Medical Records Abstraction Training

September 22nd, 2022

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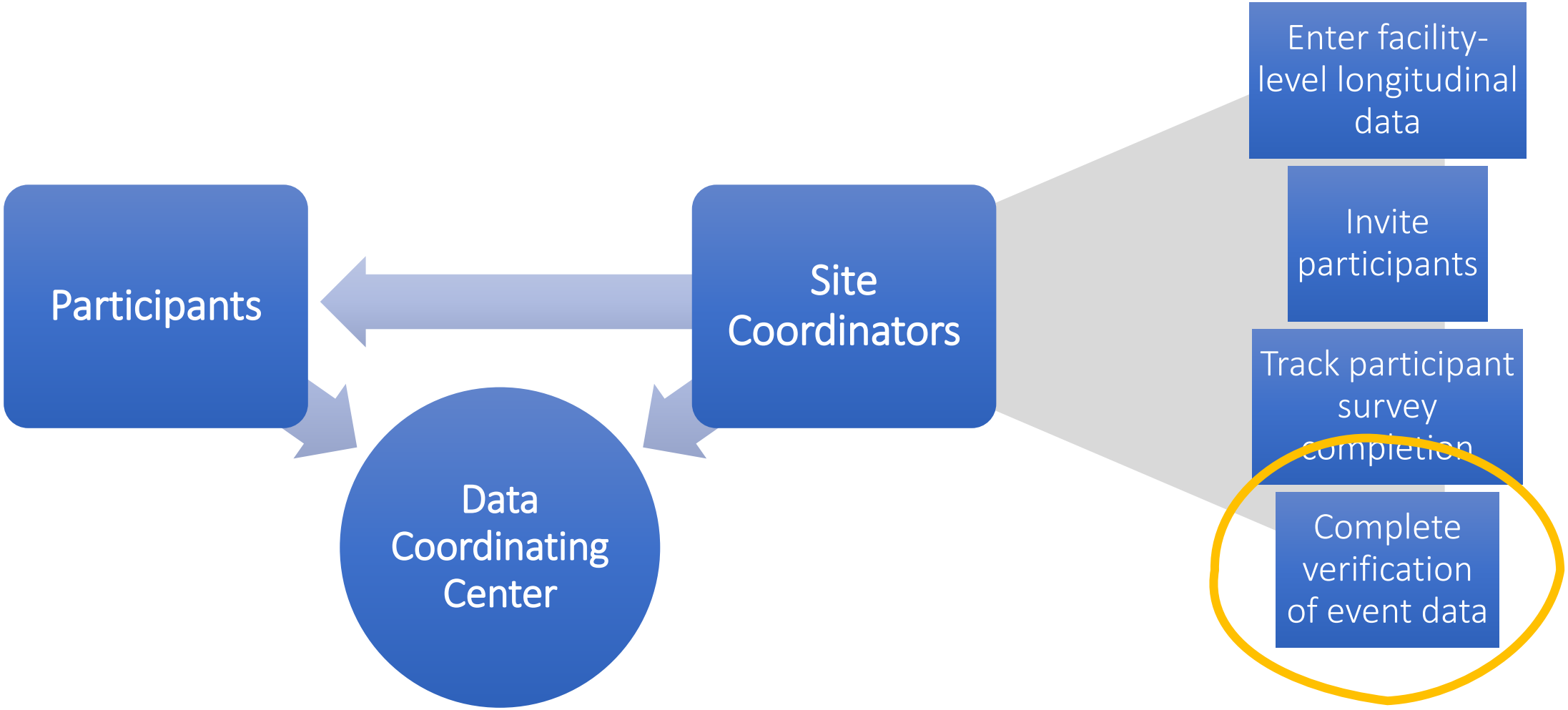
University of Iowa Hospitals and Clinics, Department of Emergency Medicine

Data Coordinating Center

Agenda

1. General information & role of site coordinator
2. Obtaining Medical Records & release of information (ROI) forms
3. Testing Verification
4. Vaccine Verification
5. Healthcare Utilization Verification
6. Abstraction Quiz

Role of Site Coordinator



Medical Records Abstraction

MOP 5.7

Methods outlined in Section 5.7 of MOP

Goal: minimize bias and maximize robustness of data

Study staff must pass short Qualtrics Quiz to be approved by DCC for abstraction

General Information:
Manual of Operating Procedures (MOP)

