
| Are users able to change the timestamps applied to records? | | | |
| Is data saved to unauthorized storage locations such as USB sticks? | | | |
| Can data be backed-up? Comment on how. | | | |
| Is data backed up in a manner permitting reconstruction of an activity? | | | |
| Does the person processing the data have the ability to influence what data is reported or how it is presented? | | | |
| Is metadata periodically reviewed? | | | |
| If you are using paper or PDF reports are used as a data record, could you reconstruct the raw data set from electronic records be reconstructed at a future date? | | | |
| Is REDCap secured to prevent the corruption of data? | | | |
| Is archived data protected against unauthorized amendment? | | | |
| Is there a disaster recovery plan in terms of retrieving both paper and electronic data records? | | | |
| Are data sets stored? Comment on where. | | | |
| Are data sets kept? Comment on how long. | | | |
| Are REDCap project users reviewed regularly to add or remove access as required? | | | |

**Resource #2: Data Control**

- Assess the overall security of the data
  - Confidentiality
  - Integrity
  - Availability

# Data Audit: Resources

**Resource #3: Audit Report**

- All versions of the protocol are reviewed in-depth
- All versions of the consent form are reviewed and compared to the associated protocol version(s)
- All study assessments performed by participating subjects are reviewed
- Source Docs & EDC are reviewed for accuracy
- Data Integrity
  - Does the data support the study aims?
- Other/MISC
  - OnCore Records
  - Data Security Form

| Protocol | | |
|---|---|---|
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| | | |
| **Consent Forms** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| **Human Subjects Review** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| **Source Documents** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| **EDC** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| **Data Integrity** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |
| **Other/MISC** | | |
| Findings | Comments | Suggestions |
| | | |
| | | |
| | | |

# Before

- **“GeriOnc Audit Schedule” in Outlook**
  - Audit dates/times for each study will be put on this calendar
- **Preparation for the audits:**
  - Scan all applicable subject documentation in the study-specific Box folder
  - Provide auditors access to the study-specific Box folder
  - Prior corrections and verifications do not occur so that:
    - Auditors assess the weaknesses
    - Auditors identify the strengths
  - Rename study Box folder and EDC to its correct short title
    - "PRMC# / Short Title / PI Last name"
- **The PI and the study team will receive an email before the audit begins**

# During

- **During the audits:**
  - All enrollment stops
    - Unless it is imperative for the grant timeline/current funding for the study
  - All data (intended to be collected up until that point) is present in the EDC
  - No data entry will occur during the audit
  - No scanning will occur during the audit

- **It may be the case that the data audit takes longer than anticipated**
  - The teams will be notified if more time is needed
  - All terms of the audit remain unless enrollment is imperative for the grant timeline/current funding for the study

# After

- **After the audit:**
  - The findings report will first be released to the PI and the PM (via Box)
    - In rare instances, the findings may have a slow-release or a delayed release
  - A meeting with be held between the PI, the PM , Clinical Research Regulatory Manager, Local Studies Info Analyst
    - The findings and suggestions will be reviewed
  - The findings report will released to the rest of the study team (via Box)
    - All CAPA's will be submitted per IRB timeline
    - Revisions & Corrections are completed within 6-months

# Phase 3: Process & Workflow

# Feasibility Assessment

Feasibility assessment will be conducted at the beginning of the SSU process for each local IIT

For Data Collection & Data Abstraction;

- Is REDCap useful for my study team to use?
  - Do they need user training?

