Electronic Data Capture Systems and Data Management Best Practices

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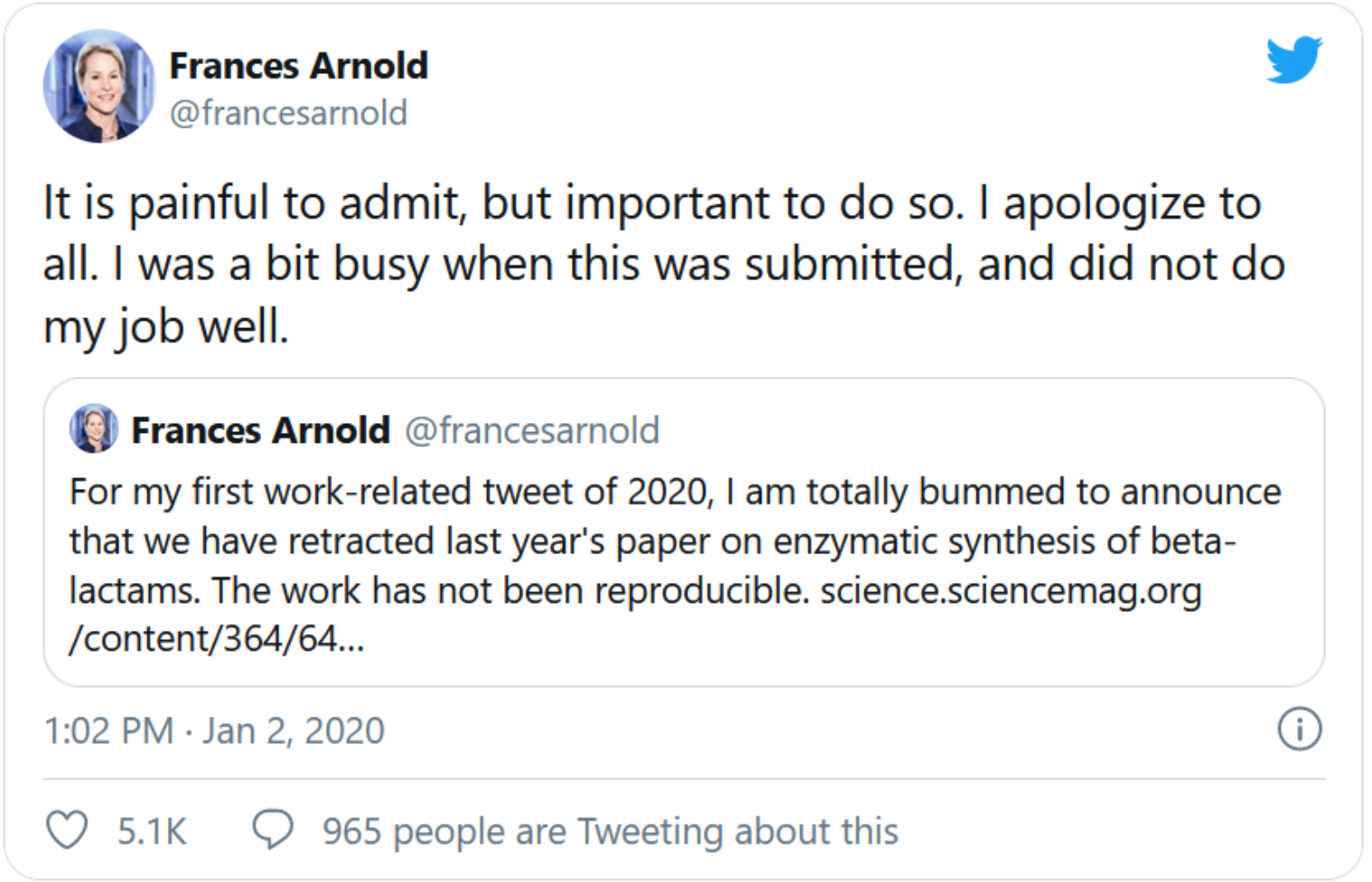
The University of Vermont
LARNER COLLEGE OF MEDICINE

Learning Objectives

JTF Clinical Research Competency Domains – 4 and 6

- Describe Good Clinical Practice guidance regarding data quality and audit trails
- Discuss the differences between Source Documents and Case Report Forms
- Apply ALCOAC-CEA principles to paper and electronic database design
- Incorporate Quality Assurance into your electronic database design

Nobel Prize-winning scientist Frances Arnold retracts paper



https://www.bbc.com/news/world-us-canada-50989423

Nobel Prize-winning scientist Frances Arnold retracts paper

"Efforts to reproduce the work showed that the enzymes do not catalyze the reactions with the activities and selectivities claimed. **Careful examination of the first author's lab notebook then revealed missing contemporaneous entries and raw data for key experiments.** The authors are therefore retracting the paper."

https://www.bbc.com/news/world-us-canada-50989423

Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, **recording and reporting trials** that involve the participation of human subjects.

Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, **and that the clinical trial data are credible**.

Good Clinical Practice (GCP)

Audit: A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and **the data were recorded, analyzed and accurately reported** according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Audit Trail: Documentation that allows reconstruction of the course of events.

- ICH GCP E6

Good Clinical Practice (GCP) - Essential Documents

- **“If it isn’t documented, it didn’t happen”.** This highlights how important record keeping/data collection is in the field of clinical research and it applies to regulatory and clinical documentation.
- The documents/data should be maintained so that an independent person, with no knowledge of the study, can review the study documents and follow the life cycle of the study without input from the study team.

Source Documents

- All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

- Section 1.51 ICH E6 GCP

Examples:

- Signed informed consent forms
- Hospital records and clinical notes
- Laboratory result reports

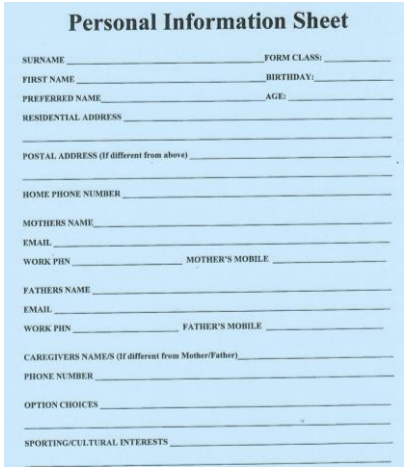
*Note: All source material must be signed and dated by the person who documented the information. This includes electronic signatures.

Case Report Forms (CRFs)

- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. - Section 1.11 ICH E6 GCP

Examples:

- A CRF to record patient demographics
- A CRF to record laboratory results

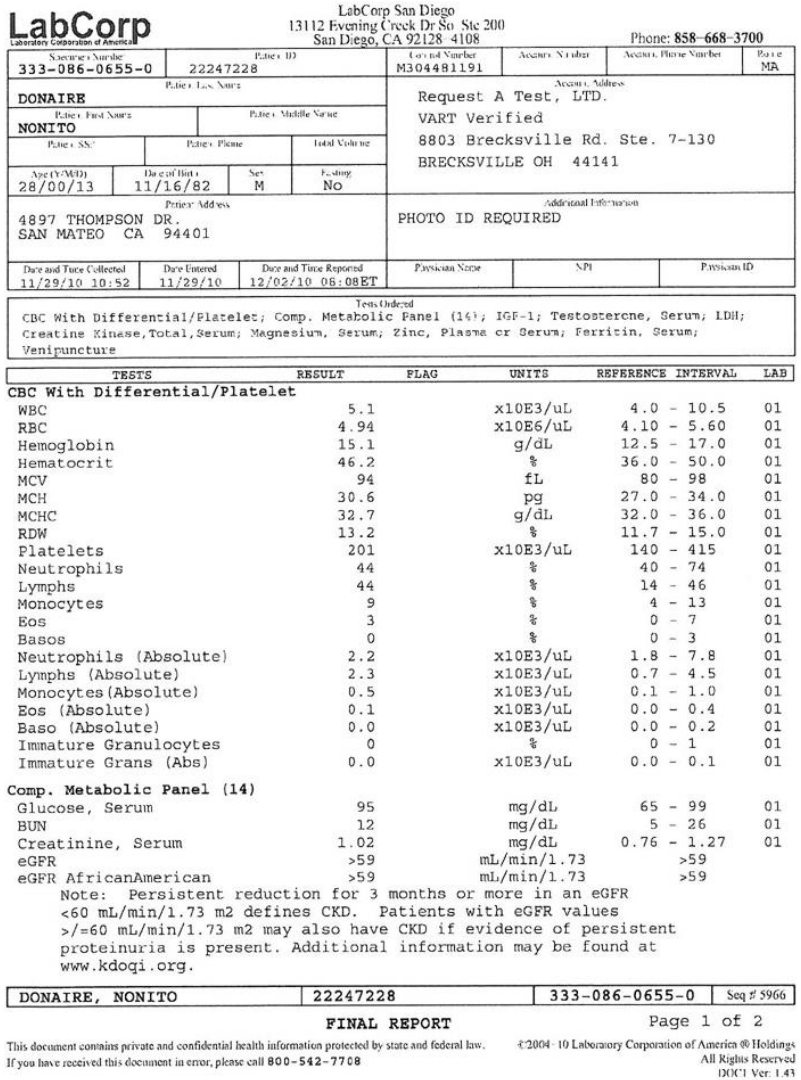

Personal Information Sheet

SURNAME _____ FORM CLASS: _____
FIRST NAME _____ BIRTHDAY: _____
PREFERRED NAME _____ AGE: _____
RESIDENTIAL ADDRESS _____
_____
POSTAL ADDRESS (If different from above) _____
_____
HOME PHONE NUMBER _____
MOTHERS NAME _____
EMAIL _____
WORK PHN _____ MOTHER'S MOBILE _____
FATHERS NAME _____
EMAIL _____
WORK PHN _____ FATHER'S MOBILE _____
CAREGIVERS NAME/S (If different from Mother/Father) _____
PHONE NUMBER _____
OPTION CHOICES _____
_____
SPORTING/CULTURAL INTERESTS _____
_____

Notes:

- CRFs can be paper or electronic (e.g. REDCap, RAVE)
- CRFs should only capture data that is specified in the approved protocol
- Every data point collected on a CRF requires complementary source data in order to be verified

Source



LabCorp
Laboratory Corporation of America

LabCorp San Diego
13112 Evening Creek Dr So Ste 200
San Diego, CA 92128-4108
Phone: 858-668-3700

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Route
333-086-0655-0	22247228	M304481191			MA

Patient Last Name: DONAIRE
Patient First Name: NONITO
Patient Middle Name:
Patient SS#:
Patient Phone:
Total Volume:
Age (Y/M/D): 28/00/13
Date of Birth: 11/16/82
Sex: M
Fasting: No
Patient Address: 4897 THOMPSON DR. SAN MATEO CA 94401

Account Address: Request A Test, LTD. VART Verified 8803 Brecksville Rd. Ste. 7-130 BRECKSVILLE OH 44141

Additional Information: PHOTO ID REQUIRED

Date and Time Collected	Date Entered	Date and Time Reported	Physician Name	NPI	Physician ID
11/29/10 10:52	11/29/10	12/02/10 06:08ET			

Tests Ordered
CBC With Differential/Platelet; Comp. Metabolic Panel (14); IGF-1; Testosterone, Serum; LDH; Creatine Kinase,Total,Serum; Magnesium, Serum; Zinc, Plasma or Serum; Ferritin, Serum; Venipuncture