4.4 Selection and Invitation

4.4.1 Site enrollment launch

The enrollment launch date for a particular site is the date when a site will begin selecting and inviting/recruiting HCP to enroll in the project from their Recruitment Log. Sites will be released to initiate enrollment when the following tasks/items are completed:

1) approval of the site-specific Recruitment Plan by the CCC,
2) site team testing of their Recruitment Plan to identify any initial issues,
3) site readiness call with the Project Manager,
4) site team required project trainings, including medical records abstraction training quiz completion for relevant site team members,
5) all site team members have access to main REDCap, and
6) receipt of project invitation link for HCP from the DCC.

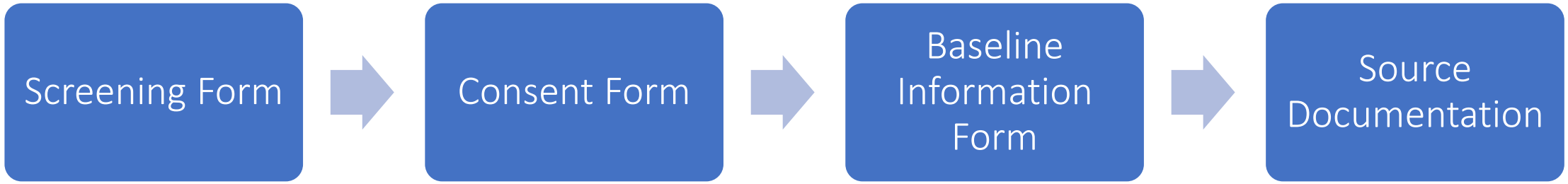
General Information:
Manual of Operating Procedures (MOP)

ALPHANUMERIC IDENTIFIER	DATA FIELD OR QUESTION	INSTRUCTIONS FOR DATA COLLECTOR
GENERAL INFORMATION		
tv3695_eip16	Type of test being reported?	**Required.** Select appropriate response. Reminder: a separate form must be filled out for **each** test obtained.
tv4729	Obtain medical records and upload test results.	**Required.** Confirm medical records release form was completed by the participant for the facility where test was done. Determine if proof of test result is already available via bulk reporting by employee health or if the records need to be requested from a specific facility.

Participant Self-Reported Data Collection

MOP 5.2.1

Baseline Enrollment



Follow-Up

Obtaining Medical Records

MOP 5.7.1

4 ways to obtain medical records:

1. Participant provides medical records themselves
2. Site team receives/extracts records from employee health system
3. Site team extracts records from EMR
4. Site team requests information from hospital/clinic (transmitted via fax or secure email)

Obtaining Medical Records

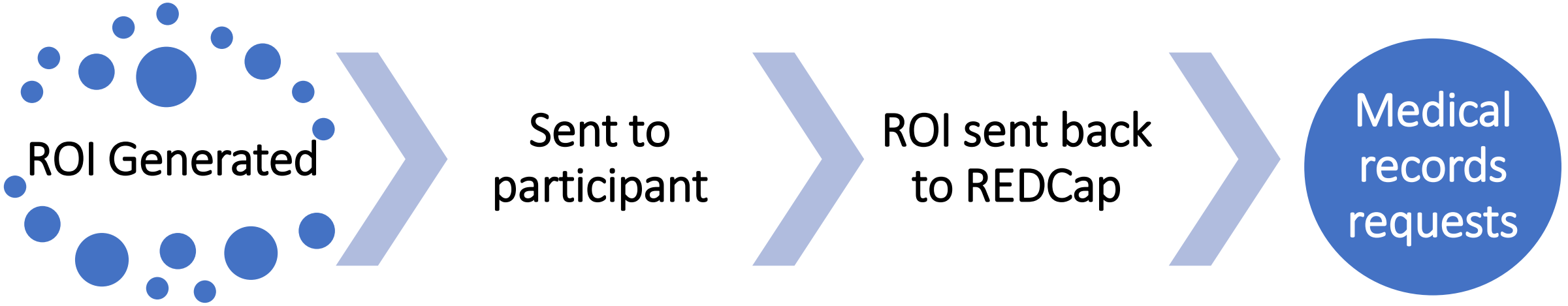
MOP 5.7.1

4. Site team requests information from hospital/clinic (transmitted via fax or secure email)

- The abstractor will be responsible for contacting the facility to initiate the request of medical records
  - Hospital/ED visits → contact hospital medical records office
  - Clinic/private practice visits → contact clinic directly
- Protected health information (PHI) must be kept confidential and secure at every stage!
- Upload medical records into REDCap