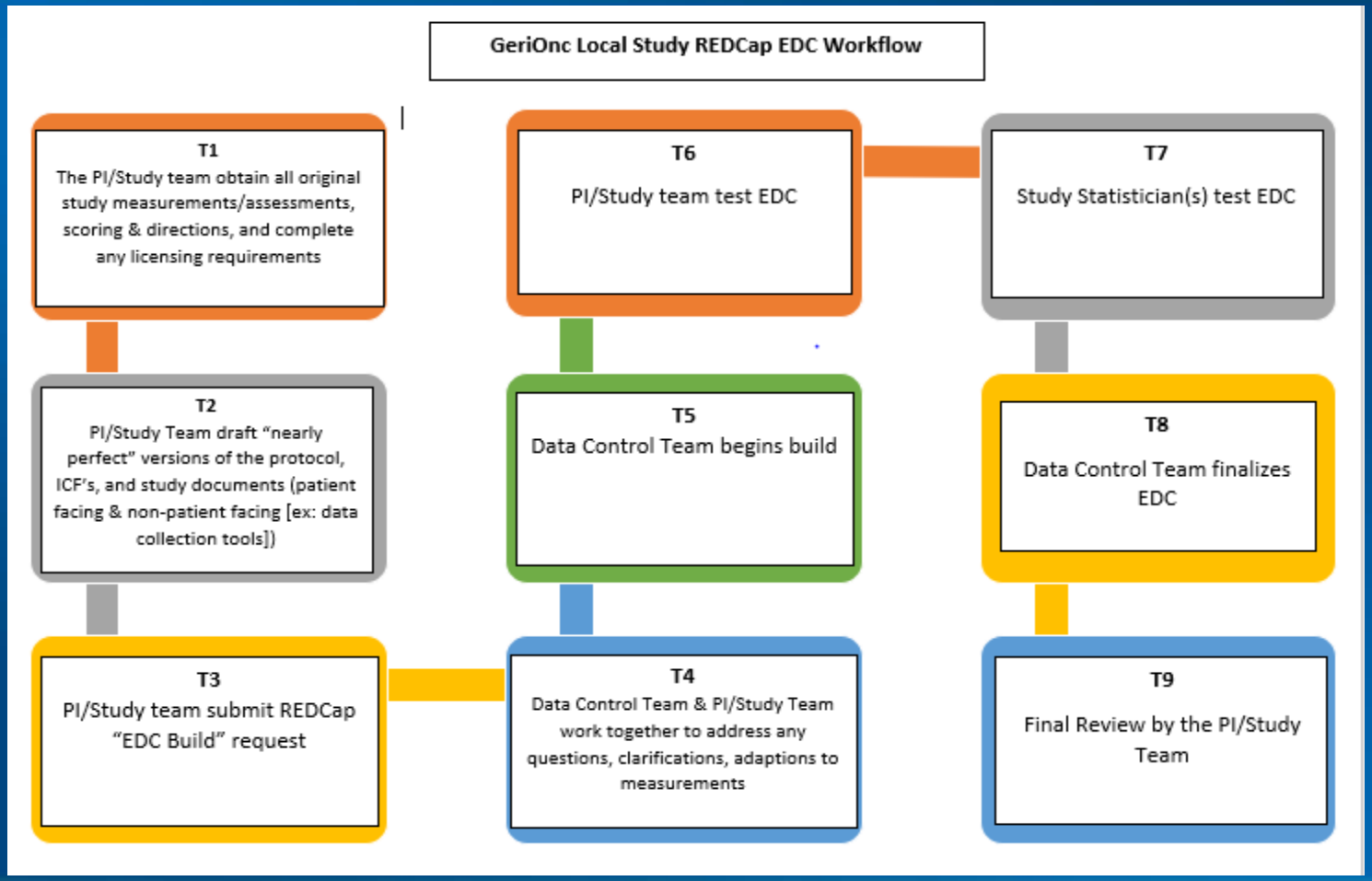
- Will REDCap support all my study needs?
  - Example: REDCap has Randomization modules
  - Example: REDCap is not useful for scheduling

# Study Start-Up (SSU)


- Before submitting to the IRB for initial approval, a request form will be completed
  - It will alert REDCap Administrator of the request
  - The REDCap Administrator will create the study EDC & Case Summaries
- The Local Studies Info Analyst will review & test the EDC

**The PI nor the study team will create CRF's/study EDC's**

# GeriOnc SSU: Local IIT's



# Amendments


- After receiving IRB approval, a request form will be completed
  - It will alert REDCap Administrator of the request
  - The REDCap Administrator will add the CRF(s) & Case Summary(s)
- The Local Studies Info Analyst will review the change(s)
- The REDCap Administrator will release the change(s)

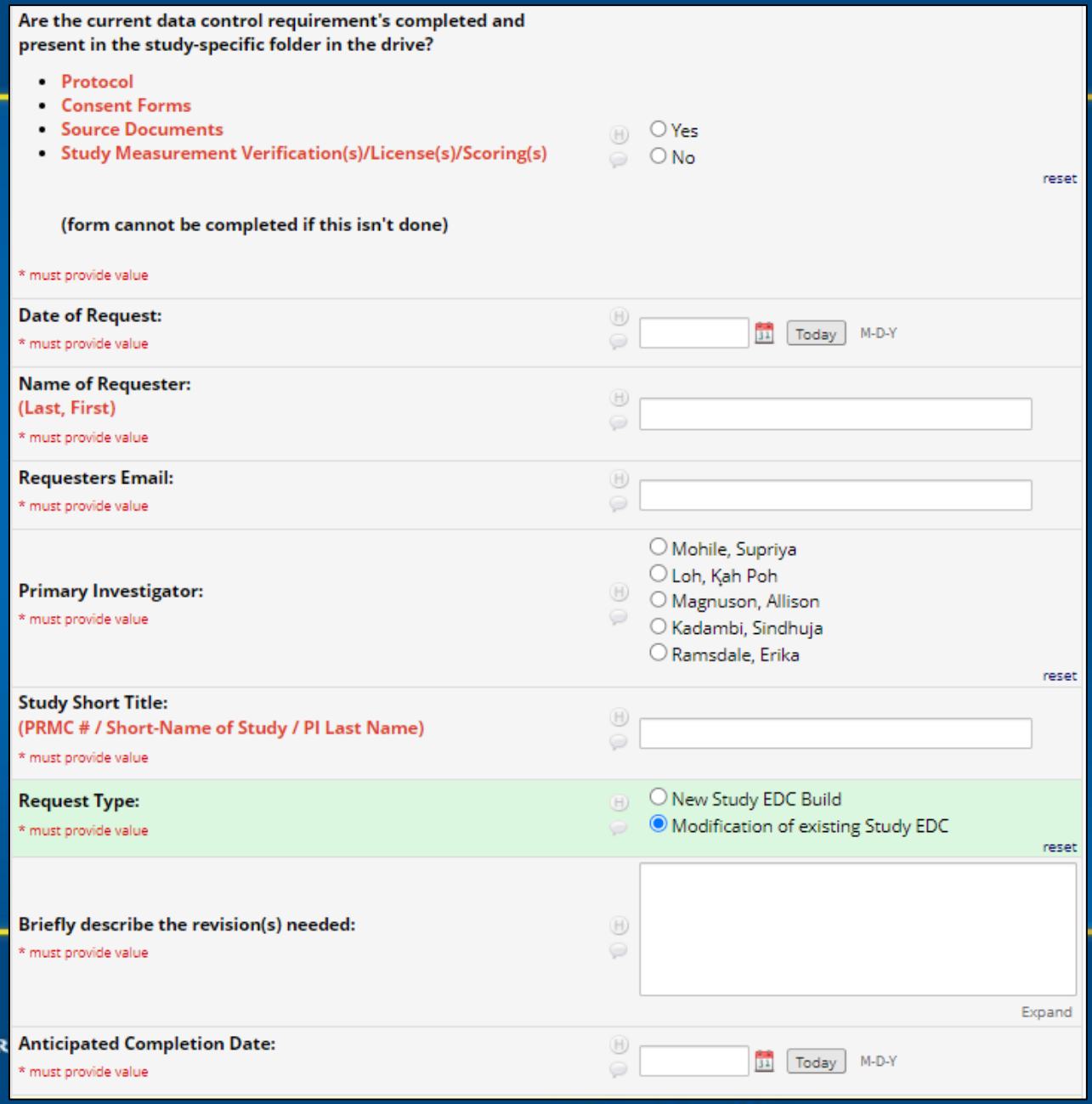
**The PI nor the study team will create CRF's/study EDC's**