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
CBC With Differential/Platelet					
WBC	5.1		x10E3/uL	4.0 - 10.5	01
RBC	4.94		x10E6/uL	4.10 - 5.60	01
Hemoglobin	15.1		g/dL	12.5 - 17.0	01
Hematocrit	46.2		%	36.0 - 50.0	01
MCV	94		fL	80 - 98	01
MCH	30.6		pg	27.0 - 34.0	01
MCHC	32.7		g/dL	32.0 - 36.0	01
RDW	13.2		%	11.7 - 15.0	01
Platelets	201		x10E3/uL	140 - 415	01
Neutrophils	44		%	40 - 74	01
Lymphs	44		%	14 - 46	01
Monocytes	9		%	4 - 13	01
Eos	3		%	0 - 7	01
Basos	0		%	0 - 3	01
Neutrophils (Absolute)	2.2		x10E3/uL	1.8 - 7.8	01
Lymphs (Absolute)	2.3		x10E3/uL	0.7 - 4.5	01
Monocytes(Absolute)	0.5		x10E3/uL	0.1 - 1.0	01
Eos (Absolute)	0.1		x10E3/uL	0.0 - 0.4	01
Baso (Absolute)	0.0		x10E3/uL	0.0 - 0.2	01
Immature Granulocytes	0		%	0 - 1	01
Immature Grans (Abs)	0.0		x10E3/uL	0.0 - 0.1	01
Comp. Metabolic Panel (14)					
Glucose, Serum	95		mg/dL	65 - 99	01
BUN	12		mg/dL	5 - 26	01
Creatinine, Serum	1.02		mg/dL	0.76 - 1.27	01
eGFR	>59		mL/min/1.73	>59	
eGFR AfricanAmerican	>59		mL/min/1.73	>59	

Note: Persistent reduction for 3 months or more in an eGFR <60 mL/min/1.73 m2 defines CKD. Patients with eGFR values >/=60 mL/min/1.73 m2 may also have CKD if evidence of persistent proteinuria is present. Additional information may be found at www.kdoqi.org.

DONAIRE, NONITO	22247228	333-086-0655-0	Seq # 5966

FINAL REPORT

Page 1 of 2

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CRF

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IRB Protocol #: 19-0001
Study PI: Dr. Smith

Research Blood Work Results

Subject ID: 001

Study Visit #: 1

Date and Time Collected: 11/29/10 @10:52

Date and Time Reported: 12/02/10 @06:08

Test	Result	Units	Clinical Significance? (Y/N)
WBC	5.1	IU	N
RBC	4.94	IU	N
Hemoglobin	15.1	g/dL	N
Hematocrit	46.2	%	N
Glucose, serum	95	mg/dL	N
BUN	12	mg/dL	N
Creatinine, serum	1.02	mg/dL	N

NOTES: Drawn from median cubital vein from right arm with 23-gauge butterfly needle using only one attempt with no complications

* Document location of blood draw, size of the needle, number of attempts, and if there were any complications or trauma to the site. (ex: Right Antecubital, 23 gauge butterfly needle, 1 attempt, no complications.)

Study Personnel Signature: *Alyssa Matthews*

Completion Date: *12/3/10*

Can a study specific CRF be used as a source document?

Yes – CRFs may be used as source documents if they are the first place that the collected data was recorded.

For Example:

- An Incentive Spirometry Measurement taken in-person for research purposes only
- The results from this measurement are recorded directly onto a study specific CRF
- This is the original record of this data, and is considered a source document
- The CRF must be signed and dated by the member of key personnel responsible for this data and this form should be filed as a source document in the subject's file

Can something be used as both a source document and a CRF?

Yes – A CRF is a document designed to record protocol specific information, so if this is the original place this data is being recorded, then a study specific CRF can also be signed and dated and considered a source document.

For Example:

REDCap is a secure database used to record and maintain data and can be used as a CRF or a source document.

- Used as a Source Document – if this is where the data was initially recorded (in-person data recording or a subject survey sent out via REDCap)
- Used as a CRF – if the original recording of the data is elsewhere (a subject's lab results where the original results are in the medical record)*

*NOTE: If being used as a CRF, the complementary source documentation is required

Do I need hard copies of all of my source documents?

No. However, there must be a verifiable audit trail for all source documentation.

- If the source documentation is being kept electronically (the EMR or a share drive) then a Note to File must accompany any CRFs in the subject file to clearly outline the path to access the source documentation.

Examples:

- "Verification of eligibility criteria can be found in subject's clinic visit note in their electronic medical record signed on 10/15/19 by Dr. Smith".
- "All lab results recorded on individual subject CRFs have complementary source documents saved in participant-specific folders on the hospital share drive. Path: S:\Groups\Stark\00-001\Labs"

All Notes to File must be signed and dated

ALCOAC-CEA Principles

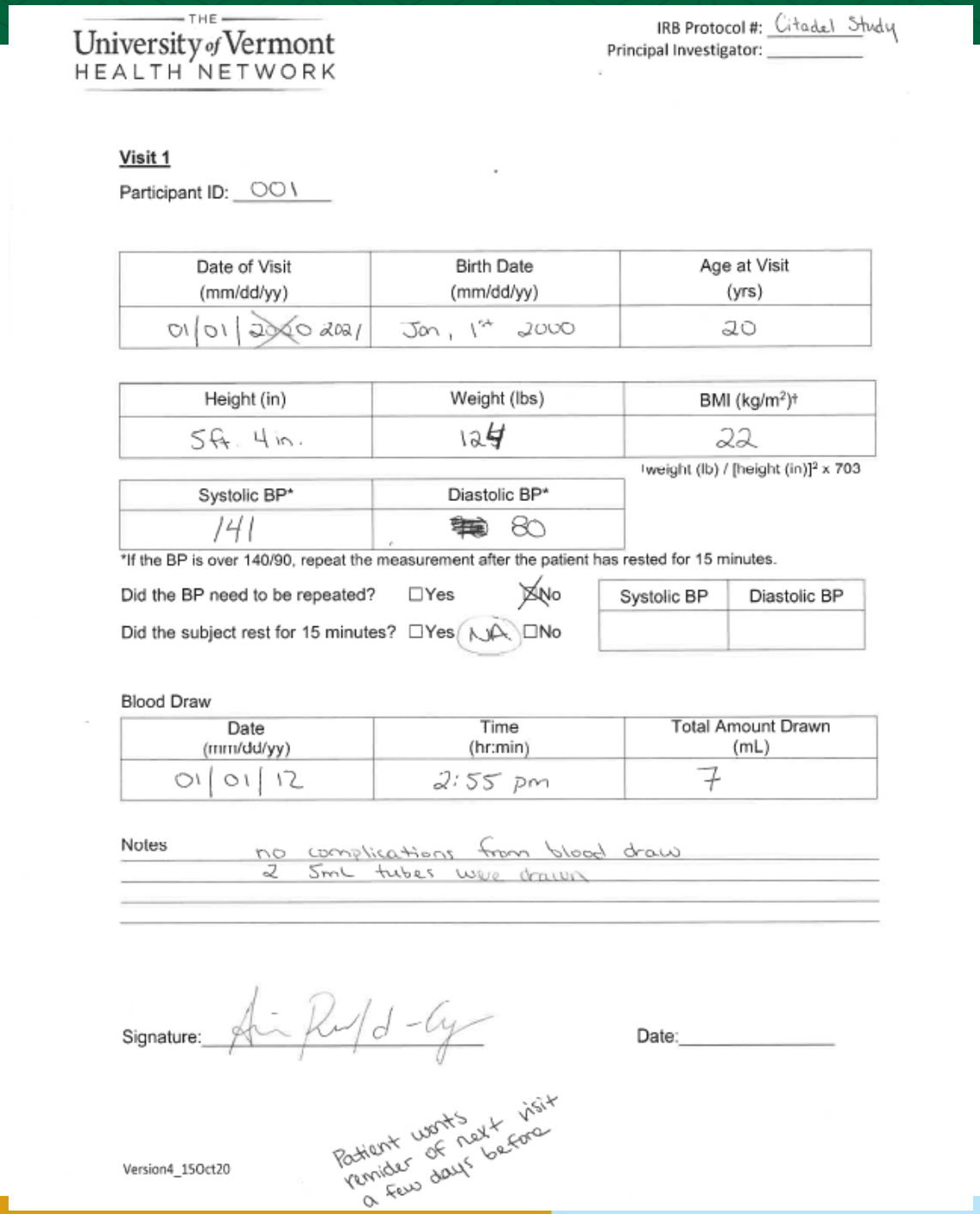
- Attributable – Who collected the data, performed a test, completed the documentation or edited the document and when.
- Legible – The documentation and all subsequent changes should be permanent and easy to read.
- Contemporaneous – Documentation should be completed and dated in real time.
- Original – Study documents should be the originals, or it should be noted where the originals are located.
- Accurate – Documentation should be comprehensive and truthfully reflect what was observed.
- Complete – Maintenance of complete and up-to-date study documents.
- Consistent – The data's sequence of events is in the expected sequence of operations and date and time stamped.
- Enduring – Paper and electronic data are appropriately recorded in lab notebooks, spreadsheets, databases etc.
- Available – Paper and electronic data are required to be readily available for review, audits, or inspections.

Correcting Study Documents Using ALCOAC-CEA

Error	Do's	Don'ts
• Correction needed on the original source document or a case report form	• Cross out wrong information with a single line, write in the correct information and initial and date the correction	• Scribble over the mistake • Use white out • Write over the original data to correct it • Destroy the originals • Forget to initial and date!
• Missing data located at a later date	• Incorporate the data into the research record and initial and date with the current date	• Ignore the missing data • Backdate or predate the information

Activity 1

Take a minute and try to find all of the ALCOAC-CEA Principle errors in this document.



THE University of Vermont HEALTH NETWORK

IRB Protocol #: Citadel Study
Principal Investigator: _____

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/~~2020~~ 2021	Jan, 1st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m²)†
5ft. 4in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐Yes ☒No

Did the subject rest for 15 minutes? ☐Yes (N/A) ☐No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: _____ Date: _____

Version4_15Oct20

Patient wants reminder of next visit a few days before

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Bad ALCOAC-CEA

THE University of Vermont HEALTH NETWORK

IRB Protocol #: Citadel Study
Principal Investigator: _____

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/~~20~~20 202/	Jan, 1st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m²)†
5ft. 4 in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	~~80~~ 80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐Yes ☒No

Did the subject rest for 15 minutes? ☐Yes (N/A) ☐No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: [signature] Date: _____

Patient wants reminder of next visit a few days before

Version4_15Oct20

Good ALCOAC-CEA

THE University of Vermont HEALTH NETWORK

IRB Protocol #: STUDY01234
Principal Investigator: Dr. Samuell Torrey

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
~~01/01/20~~ APC 1/1/21 01/01/21	01/01/20	21

Height (in)	Weight (lbs)	BMI (kg/m²)†
64	~~125~~ APC 1/1/21 124	21.3

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	~~90~~ APC 1/1/21 80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☒Yes ☐No

Did the subject rest for 15 minutes? ☒Yes ☐No

Systolic BP	Diastolic BP
135	75

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/21	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: [signature] Date: 01/01/21

Version4_15Oct20

Patient wants a reminder of their next visit a few days before the visit APC 1/1/21

Options for Data Collection

- Paper Forms
- Electronic Forms
  - Electronic Health Record (EHR) Epic
  - Electronic Data Capture (EDC) REDCap, RAVE
  - Clinical Trials Management System (CTMS) OnCore, Velos
- Combination of Paper and Electronic

Electronic Database Development - Where to Begin?

Start at the end!

- What specific data points are required to perform the statistical analysis?
- What specific data points are on the Case Report Forms (CRFs)?
- What is described in the protocol and other study documents?