Release of Information and DocuSign

MOP 5.7.1.1



Triggered by COVID-19 testing or health care reported in 28-day window on baseline survey

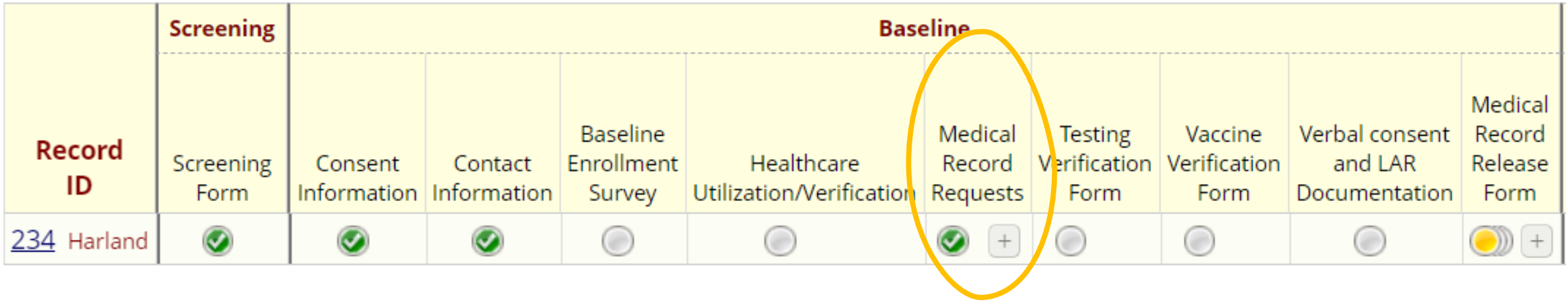
ROI sent to participant via email for electronic signature

Once signed, completed ROI is electronically sent back to REDCap in participant's record

Abstractors may print completed ROI forms from REDCap as-needed

Manually Initiating an ROI Form

MOP 5.7.1.2



Record ID	Screening	Baseline								
	Screening Form	Consent Information	Contact Information	Baseline Enrollment Survey	Healthcare Utilization/Verification	Medical Record Requests	Testing Verification Form	Vaccine Verification Form	Verbal consent and LAR Documentation	Medical Record Release Form
234 Harland	✓	✓	✓			✓ +				+

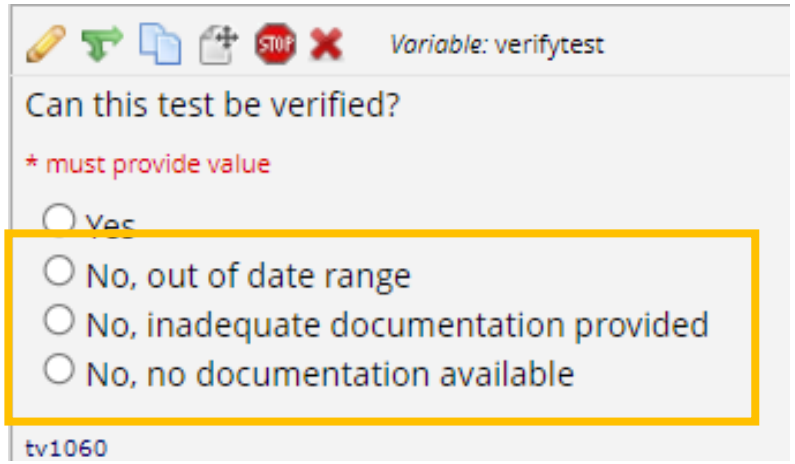
The following information must be entered on the medical record requests form:

1. Name of facility or provider (e.g. Mercy Family Medicine)
2. Information to be requested (e.g. COVID-19 testing)
3. City and State of the facility or provider (e.g. Cedar Rapids, IA)