# REDCap Request Form

## Geriatric Oncology: REDCap EDC Requests

## This will be a Public REDCap Link!

## In GeriOnc, we keep use a strict filing system in our research drive that holds all in-process essential study documentation while a study is in the SSU process



**Are the current data control requirement's completed and present in the study-specific folder in the drive?**

- Protocol
- Consent Forms
- Source Documents
- Study Measurement Verification(s)/License(s)/Scoring(s)

○ Yes
○ No

reset

**(form cannot be completed if this isn't done)**

* must provide value

**Date of Request:**
* must provide value

Today M-D-Y

**Name of Requester:**
(Last, First)
* must provide value

**Requesters Email:**
* must provide value

**Primary Investigator:**
* must provide value

○ Mohile, Supriya
○ Loh, Kah Poh
○ Magnuson, Allison
○ Kadambi, Sindhuja
○ Ramsdale, Erika

reset

**Study Short Title:**
(PRMC # / Short-Name of Study / PI Last Name)
* must provide value

**Request Type:**
* must provide value

○ New Study EDC Build
◉ Modification of existing Study EDC

reset

**Briefly describe the revision(s) needed:**
* must provide value

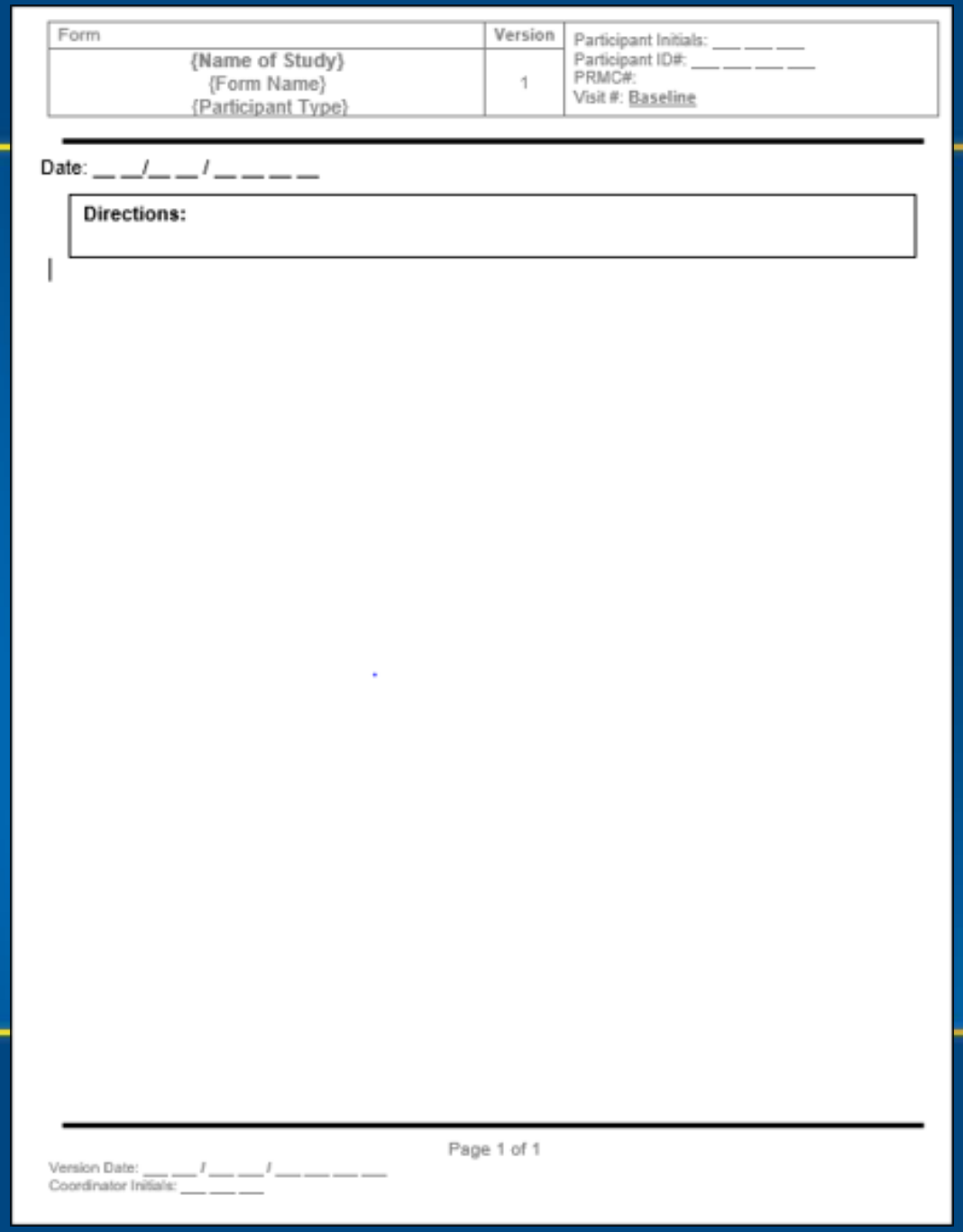
Expand

**Anticipated Completion Date:**
* must provide value

Today M-D-Y

# Source Document Consistency

- GeriOnc Source Document Template
  - W:\0. Local Research Studies\4. Local Study Data Control
  - All new studies will use the same template
  - It is **highly recommended** that current open to accrual studies (that are not close to reaching their accrual goal) switch to this template



| Form | Version | Participant Initials: __ __ __<br>Participant ID#: __ __ __ __ __<br>PRMC#:<br>Visit #: Baseline |
|---|---|---|
| {Name of Study}<br>{Form Name}<br>{Participant Type} | 1 | |

Date: __ __/__ __/__ __ __ __

**Directions:**

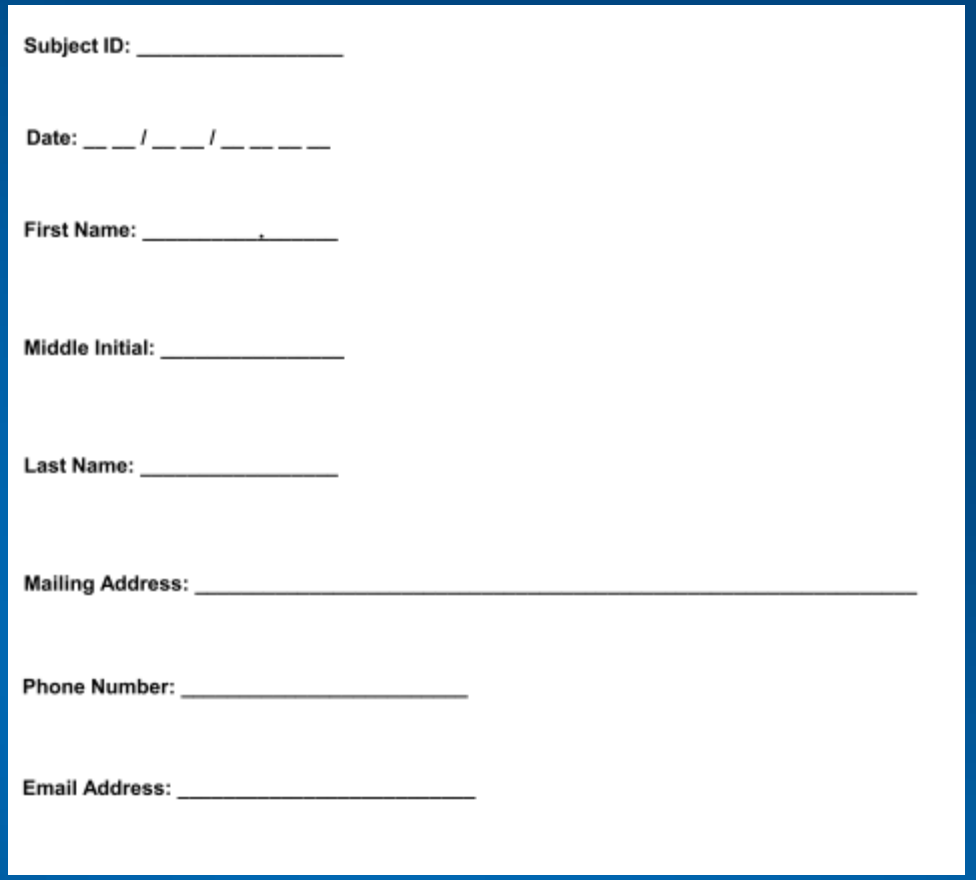
Page 1 of 1

Version Date: __ __/__ __/__ __ __ __
Coordinator Initials: __ __ __

# Example

Source Doc: Subject Contact Form

- First source document a subject completes
  - Completes at consent
- First instrument in REDCap EDC
  - Can take this information and “pipe” it to other instruments to:
    - Provide an informative header
    - Reduce duplicate data entry