Electronic Database Development – Team Work

All study team members involved in data collection, data entry, or data analysis must be actively involved in the

- Development
- Testing
- Training

Electronic Database Development - Preparation

Database development requires very detailed knowledge about each data point/field.

- What is being collected and in what format?
  - Weight: lbs or kg?
- When is it being collected? (Every 12 weeks +/- 7 days)
  - Base off of which starting date? Date of Consent, Date of Enrollment, Day 1 Rx?
- Who is collecting it?
  - Who needs access, who needs to be involved in the process?

Electronic Database Development - Preparation

STUDY DESIGN AND SCHEDULE OF ASSESSMENTS

Assessment	Screening	Run-in	Baseline	Treatment				Follow-up		
Study Week	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**8**
Informed Consent	x									
History	x									
Physical Exam.	x									x
Effectiveness										
primary variable	x	x	x	x	x	x	x	x	x	x
secondary variable	x	x	x	x		x			x	x
Safety										
Adverse events	x	x	x	x	x	x	x	x	x	x
Lab. tests	x		x	x			x		x	x
Body weight	x		x						x	x

Electronic Database Development - Preparation

But my study uses EHR (source) and RAVE (CRF), this doesn't apply to me.

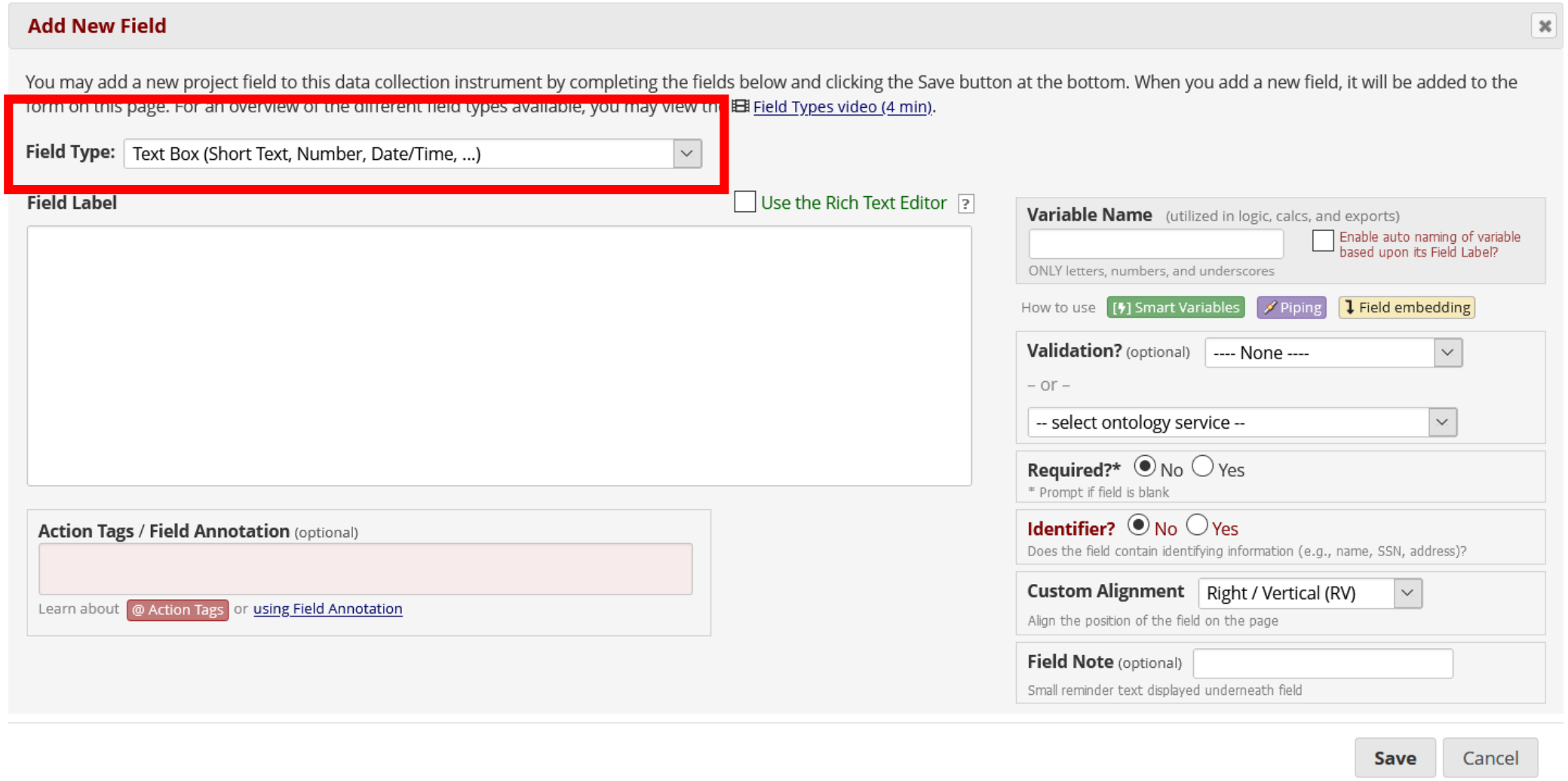
Electronic Database Development – Quality Assurance

Maximize features that minimize errors

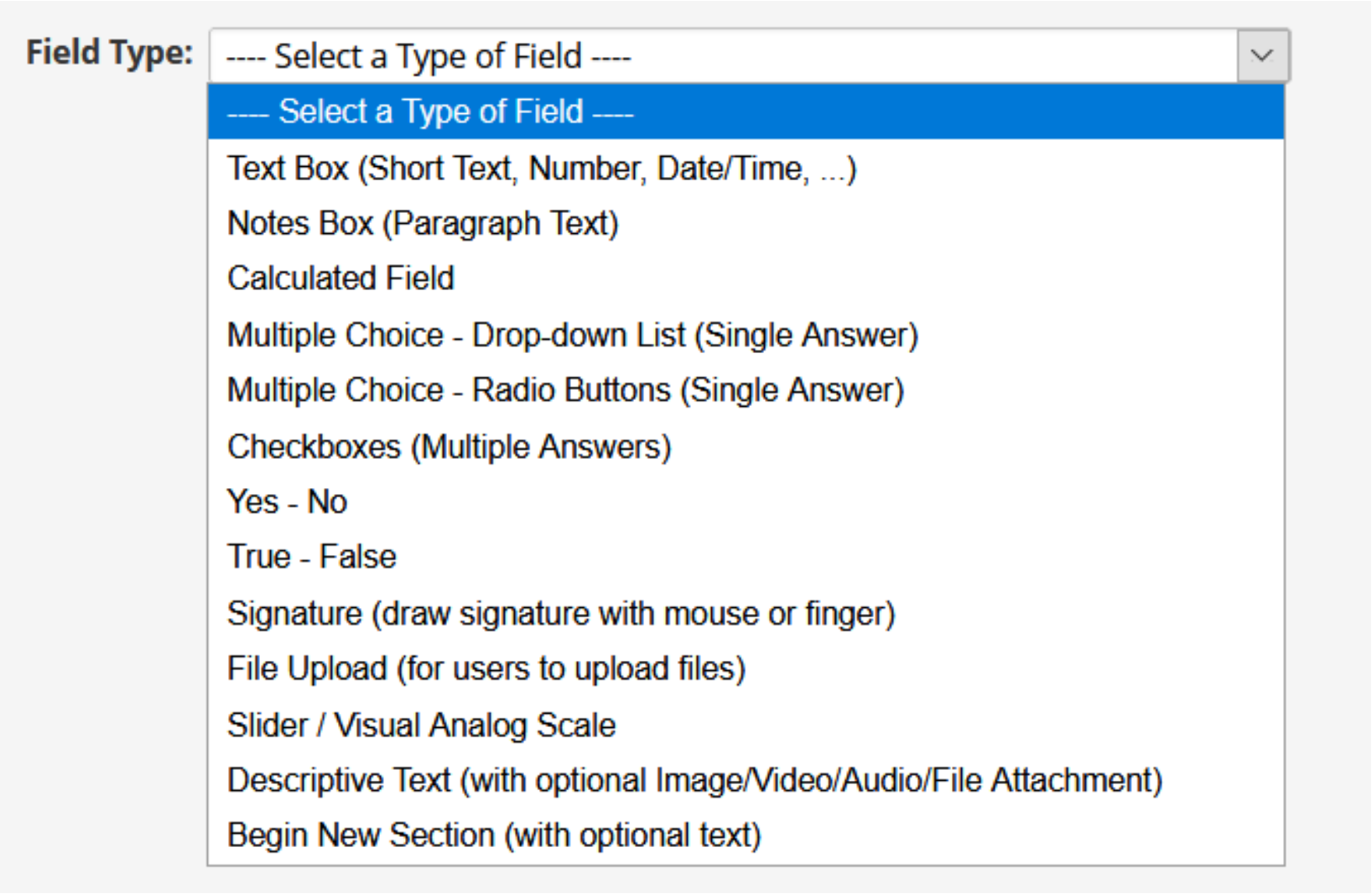
- Field validation
- Calculation
- Logic
- Remote Data Capture
- Automation
- Alerts

- Scheduling
- Double Entry
- Queries
- Audit Trail
- Reports

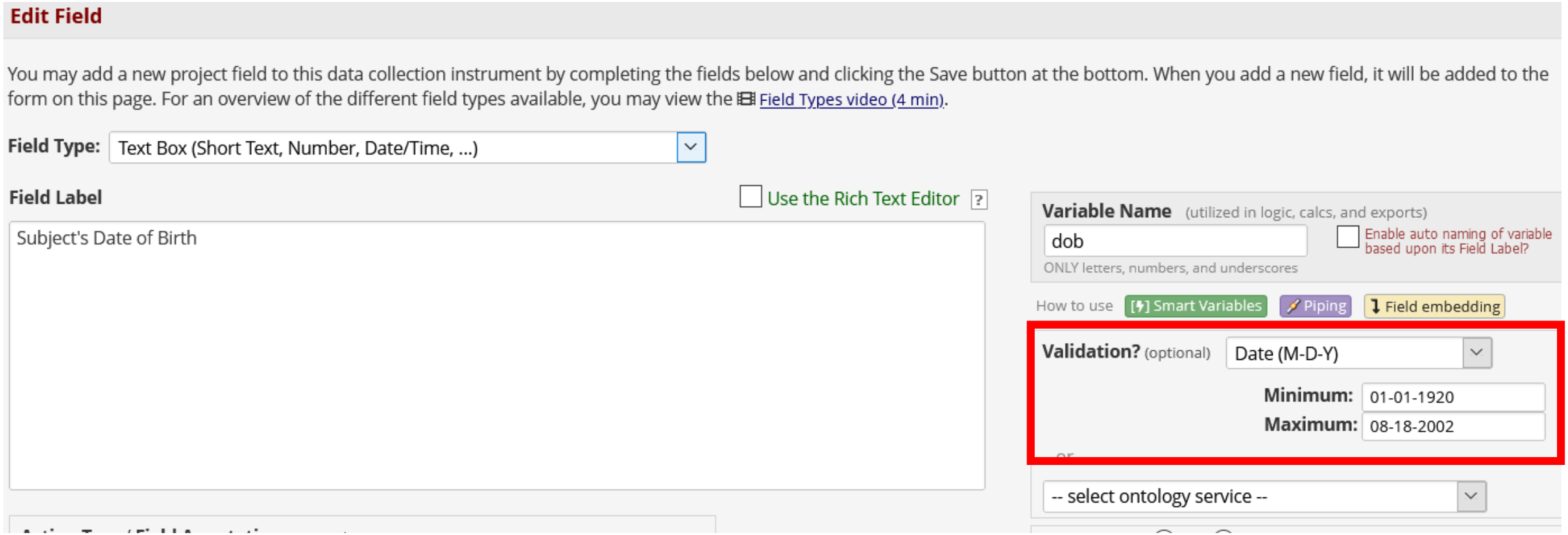
Electronic Database Development – Data Field