Participant Uploads Incorrect/Insufficient Documentation

MOP 5.7.1.3

- Abstractor is responsible ensuring documentation that is uploaded contains all information required by the project
- If the test cannot be verified, select the most appropriate reason

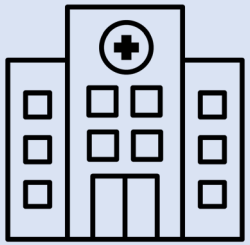


Verification of Self-Reported Records

MOP 6.0

COVID-19 Testing

COVID-19 Vaccinations



Health Care Utilization

COVID-19 Testing Verification

MOP 5.7.2

*Index Date Definition

1. Start of symptoms (symptomatic cases and controls)
2. Index test (asymptomatic controls)

COVID-19 Testing Verification - Laboratory

MOP 5.7.2

RT-PCR SARS-CoV-2 or antigen test results from a laboratory must be verified using one of the following sources:

1. Medical record of occupational health/employee health/health system (MAY include a dataset with bulk reporting of COVID-19 test results)
2. Medical record of primary care physician or another testing center
3. Participant submitted photograph or test result

COVID-19 Testing Verification - Laboratory

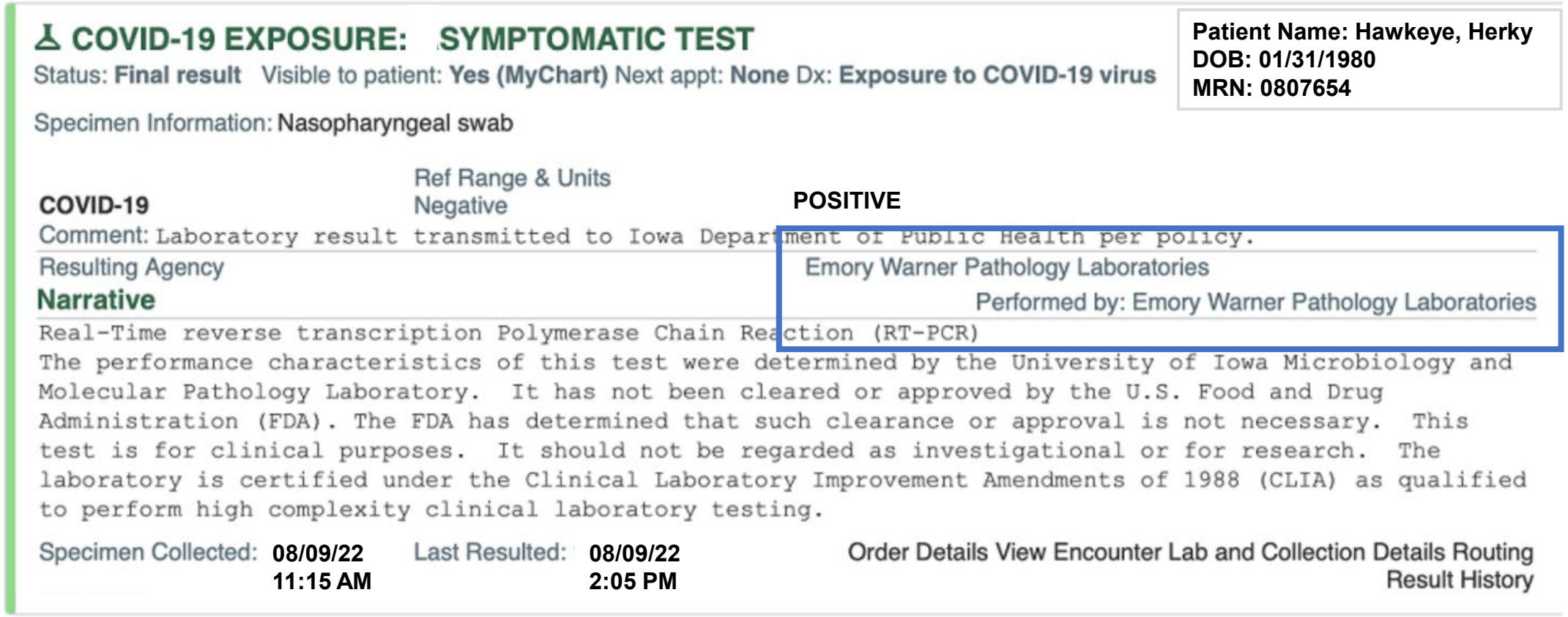
MOP 6.1

Lab testing source documents must contain all the following:

- Official result from health care provider
- Participant identifier (Name)
- Date of test
- Identifying information about the organization reporting the test
- Type of assay performed (e.g., RT-PCR).
- Test result (Samples that are positive for COVID-19 may be reported as “Positive,” “Present,” or “+.”)