Subject ID: _____

Date: __ __ / __ __ / __ __ __ __

First Name: _____

Middle Initial: _____

Last Name: _____

Mailing Address: _____

Phone Number: _____

Email Address: _____

# Phase 4: Closed to Accrual Study Audits

# Closed to Accrual Study Audits

- It will be the PI's decision if CTA studies will undergo a full data audit
- It is up to the PI if they would like the CTA study(s) to undergo "soft" audits
  - The auditors will either:
    - Select a random sample of subjects enrolled
    - Or, all subjects will be audited but over a much longer period of time
- It is not required that CTA studies undergo a full data audit
  - However, it is highly recommended a data audit is performed because:
    - Inaccurate analysis
    - Publication accuracy and queries
    - Referring old data and running secondary, tertiary analysis on "bad" data

# Phase 5: Governance

# Long-Term Fortified Processes

- User Rights System
- Data Verification Systems
  - Missing Data Process
  - Case Summaries
  - Internal Audits
- Study-Specific Reports
  - As needed and/or request for each study for data analysis
- Data Recovery System

# User Rights System

- EDC user rights have roles that equate to GeriOnc's delegation system
- Based on the user's delegated role, they are permitted the equivalence of that responsibility

**PI**
- Survey Tools
- Alerts
- Reports
- Stats & Charts
- Data Tools
- Logging
- Data Quality
- Create Records
- Rename Records
- Delete Records
- View & Edit Responses
- Full Data Set

**Sub-Investigator**
- Survey Tools
- Alerts
- Reports
- Stats & Charts
- Logging
- Data Quality
- Create Records
- View & Edit Responses
- Full Data Set

**Research Coordinator**
- Survey Tools
- Alerts
- Stats & Charts
- Logging
- Data Quality
- Create Records
- View & Edit Responses
- Full Data Set

**Data Manager**
- Full Rights

**Statistician**
- Survey Tools
- Alerts
- Reports
- Stats & Charts
- Data Tools
- Logging
- Data Quality
- Create Records
- Full Data Set

# Missing Data Process: Paper

In-Person:

- The Study team member will review the source doc(s) with the subject present and attempt to confirm and complete any missing or ineligible answers, using blue or black ink, on the questionnaire and utilize the guidelines of GDP to reflect accurate corrections by:
  - Have the subject fill in the missing fields
  - Or, the study team member fills in the missing fields per the subjects responses and initials/dates next to the field at the time of the correction(s)

Mailed/Completed at Home:

- The study team member will attempt to contact the subject via phone to confirm and complete any missing or ineligible answers, using blue or black ink, on the questionnaire and utilize the guidelines of GDP to reflect accurate corrections by:
  - The study team member fills in the missing fields per the subjects responses and initials/dates next to the field at the time of the correction(s)
  - Cross out the illegible answer(s) with a single line, then initialing and dating next to the answer(s) per the subject response at the time of the correction(s)

# Missing Data Process

- If a subject does not want to answer a question, the study team will use the comment function in REDCap to document this and why, if applicable
  - EXAMPLE: Patient stated the questionnaire was "too depressing"

NTF's

- A NTF will only be used if an entire instrument/test/assessment is missing/incomplete
  - A comment will be added at the end of the REDCap
  - The CRF will remain blank "greyed"
  - Deviation will be recorded in OnCore
  - NTF will be filed in research chart (paper & electronic)

# Missing Data Process: Electronic

- The study team member will attempt to contact the subject via phone to confirm any missing fields. They will complete any missing answers on the survey in REDCap by:
  - Editing the survey response and complete the missing field per the subject's answer
  - Use the comment function next to the field to document:
    - When the subject was contacted
    - Why they were contacted
    - What was changed

# Case Summaries

Case summaries are used in research to review data and document reasons for missing data

**GeriOnc Process:**

- Case summaries will be built for each CRF, at each timepoint
- Case summaries will be edited to incorporate any for new CRF's during amendments
- When a subject completes a timepoint, the PM will complete the associated case summary