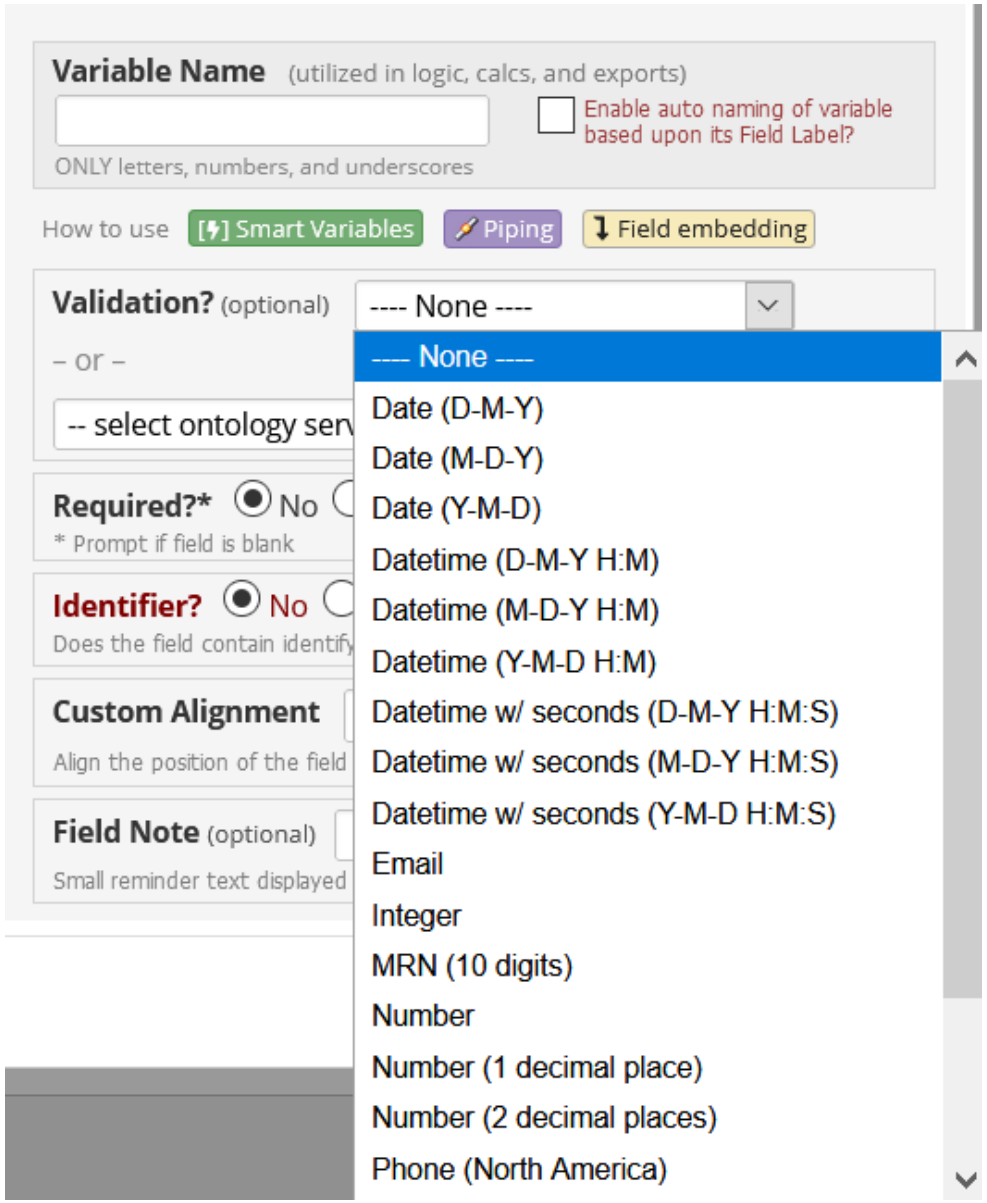
Electronic Database Development - Field Type



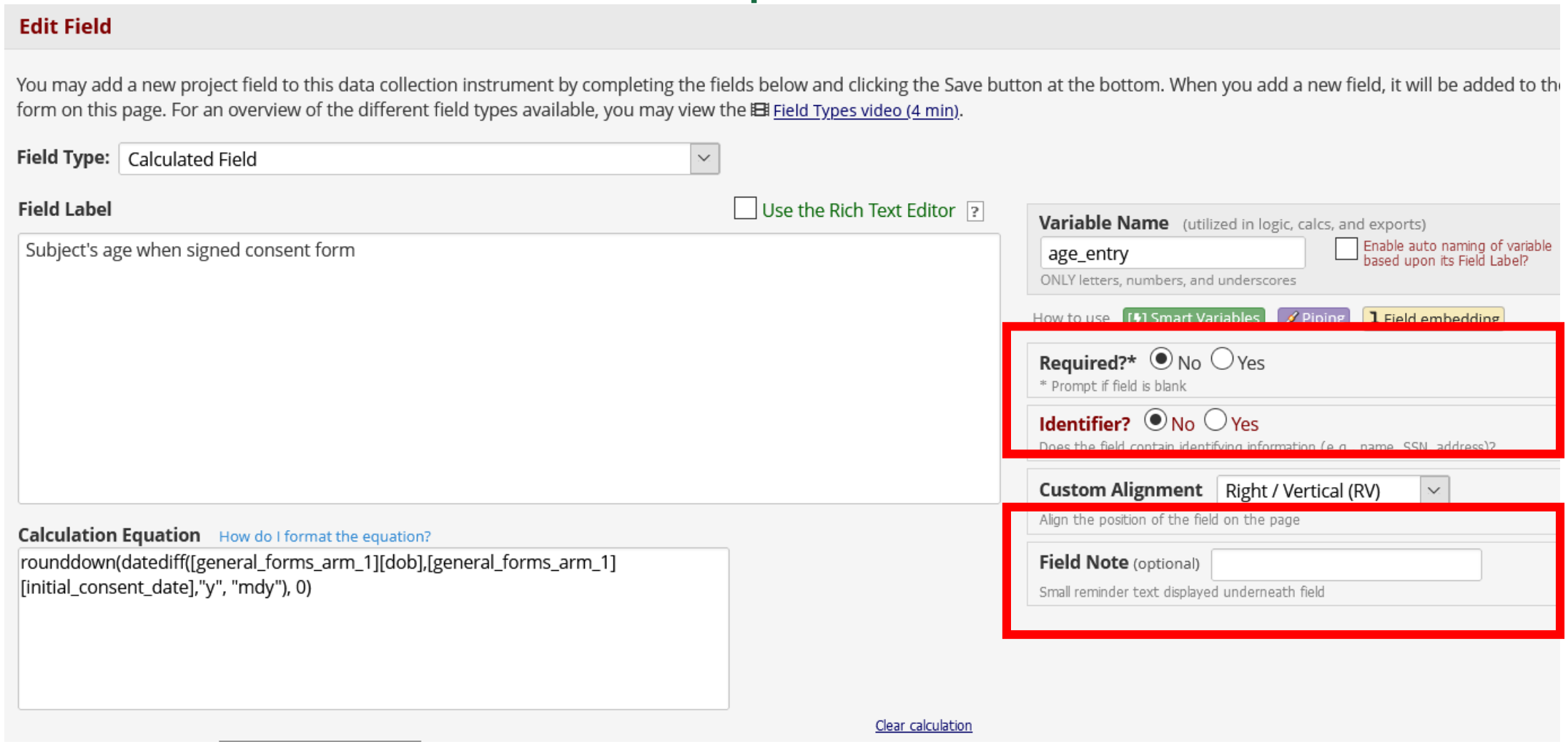
Electronic Database Development - Field Validation



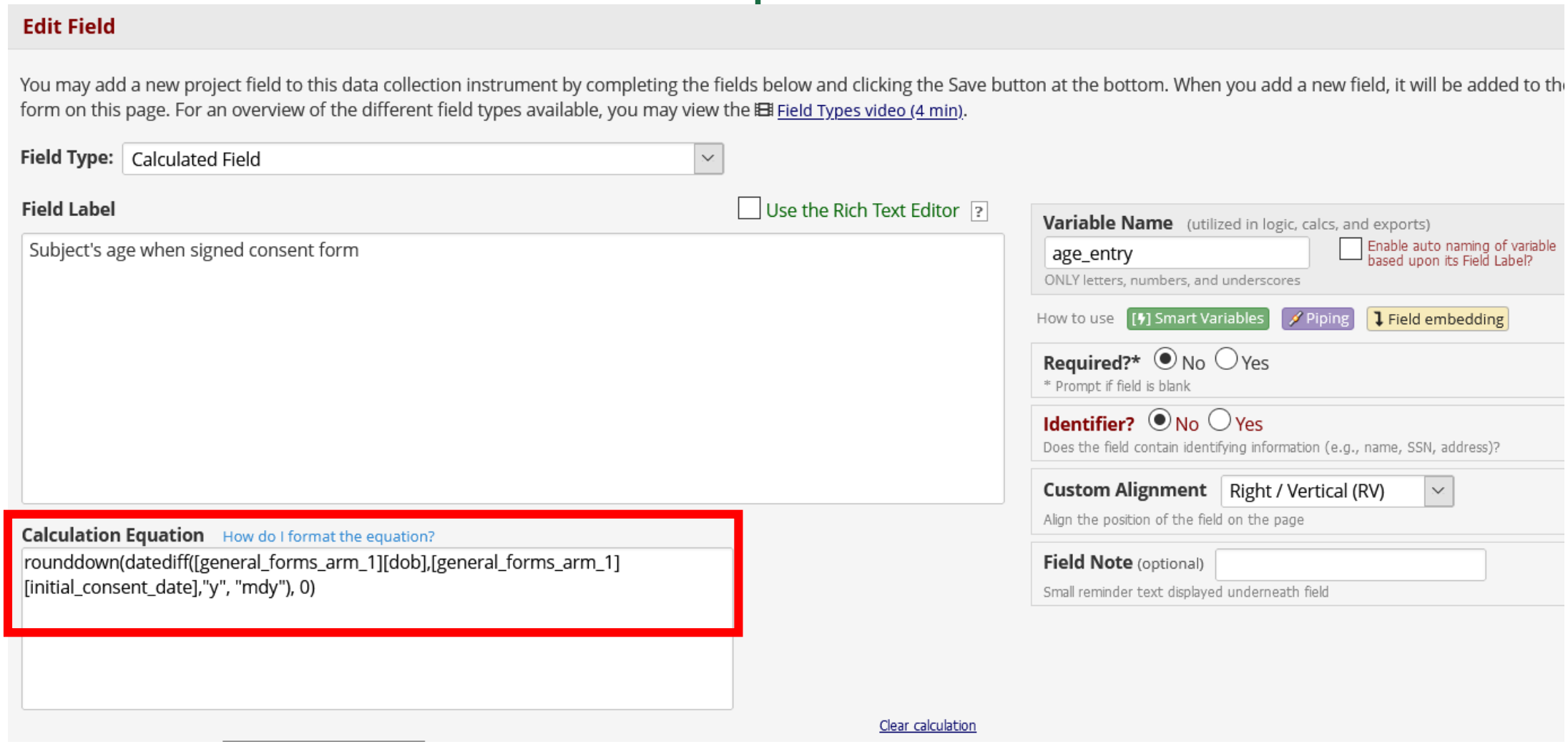
Electronic Database Development - Field Validation