COVID-19 Testing Verification - Laboratory

MOP 6.1



COVID-19 EXPOSURE: SYMPTOMATIC TEST

Status: **Final result** Visible to patient: **Yes (MyChart)** Next appt: **None** Dx: **Exposure to COVID-19 virus**

Specimen Information: Nasopharyngeal swab

Patient Name: Hawkeye, Herky
DOB: 01/31/1980
MRN: 0807654

	Ref Range & Units	
COVID-19	Negative	**POSITIVE**

Comment: Laboratory result transmitted to Iowa Department of Public Health per policy.

Resulting Agency: Emory Warner Pathology Laboratories

Narrative

Performed by: Emory Warner Pathology Laboratories

Real-Time reverse transcription Polymerase Chain Reaction (RT-PCR)
The performance characteristics of this test were determined by the University of Iowa Microbiology and Molecular Pathology Laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is for clinical purposes. It should not be regarded as investigational or for research. The laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

Specimen Collected: **08/09/22 11:15 AM** Last Resulted: **08/09/22 2:05 PM**

Order Details View Encounter Lab and Collection Details Routing Result History

Official result from health care provider/ Reporting Agency

COVID-19 Testing Verification - Laboratory

MOP 6.1

Patient Name: Hawkeye, Herky
DOB: 01/31/1980
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Participant Identifier

COVID-19 Testing Verification - Laboratory

MOP 6.1

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Order Details View Encounter Lab and Collection Details Routing Result History

Date of Test

COVID-19 Testing Verification - Laboratory

MOP 6.1

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DOB: 01/31/1980
MRN: 0807654

Specimen Information: Nasopharyngeal swab

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Order Details View Encounter Lab and Collection Details Routing Result History

Type of Assay Performed

COVID-19 Testing Verification - Laboratory

MOP 6.1

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Status: **Final result** Visible to patient: **Yes (MyChart)** Next appt: **None** Dx: **Exposure to COVID-19 virus**

Patient Name: Hawkeye, Herky
DOB: 01/31/1980
MRN: 0807654

Specimen Information: Nasopharyngeal swab

	Ref Range & Units	
COVID-19	Negative	**POSITIVE**

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Specimen Collected: **08/09/22 11:15 AM** Last Resulted: **08/09/22 2:05 PM**

Order Details View Encounter Lab and Collection Details Routing Result History

Test Result

COVID-19 Testing Verification - Home

MOP 5.7.2, 6.1

Antigen home tests resulted at home require a photograph or image of the test. It does not require test result.

Acceptable documentation includes:

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Select: Molecular Diagnostic Tests for SARS-CoV-2

In Vitro Diagnostics EUAs

Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

Blood Purification Devices EUAs

Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs

In Vitro Diagnostics EUAs

Infusion Pump EUAs

Personal Protective Equipment EUAs

Remote or Wearable Patient Monitoring Devices EUAs

Respiratory Assist Devices EUAs

Ventilators and Ventilator Accessories

In vitro diagnostic (IVD) devices are tests performed on samples taken from the human body, such as swabs of mucus from inside the nose or back of the throat, or blood taken from a vein or fingerstick. IVDs can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases.

There are several types of SARS-CoV-2 and COVID-19 related IVDs:

- **Diagnostic Tests:** Tests that can be used to diagnose infection with the SARS-CoV-2 virus. These include molecular tests, such as nucleic acid amplification tests, and antigen tests, as well as diagnostic tests that analyze breath samples.
- **Serology/Antibody and Other Adaptive Immune Response Tests:** Tests that detect antibodies (for example, IgM, IgG) to the SARS-CoV-2 virus or that measure a different adaptive immune response (such as, T cell immune response) to the SARS-CoV-2 virus. These types of tests cannot be used to diagnose a current infection.
- **Tests for Management of COVID-19 Patients:** Beyond tests that diagnose or detect SARS-CoV-2 virus or antibodies, there are also tests that are authorized for use in the management of patients with COVID-19, such as to detect biomarkers related to inflammation. Once patients are diagnosed with COVID-19 disease, these additional tests can be used to inform patient management decisions.