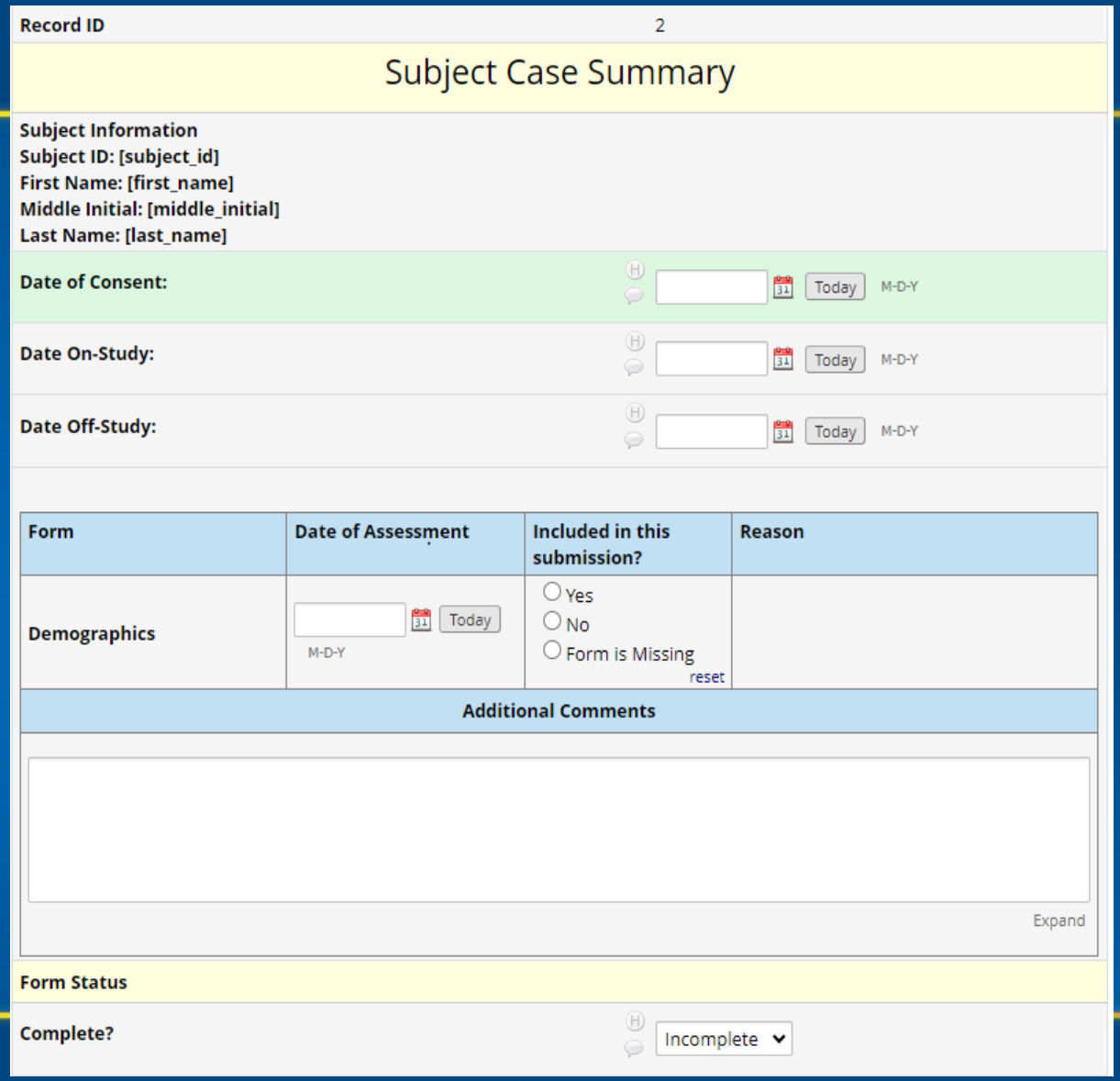
# Case Summary Template

Subject information is piped in from the *Subject Contact Form instrument*

Key study information

Each instrument used will have it's own field

Commentary, if needed



**Record ID** 2

## Subject Case Summary

**Subject Information**
**Subject ID: [subject_id]**
**First Name: [first_name]**
**Middle Initial: [middle_initial]**
**Last Name: [last_name]**

**Date of Consent:** Today M-D-Y

**Date On-Study:** Today M-D-Y

**Date Off-Study:** Today M-D-Y

| Form | Date of Assessment | Included in this submission? | Reason |
|---|---|---|---|
| **Demographics** | Today M-D-Y | Yes / No / Form is Missing reset | |

**Additional Comments**

Expand

**Form Status**

**Complete?** Incomplete

# Case Summary: Example

**Date of Consent:** 11-01-2023 Today M-D-Y

**Date On-Study:** 11-01-2023 Today M-D-Y

**Date Off-Study:** 12-19-2023 Today M-D-Y

| Form | Date of Assessment | Included in this submission? | Reason |
|---|---|---|---|
| **Demographics** | 01-22-2024 Today M-D-Y | ○ Yes<br>○ No<br>◉ Form is Missing<br>reset | 07 - Subject withdrew |

**Additional Comments**

Subject withdrew from study on 12/19/2023. See NTF in subject's research chart dated 12/21/2023 detailing why the subject withdrew.