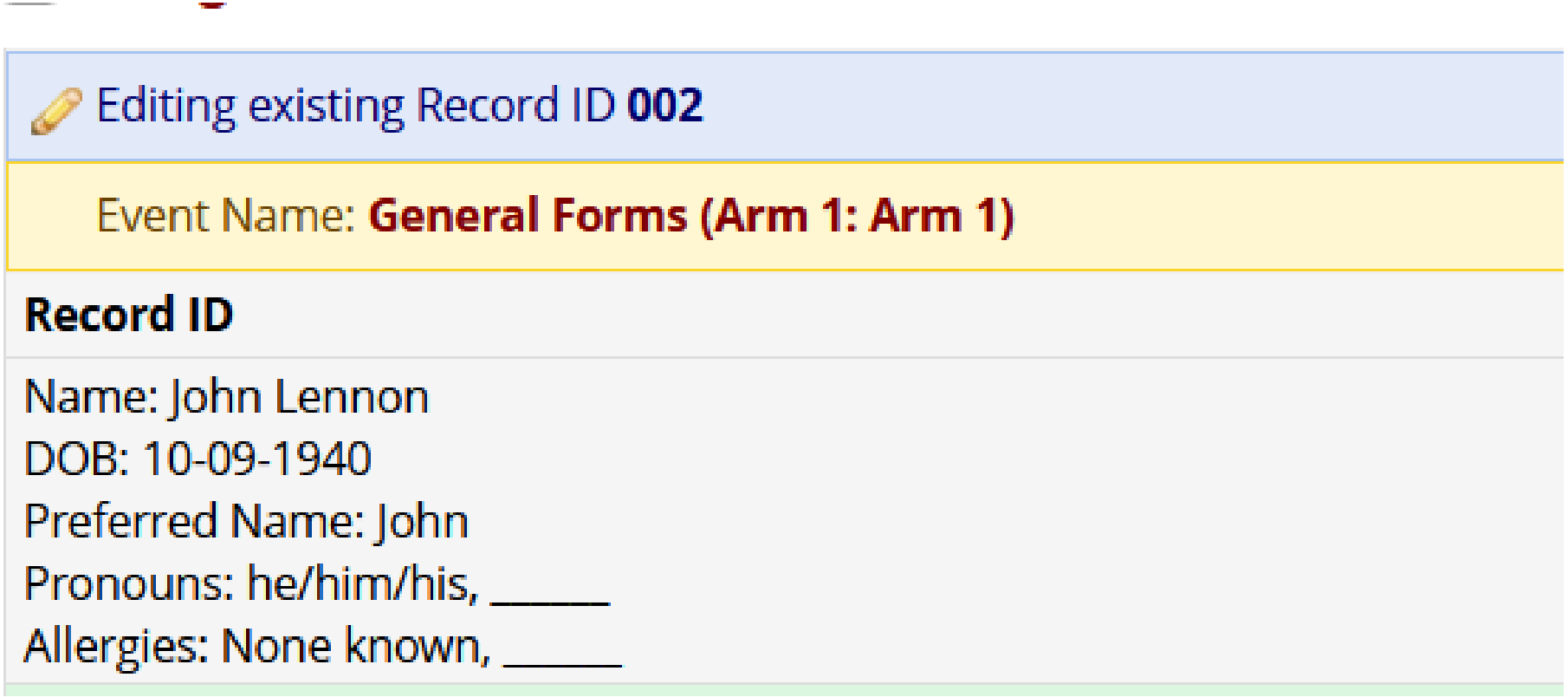
Electronic Database Development - Validation



Electronic Database Development - Field Calculation



Electronic Database Development - Piping



Electronic Database Development – Logic

Have you traveled outside your state of residence in the last 14 days for non-essential travel?

- (●) Yes
- ( ) No

Link to answers for travel questions and definitions of essential travel

* must provide value

According to the Vermont Department of Health (VDH) website does the county you traveled from require quarantining at this time?

- ( ) Yes
- ( ) No

Map of quarantine and non-quarantine counties throughout the Northeast

* must provide value

Have you traveled outside your state of residence in the last 14 days for non-essential travel?

- ( ) Yes
- (●) No

Link to answers for travel questions and definitions of essential travel

* must provide value

Please check the appropriate box (yes or no) to the following quest COVID-19 symptoms that cannot be attributed to a pre-existing co

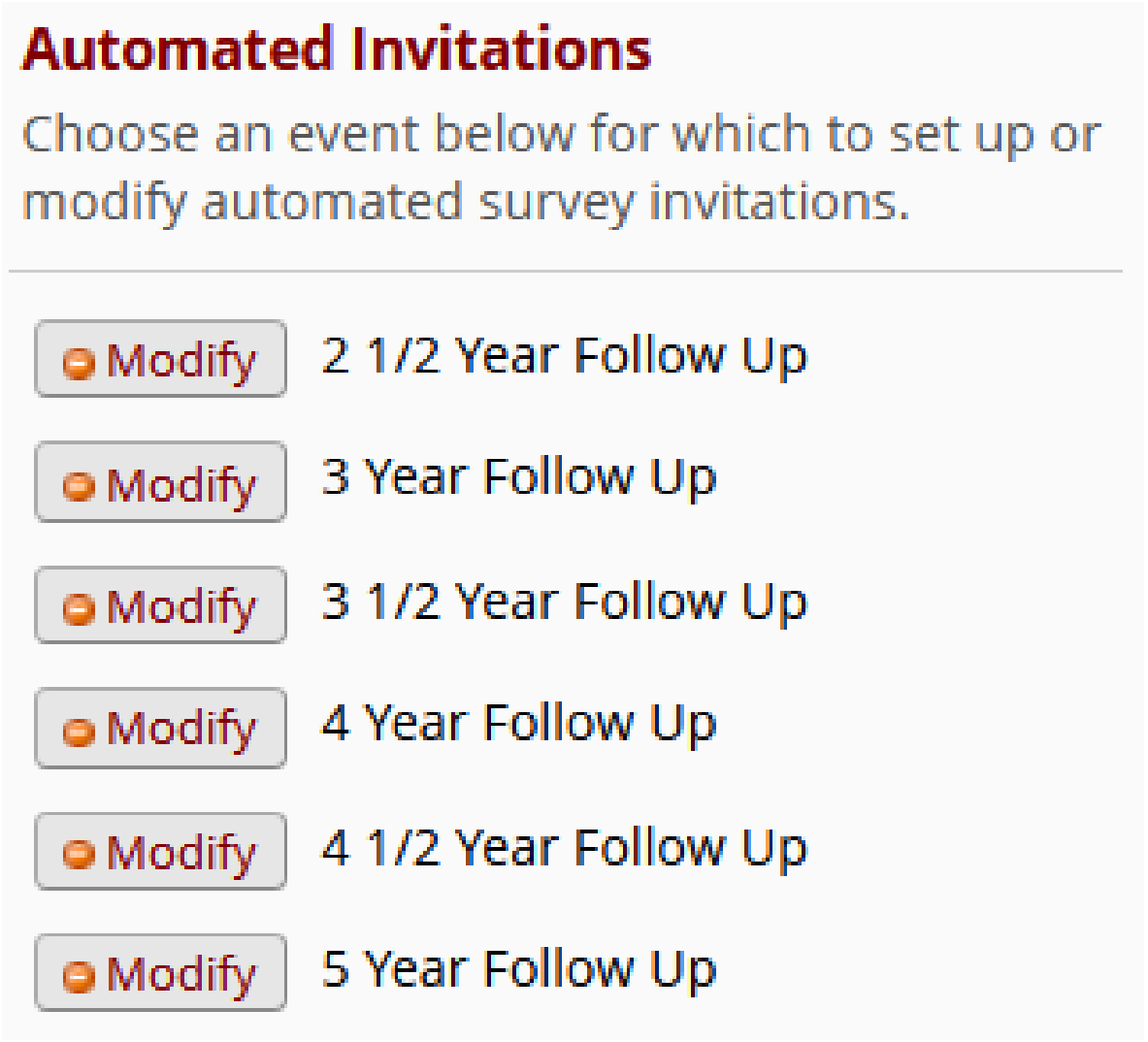
Have you had a fever (100.4°F/38°C or higher) in the last 14 days?

* must provide value

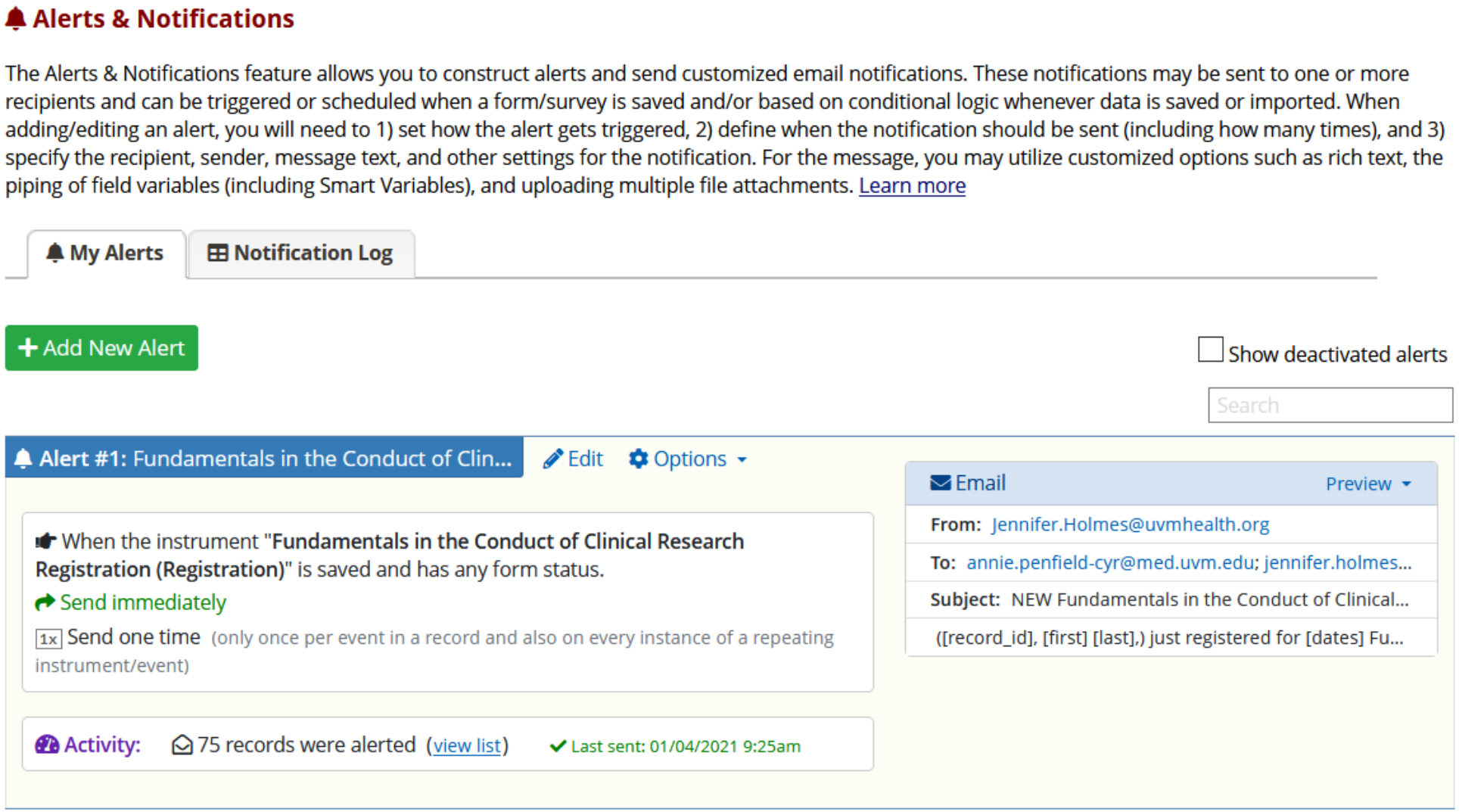
- ( ) Yes
- ( ) No

Electronic Database Development – Remote Data Collection

Electronic Database Development - Automation



Electronic Database Development - Alerts



Electronic Database Development - Scheduling

Arm name: **Arm 1**

	Event #	Days Offset	Offset Range Min / Max	Event Name
	1	-1	-15/+0	General Forms
	2	0	-14/+0	Day 1 - Visit
	3	7	-3/+3	Day 8 - Phone Call
	4	28	-3/+3	Day 29 - Visit
	5	35	-3/+3	Day 36 - Phone Call
	6	56	-3/+3	Day 57 - Visit
	7	89	-5/+5	Day 90 - Visit
	8	179	-10/+10	Day 180 - Visit
	9	359	-15/+15	Day 360 - Visit
	10	729	-30/+30	Day 730 - Visit
	11	730	-0/+0	Unscheduled Visit
	12	731	-0/+0	Miscellaneous Forms