Tables of IVD EUAs:

- Molecular Diagnostic Tests for SARS-CoV-2
  - Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2
  - Revision Concerning Viral Mutation
  - Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2

Content current as of:
06/10/2022

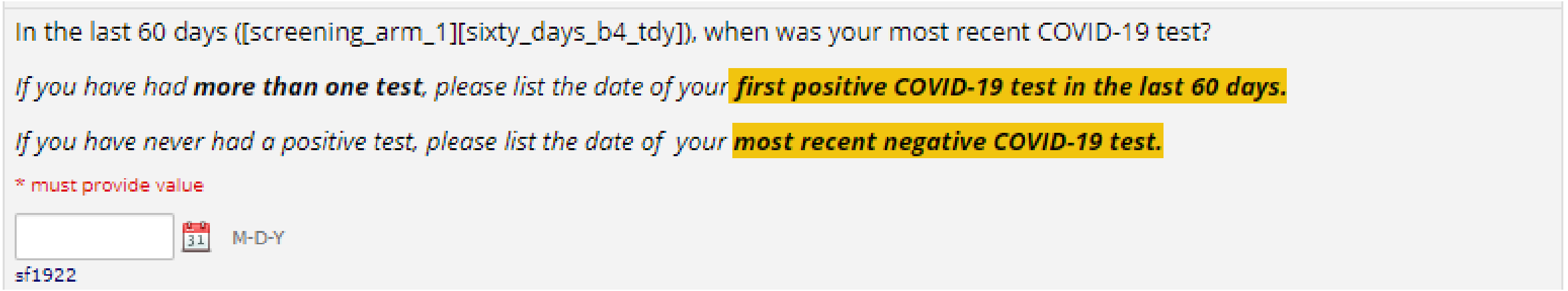
Regulated Product(s)
Medical Devices

Health Topic(s)
Coronavirus

Search for test manufacturer to confirm EUA

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Original Issue	Attributes[3]	Authorized Setting(s)[1]	Authorization Documents[2]
09/16/2022	Quidel Corporation	Lyra SARS-CoV-2 Assay 03/17/2020	Real-time RT-PCR, Single Target	H	HCP, Patients, IFU
09/15/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 RNA STAR Complete 10/14/2020	RT, qSTAR amplification, Home Collection, Screening, Pooling, Single Target	H	HCP, Patients, IFU
09/13/2022	Predicine, Inc.	Predicine SARS-CoV-2 RT-PCR Test 07/19/2022	Real-time RT-PCR, Home Collection, Multiple Targets, Screening, Pooling	H	HCP, Patients, EUA Summary, IFU (Home Collect)
09/13/2022	Rheonix, Inc.	Rheonix COVID-19 MDx Assay 04/29/2020	RT-PCR, Home Collection, Saliva, Single Target	H, M	HCP, Patients, IFU, IFU (Home Collect)
09/12/2022	PerkinElmer, Inc.	PerkinElmer New Coronavirus Nucleic Acid Detection Kit 03/24/2020	Real-time RT-PCR, Pooling, Screening, Saliva, Multiple Targets	H	HCP, Patients, IFU
09/09/2022	Uh-Oh Labs Inc.	UOL COVID-19 Test 02/08/2022	RT-LAMP, Single Target	H, M, W	HCP, Patients, IFU
09/06/2022	INNO Diagnostics Reference Laboratory, Ponce Medical School	PMSF-INNO SARS-CoV-2 RT-PCR Test (Authorized by HHS/OASH) 01/19/2021	Real-time RT-PCR, Multiple Targets	H	HCP, Patients, EUA Summary
08/31/2022	Thermo Fisher Scientific, Inc.	TaqPath COVID-19 Combo Kit 03/13/2020	Real-time RT-PCR, Home Collection, Multiple Targets	H	HCP, Patients, IFU

Verification of Index COVID-19 Test Date


In the last 60 days ([screening_arm_1][sixty_days_b4_tdy]), when was your most recent COVID-19 test?