Expand

**Form Status**

**Complete?** Complete

Save & Exit Form | Save & ... | – Cancel –

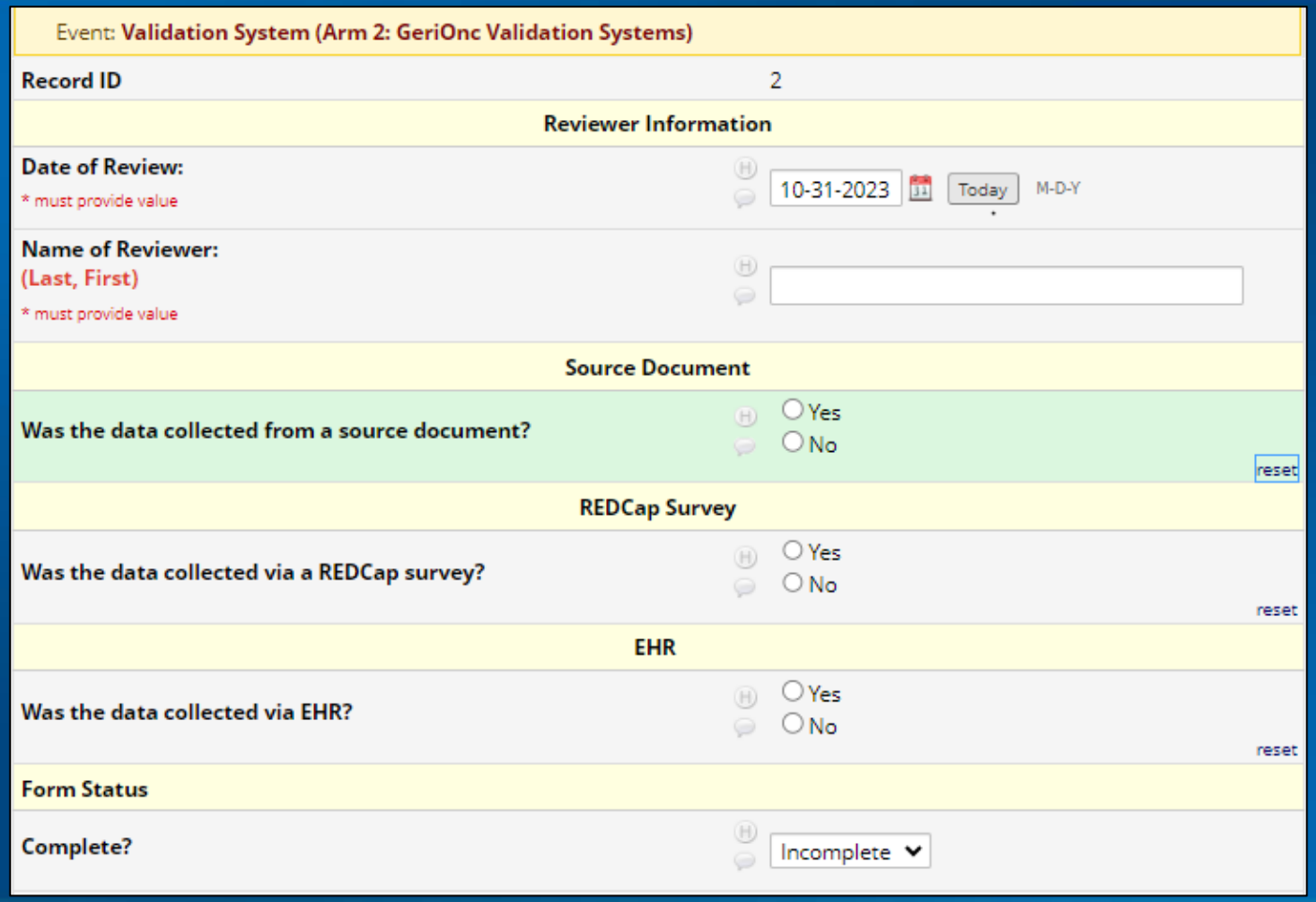
# Internal Audits

**Internal Audits will be held for each study, active and CTA, bi-annually**

**In relation to study data, Internal audits will verify:**

- The data is approved to be collected per the protocol
- The method of data collection is approved per the protocol
- The source document matches the CRF
- The data on the source doc matches the data in the EDC