Electronic Database Development - Scheduling

Arm name: **On Study**

Begin Editing | Save

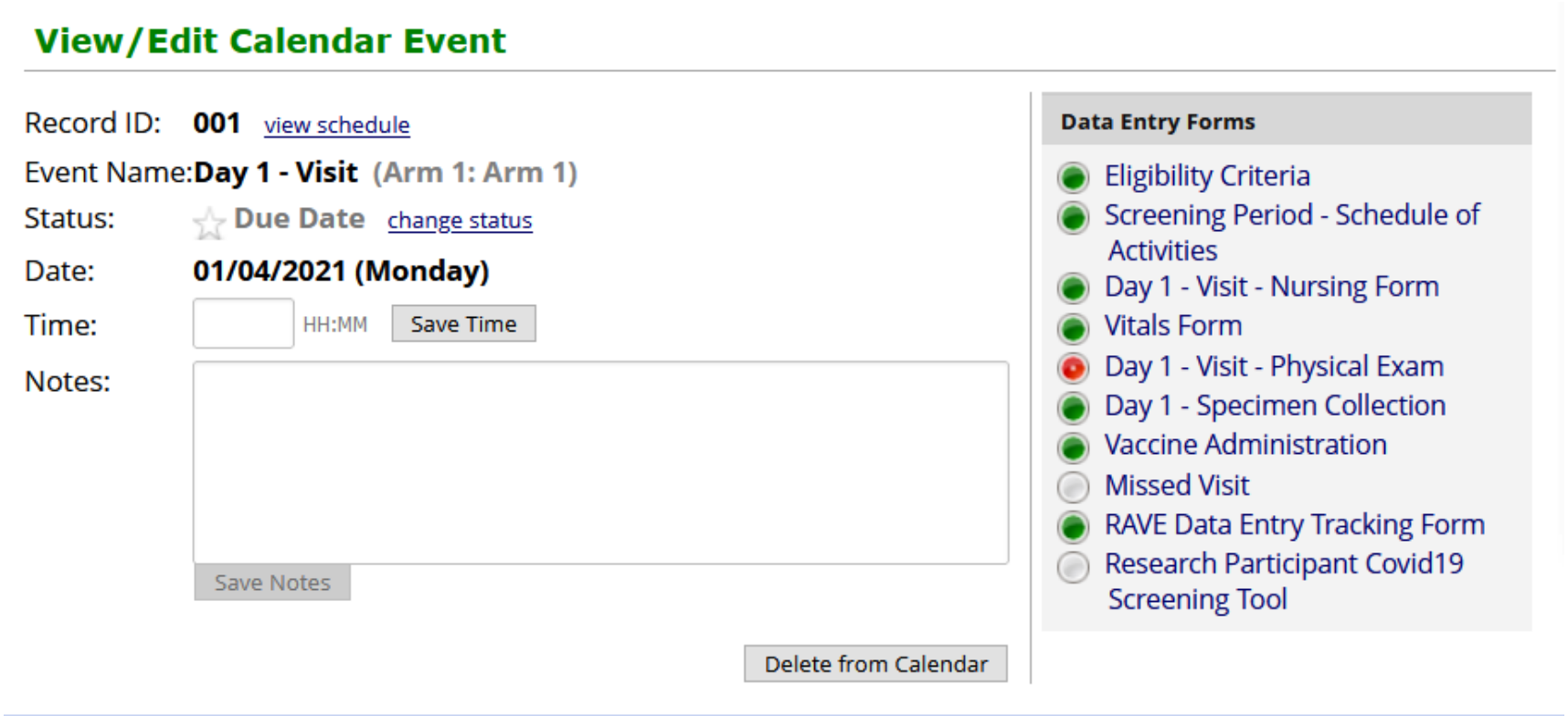
Data Collection Instrument	Injury (1)	Registration (2)	Screening/enrollment (3)	Week 0 Day1 (4)	Week 1 (5)	Week 2 Day 1 Visit (6)	Week 10 (7)	Week 3 (8)	Week 4 (9)	Week 5 (10)	Week 6 Visit (11)
Injury	✔										
Screening/enrollment			✔								
Registration		✔									
Week 0 Day 1				✔							
Week 1 - Medication Compliance Phone Call					✔						
Week 2 Day 1						✔					
Week 3 - Medication Compliance Phone Call								✔			
Week 4									✔		
Week 5										✔	
Week 6 Visit											✔
Week 8											
Week 10							✔				
Week 12 Visit											
Week 24 Visit											
Week 52 Visit											

Electronic Database Development - Scheduling

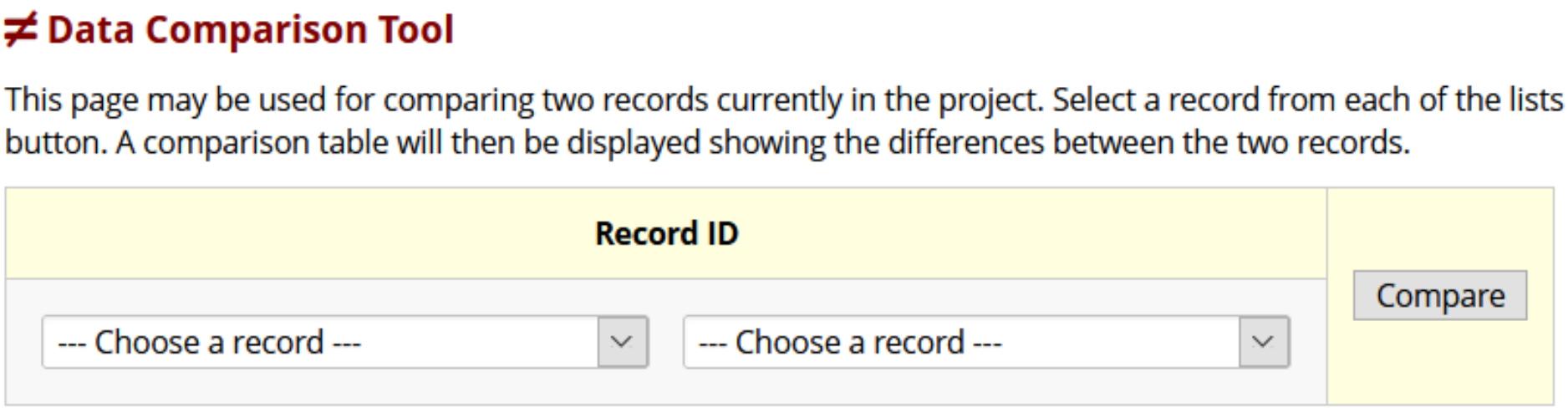
January 2021 Print Calendar

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					+ New 1	+ New 2
+ New 3 ☆ 001 (General Forms)	+ New 4 ☆ 001 (Day 1 - Visit)	+ New 5	+ New 6	+ New 7	+ New 8	+ New 9
+ New 10	+ New 11 ☆ 001 (Day 8 - Phone...	+ New 12	+ New 13	+ New 14	+ New 15	+ New 16
+ New 17	+ New 18	+ New 19	+ New 20	+ New 21	+ New 22	+ New 23
+ New 24	+ New 25	+ New 26	+ New 27	+ New 28	+ New 29	+ New 30

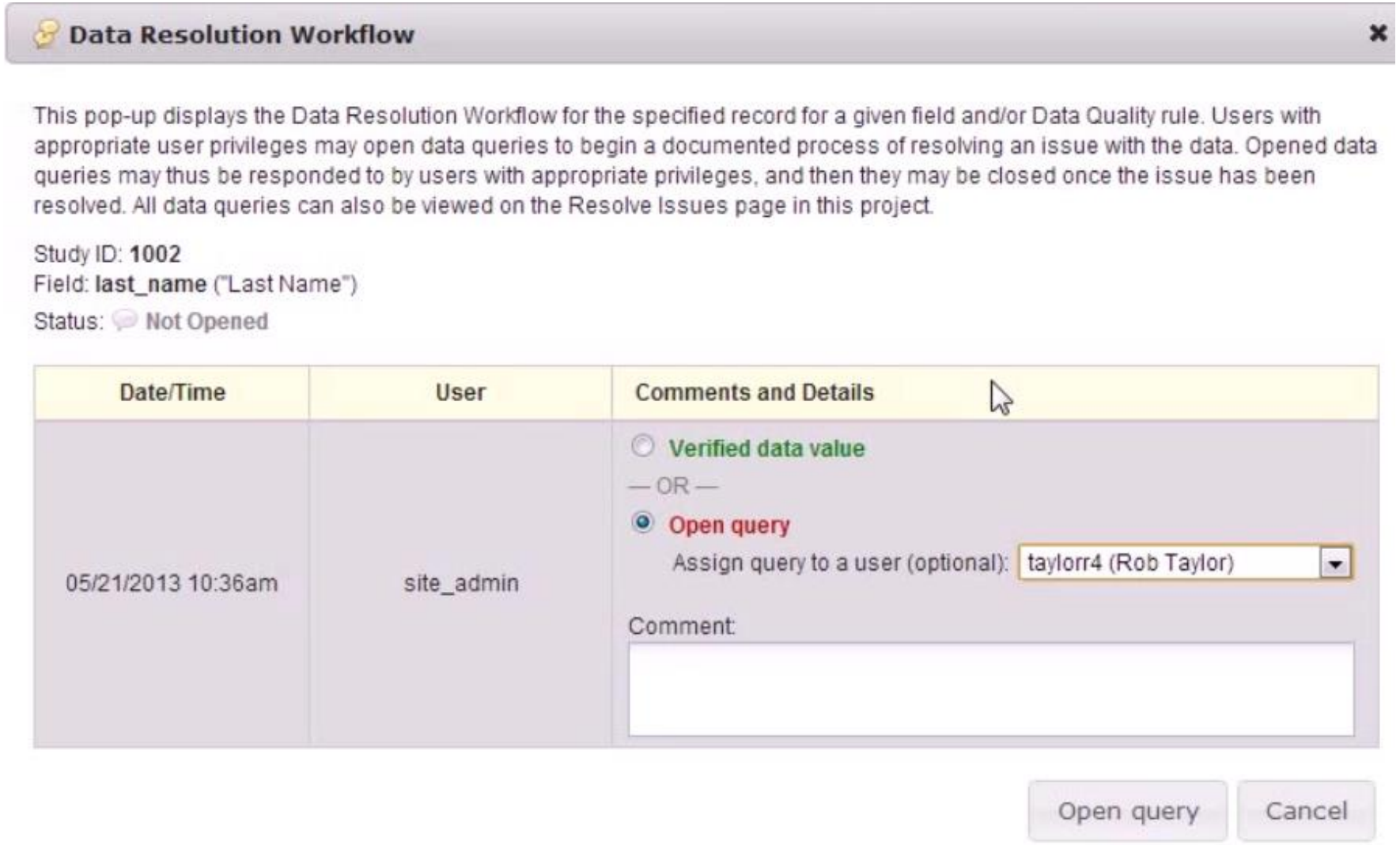
Electronic Database Development - Scheduling



Electronic Database Development – Double Entry



Electronic Database Development – Queries



Electronic Database Development – Built-in Notes to File

Electronic Database Development – Audit Trail

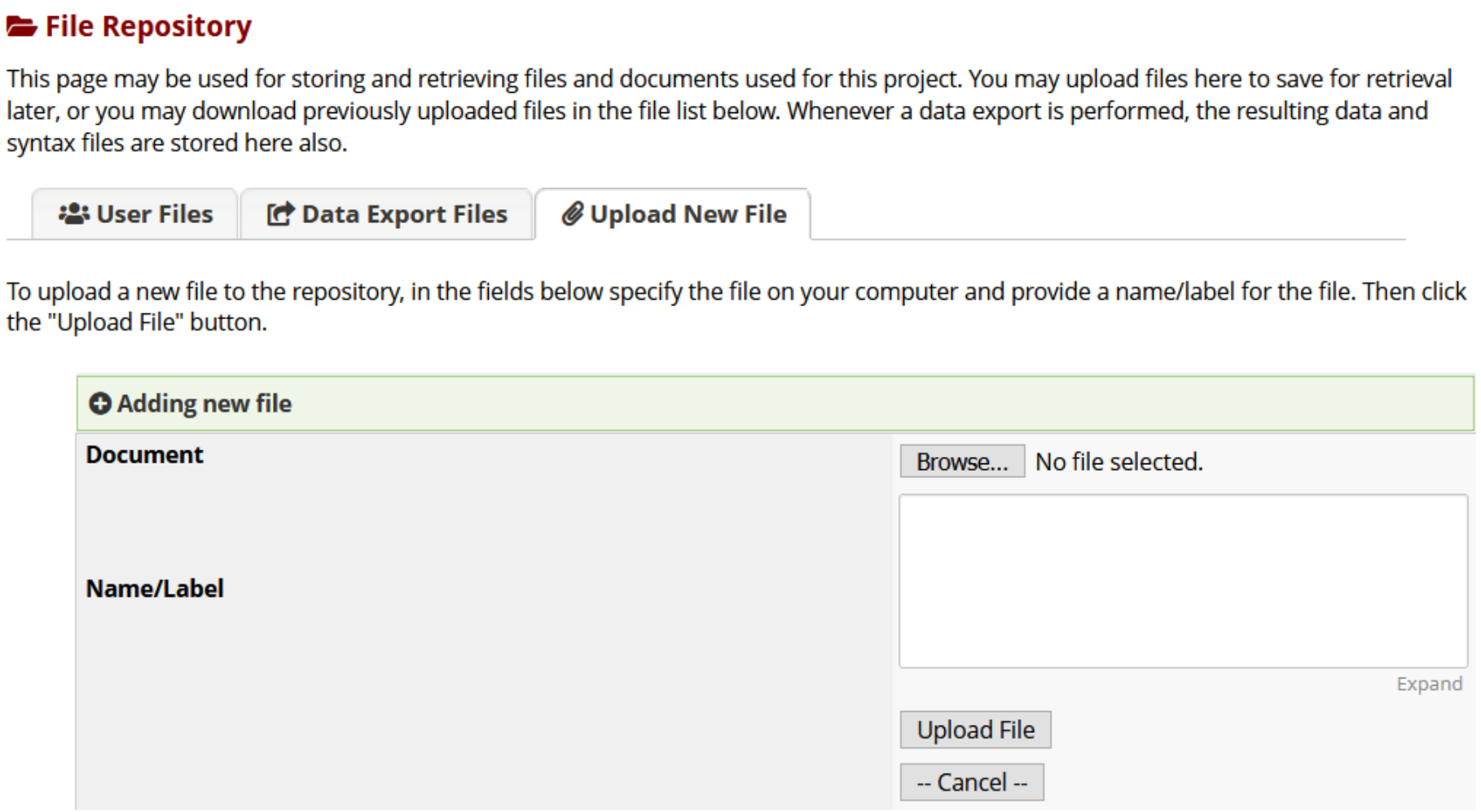
11/23/2020 1:42pm	a_penfield-cyr	Manage/Design Deactivate alert	Alert #1
11/23/2020 1:42pm	a_penfield-cyr	Created Record Test2 (Baseline Visit)	first_dem = 'Annie', last_dem = 'PC', email = 'annie.penfield-cyr@med.uvm.edu', phone = '8028028022', demographics_complete = '2', record_id = 'Test2'
11/23/2020 1:39pm	jholmes	Manage/Design	Send survey invitation to participants (via email)
11/23/2020 1:39pm	jholmes	Created Record test (Baseline Visit)	email = 'qowands@me.com', demographics_complete = '0', record_id = 'test'
10/19/2020 9:06am	jholmes	Manage/Design	Add/edit branching logic
10/19/2020 9:06am	jholmes	Manage/Design	Create project field
10/19/2020 9:03am	jholmes	Manage/Design	Reorder project fields
10/19/2020 9:03am	jholmes	Manage/Design	Create project field
10/14/2020 12:35pm	jholmes	Deleted Record 001	record_id = '001'
10/14/2020 12:34pm	jholmes	Updated Record 001 (Baseline Visit)	electronic_consent_complete = '0'
10/14/2020 12:34pm	jholmes	Created Record 001 (Baseline	first_dem = 'Jennifer', last_dem = 'Holmes',

Electronic Database Development – Reports

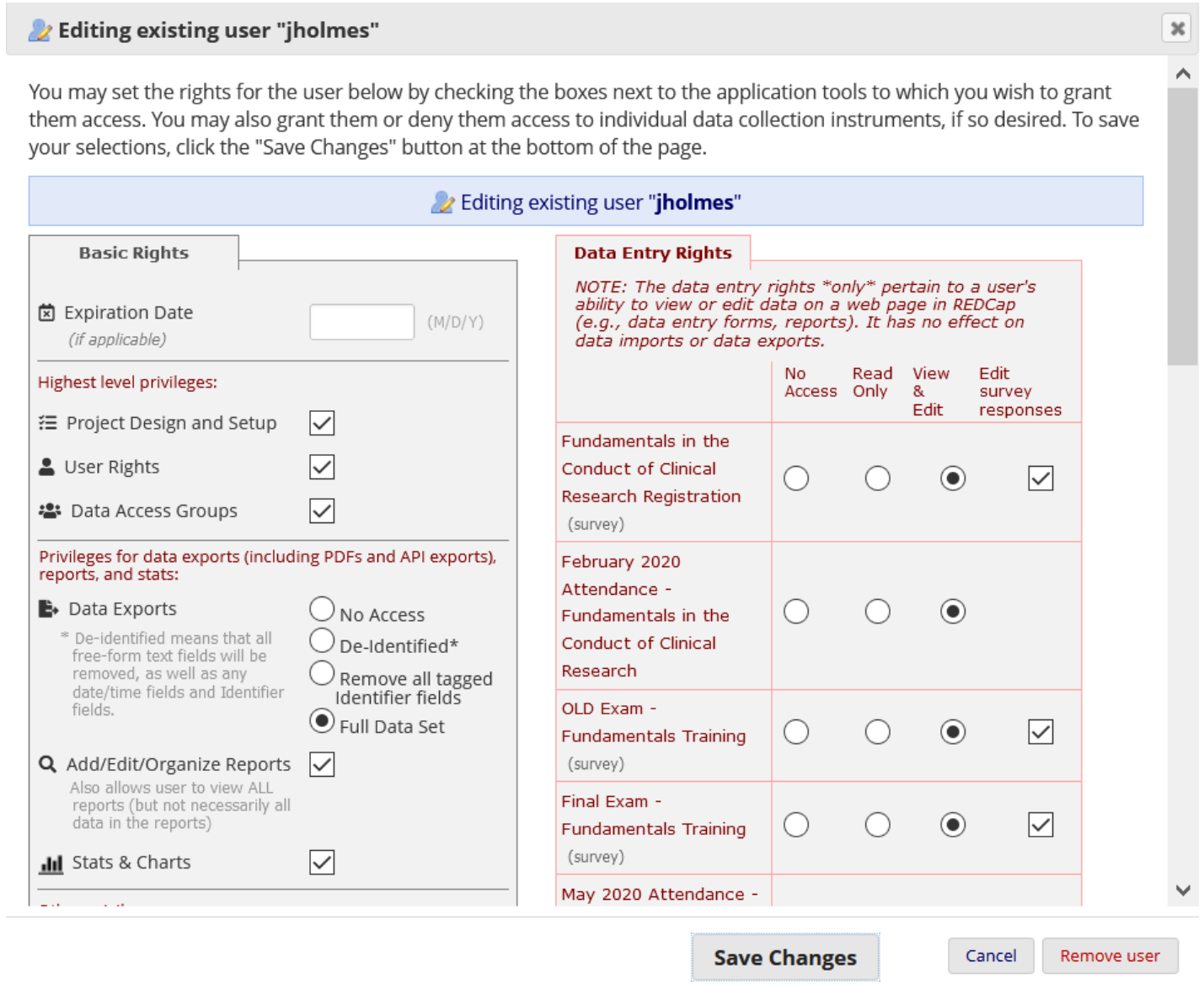
My Reports & Exports

	Report name	View/Export Options	Management Options	Report ID (auto-generated)
A	**All data** (all records and fields)	View Report · Export Data · Stats & Charts		
B	**Selected instruments and/or events** (all records)	Make custom selections		
1	People in Database	View Report · Export Data · Stats & Charts	Edit · Copy · Delete	8422
2	January 2021 Fundamentals Registration	View Report · Export Data · Stats & Charts	Edit · Copy · Delete	9275
3	November 2020 Fundamentals Registration	View Report · Export Data · Stats & Charts	Edit · Copy · Delete	8952

Electronic Database Development – File Repository



Electronic Database Development – Permissions



Electronic Database Development – Part 11 Compliance

21 CFR Part 11 compliant?

The first is the IT level, which includes providing regular systems upgrades and daily backups as well as secure logins that are provided and monitored by the institution's administrators.

The second is the project level, which means it is the responsibility of the investigator to ensure training and compliance while using the EDC. This includes establishing appropriate standard operating procedures; to protect the collection and maintenance of data, ensuring the proper delegation of study specific roles and responsibilities to members of the study team, and instituting policies and procedures for the necessary training and oversight required throughout the study's operation.

Electronic Database Development - Tips

- Standardization is key (use as little free text as possible)
- Use features to minimize errors (build in QA)
- TEST TEST TEST and then TEST some more!
- Develop a manual/SOPs (update when database is updated)
- Training (new study team members or when database is updated)
- Process in case system is down
  - PDFs of form/instruments (system to download copies when database is updated)
  - Build in flexibility with IRB for these occasions

ALCOAC-CEA Principles

- Attributable – Who collected the data, performed a test, completed the documentation or edited the document and when.
- Legible – The documentation and all subsequent changes should be permanent and easy to read.
- Contemporaneous – Documentation should be completed and dated in real time.
- Original – Study documents should be the originals, or it should be noted where the originals are located.
- Accurate – Documentation should be comprehensive and truthfully reflect what was observed.
- Complete – Maintenance of complete and up-to-date study documents.
- Consistent – The data's sequence of events is in the expected sequence of operations and date and time stamped.
- Enduring – Paper and electronic data are appropriately recorded in lab notebooks, spreadsheets, databases etc.
- Available – Paper and electronic data are required to be readily available for review, audits, or inspections.