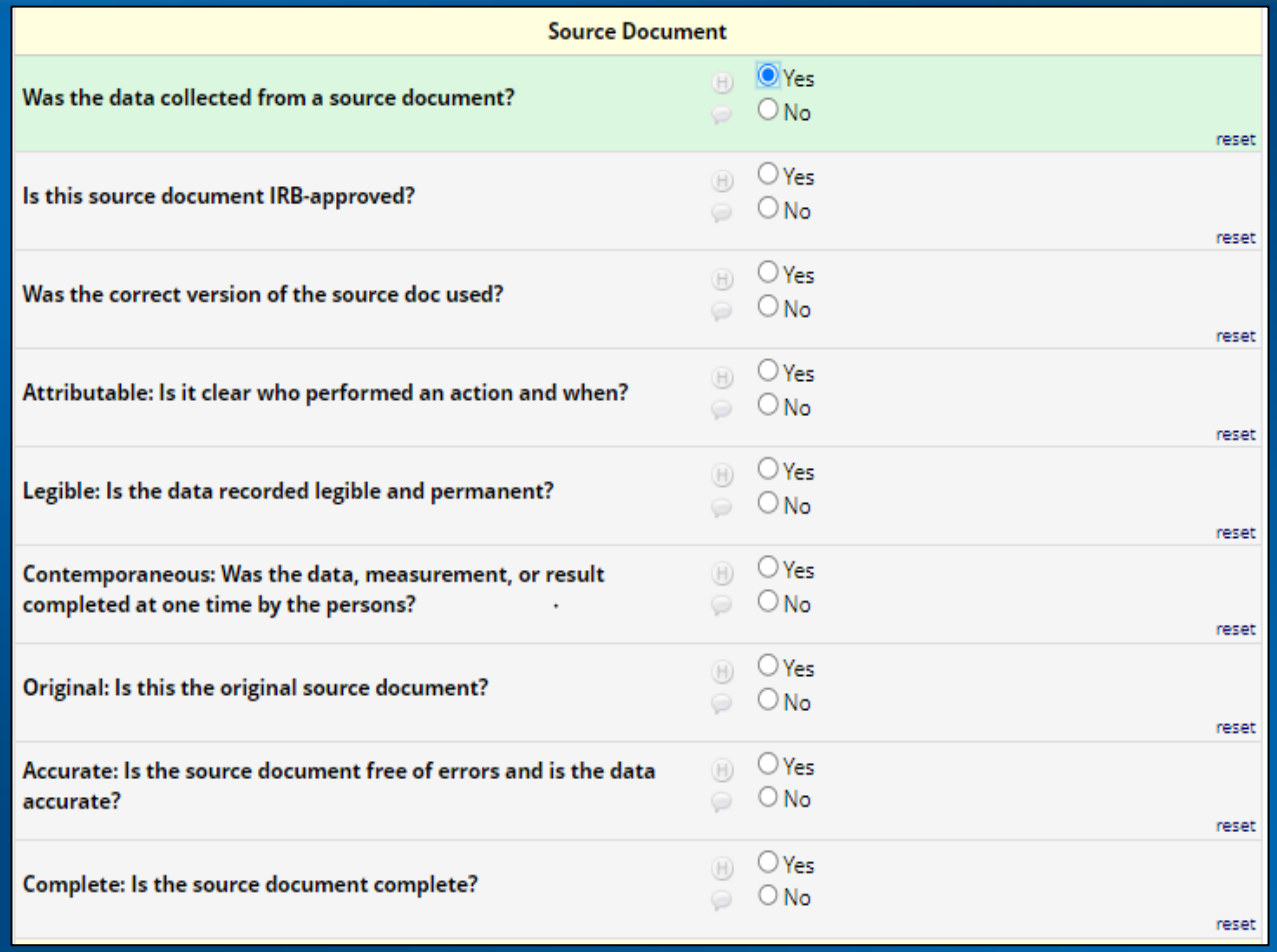
# Internal Audits: Data Review



Event: **Validation System (Arm 2: GeriOnc Validation Systems)**

| | |
|---|---|
| **Record ID** | 2 |
| **Reviewer Information** | |
| **Date of Review:** * must provide value | 10-31-2023 Today M-D-Y |
| **Name of Reviewer: (Last, First)** * must provide value | |
| **Source Document** | |
| **Was the data collected from a source document?** | Yes / No reset |
| **REDCap Survey** | |
| **Was the data collected via a REDCap survey?** | Yes / No reset |
| **EHR** | |
| **Was the data collected via EHR?** | Yes / No reset |
| **Form Status** | |
| **Complete?** | Incomplete |

# Internal Audits: Option 1



| Source Document | | |
|---|---|---|
| Was the data collected from a source document? | ◉ Yes ○ No | reset |
| Is this source document IRB-approved? | ○ Yes ○ No | reset |
| Was the correct version of the source doc used? | ○ Yes ○ No | reset |
| Attributable: Is it clear who performed an action and when? | ○ Yes ○ No | reset |
| Legible: Is the data recorded legible and permanent? | ○ Yes ○ No | reset |
| Contemporaneous: Was the data, measurement, or result completed at one time by the persons? | ○ Yes ○ No | reset |
| Original: Is this the original source document? | ○ Yes ○ No | reset |
| Accurate: Is the source document free of errors and is the data accurate? | ○ Yes ○ No | reset |
| Complete: Is the source document complete? | ○ Yes ○ No | reset |

# Data Verification: Option 2

| REDCap Survey | | |
|---|---|---|
| **Was the data collected via a REDCap survey?** | (H) (comment) | ◉ Yes ○ No reset |
| **Is the study approved to collect data via REDCap survey?** | (H) (comment) | ○ Yes ○ No reset |
| **Is the measure IRB-approved?** | (H) (comment) | ○ Yes ○ No reset |
| **Was the REDCap survey completed by the intended individual?** | (H) (comment) | ○ Yes ○ No reset |

# Data Verification: Option 3

| EHR | | |
|---|---|---|
| Was the data collected via EHR? | ◉ Yes ○ No | reset |
| Is the study approved to collect this data from the EHR? | ○ Yes ○ No | reset |
| Does the data from the EHR match the data on the CRF? | ○ Yes ○ No | reset |

# Data Recovery System

- An alert will be sent to the GeriOnc Local Studies Information Analyst every 30 days:
  - For each study EDC
  - To retrieve the full dataset from REDCap

- This will help:
  - Support continuity
  - Minimize data loss
  - Restore/recover lost data
  - Confirm any unwarranted data changes

# Centrality

- Firm SSU & Amendment workflow
- SOP's
- Internal Audits
  - Bi-annually for each active and CTA study
- Training
- Resources
- Experience & Knowledge from data audits
- Re-Evaluation of processes
  - Adjust & Adapt as needed

# 2024: Current Stats

- SSU Studies Reviewed & Corrected before activation: 4
  - Tested, refined, and implemented new Data Control practices
- Active Studies
  - Audits Completed: 4
  - Audits Pending: 3
    - 2 out of the 4 active studies audited were CTA'ed
    - 10 events of non-compliance identified and reported to IRB with detailed CAPA's
- CTA Studies
  - Audits Completed: 1 (Soft)
    - 2 events of non-compliance identified & reported to IRB with detailed CAPA's
  - Audits Pending: TBD

# Conclusion

- GeriOnc does not allow the PI or the study team to create or amend the study EDC

- GeriOnc retired and removed any old:
  - Verification/Validation systems
  - Non-central and non-tested CRF's
  - Non-central source document templates
  - User rights structures

# Conclusion

- Infusing quality in IIT's is challenging
  - GeriOnc is trying to be preventable but also reliable
  - Finding a balance: *What is too much and what is not enough?*
- Consistent training and support is key
  - The goal is to enforce *good practice* through *good practices*
- This is a "all hands on deck" project
  - Teamwork
- It's expected that some pieces of this project may succeed and some may fail
  - But that's okay!
  - Research is constantly evolving and so are we

# Questions?