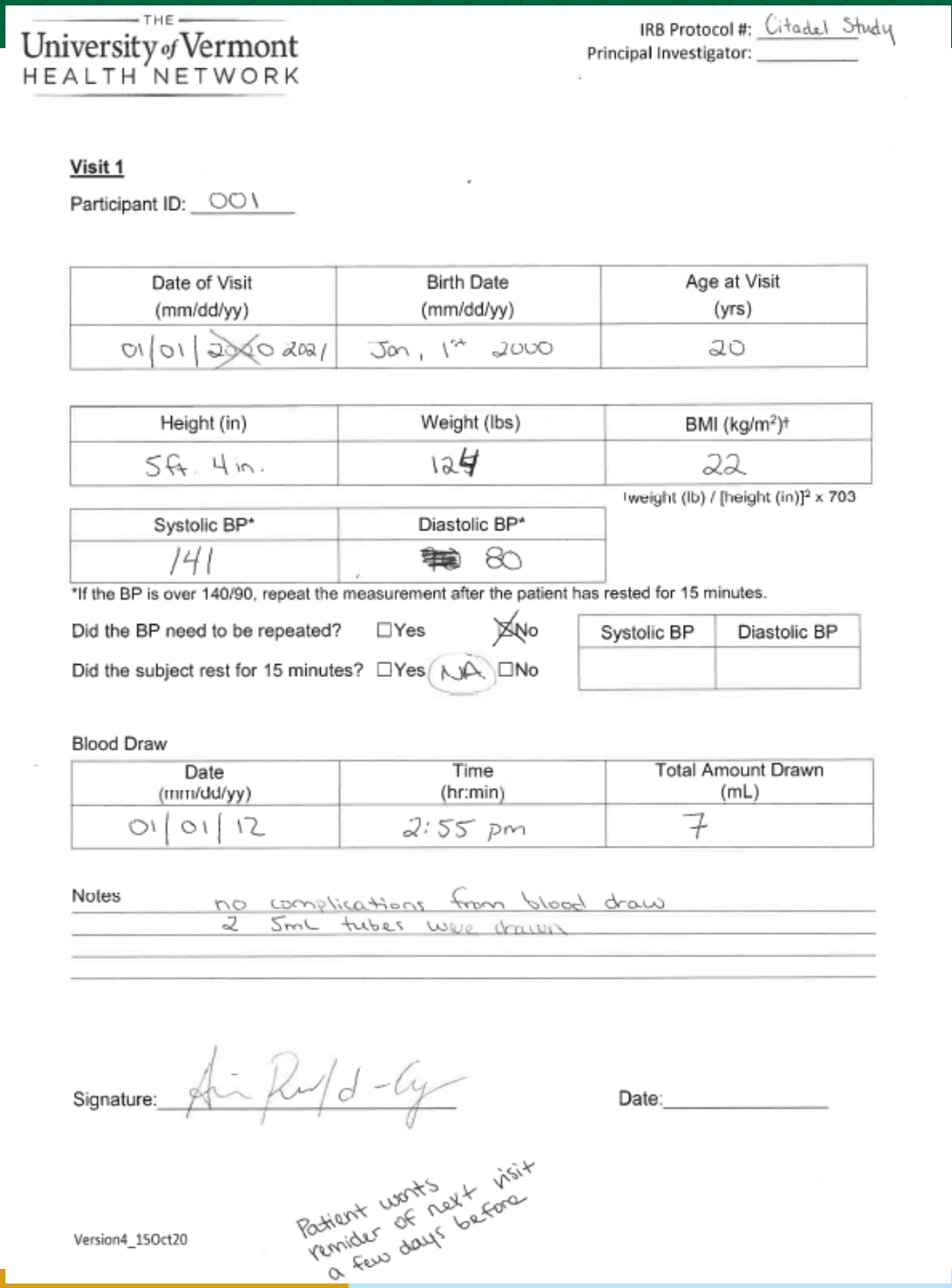
Activity 2

Determine how the EDC features discussed in our presentation could be used to improve the quality of the data being collected electronically compared to this paper form

Attributable Legible Contemporaneous

Original Accurate Complete

Consistent Enduring Available



THE University of Vermont HEALTH NETWORK

IRB Protocol #: Citadel Study
Principal Investigator: _____

Visit 1

Participant ID: 001

Date of Visit (mm/dd/yy)	Birth Date (mm/dd/yy)	Age at Visit (yrs)
01/01/~~20~~20 2021	Jan, 1st 2000	20

Height (in)	Weight (lbs)	BMI (kg/m²)†
5ft. 4in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	~~80~~ 80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐Yes ☒No

Did the subject rest for 15 minutes? ☐Yes (NA) ☐No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: _____ Date: _____

Version4_15Oct20

Patient wants reminder of next visit a few days before

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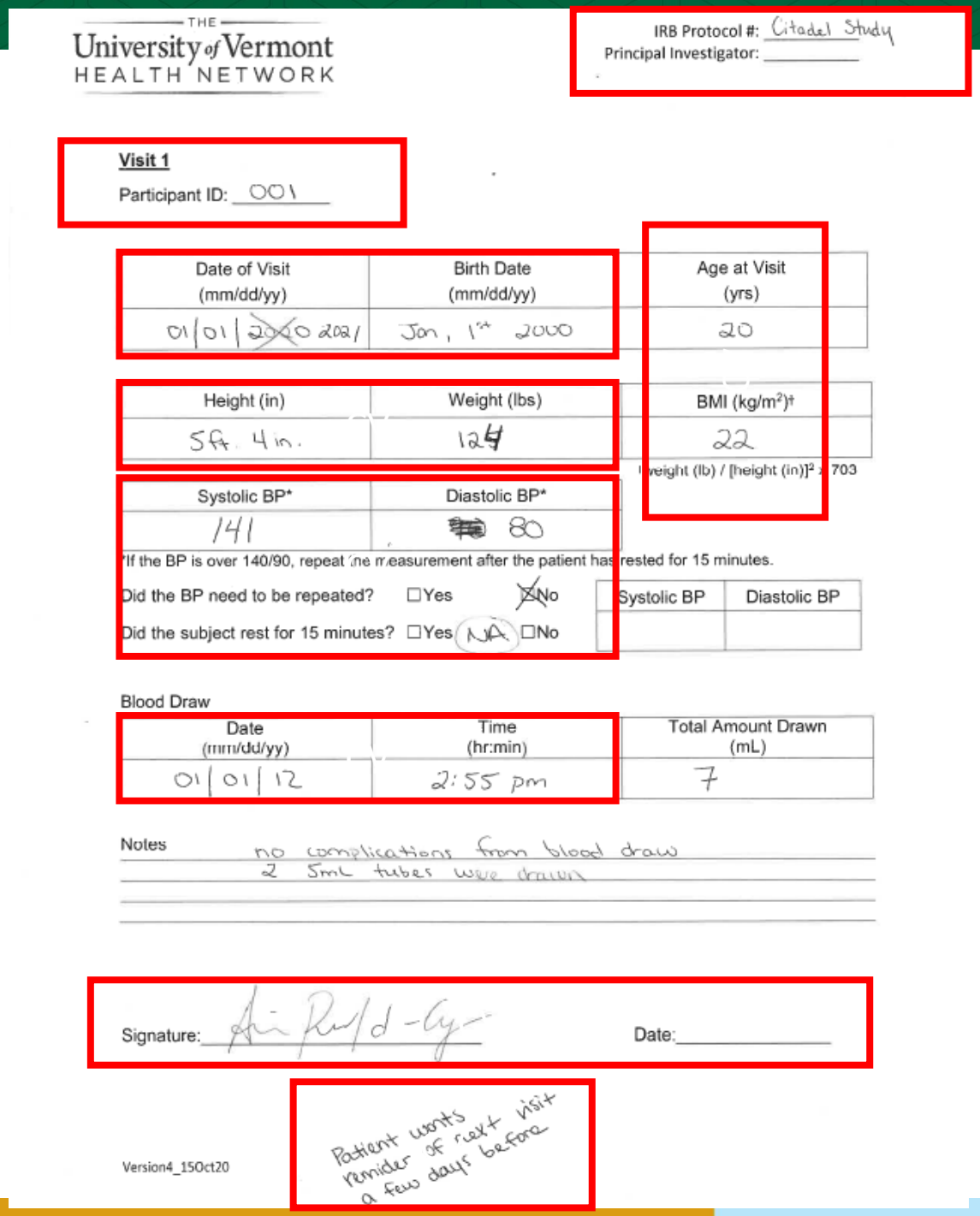
Activity 2

How EDC's Improve Data Collection



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5ft. 4in.	124	22

†weight (lb) / [height (in)]² x 703

Systolic BP*	Diastolic BP*
141	~~120~~ 80

*If the BP is over 140/90, repeat the measurement after the patient has rested for 15 minutes.

Did the BP need to be repeated? ☐Yes ☒No

Did the subject rest for 15 minutes? ☐Yes N/A ☐No

Systolic BP	Diastolic BP

Blood Draw

Date (mm/dd/yy)	Time (hr:min)	Total Amount Drawn (mL)
01/01/12	2:55 pm	7

Notes: no complications from blood draw
2 5mL tubes were drawn

Signature: _____ Date: _____

Version4_15Oct20

Patient wants reminder of next visit a few days before

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Activity 2 – Examples of how an EDC can improve data entry

1. Headers can be piped in so they are auto-generated at the top of each form
2. Date fields can be validated so they are all consistent in their entry
3. You can create field notes that state what units should be used for each field and use field validation so that if someone tries to type “ft” into an integer field, it will error.
4. Calculated fields can be set up so that there is no question if they were done correctly.
5. The systolic and diastolic blood pressure fields could have a flag attached to it so that if the systolic pressure is above 140 or the diastolic is above 90 then it will notify the study team that they need to retake this measurement. Branching logic could also be used here so that the second question won’t appear if the first question is answered with a “No”.
6. Again, these date and time fields can use field validation to answer them in a consistent way and with the date field there is even a “Today” button which allows researchers to just hit the button to fill in todays date instead of having to type it in. There is a similar button for time fields which allows you to click “Now” and it will fill in the current time if you’re doing data entry in real time.
7. EDCs automatically log who was entering data and when on the back end of the system, so this is taken care of by the logging function of an EDC. However, if you did need or want a signature on your electronic form, there is a signature field that allows users to sign with their mouse or finger.
8. And then finally for the note at the bottom, you can create a notes field for free text if you find it would be helpful to have a place to document things that come up over the course of your subject’s visit. But also with this particular note here, if your study team decided that reaching out to remind patients of their next visit a few days in advance was a best practice and you wanted to do this for all of your participants, the EDC can be set up to send email reminders to your participants a few days before their next visit based on their study calendar dates.

Research Professionals Network

“Our overarching goal is to enhance the quality of clinical research by supporting the professional development of clinical research faculty and staff.”

Site Specific REDCap Information

BU Med Campus/BMC:

To get started with REDCap you should: 1) Submit end user agreement: https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX; 2) Review training videos & FAQ: https://redcap.bumc.bu.edu/index.php?action=training; 3) Request a REDCap consult: rchelp@bu.edu

UF: https://www.ctsi.ufl.edu/research/study-design-and-analysis/redcap/

UVM: https://www.uvm.edu/biostatistics/redcap

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Questions

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