*If you have had **more than one test**, please list the date of your **first positive COVID-19 test in the last 60 days.***

*If you have never had a positive test, please list the date of your **most recent negative COVID-19 test.***

* must provide value

M-D-Y

sf1922

All participants will be prompted to self-report their COVID-19 test date in the screening form.

Verification of Index COVID-19 Test Date

This self-reported index COVID test date will also appear in the Project Completion Tracking form

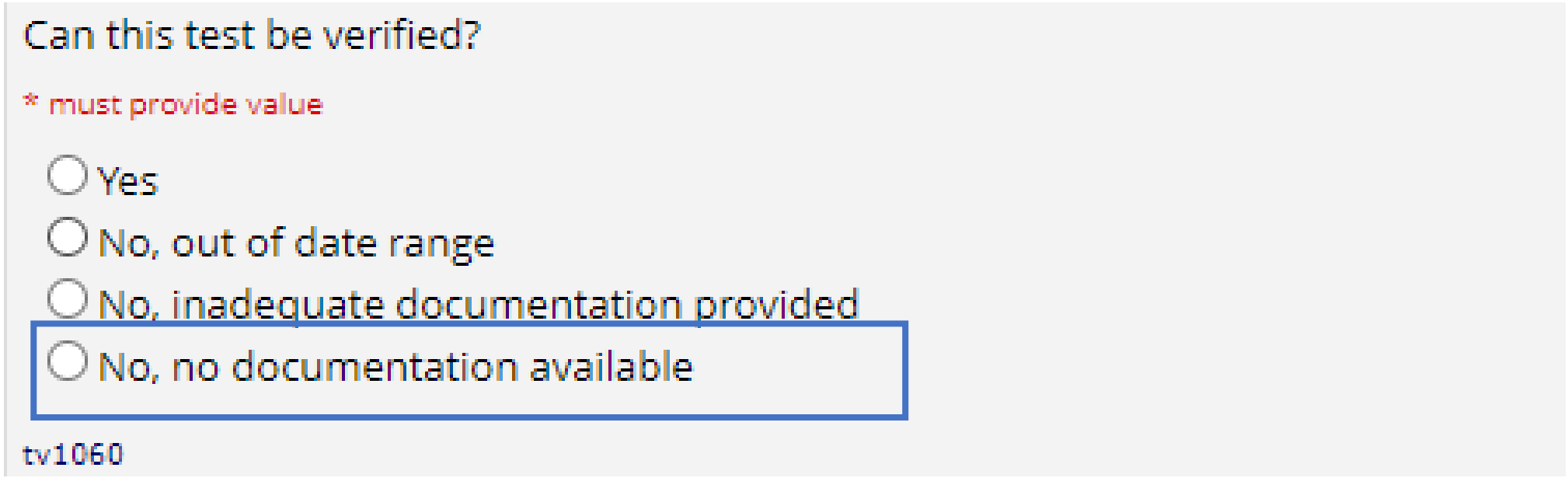
Record ID	70043		
This form displays survey completion dates as well as expected timeline for each participant. This is a READ-ONLY form except for the survey queue link.			
Screening date:	07-28-2022		
Eligibility status:	Eligible		
Consent date:	07-28-2022		
Index COVID test date:	07-24-2022		
	Date	**Begin Index Period**	**End Index Period**
Index date	07-17-2022	07-03-2022	07-31-2022
	Completion date	**Ideal date**	**Overdue date**
Baseline	08-01-2022	07-31-2022	08-07-2022
6 Week Follow-up	_____	08-28-2022	09-04-2022
12 Week Follow-up	_____	10-09-2022	10-16-2022
6 Month Follow-up	_____	01-14-2023	01-21-2023

Asymptomatic Controls

Record ID	70061		
This form displays survey completion dates as well as expected timeline for each participant. This is a READ-ONLY form except for the survey queue link.			
Screening date:	09-21-2022		
Eligibility status:	Eligible		
Consent date:	09-21-2022		
Index COVID test date:	09-05-2022		
	Date	**Begin Index Period**	**End Index Period**
Index date	09-05-2022	08-22-2022	09-19-2022
	Completion date	**Ideal date**	**Overdue date**
Baseline	_____	09-19-2022	09-26-2022
6 Week Follow-up	_____	10-17-2022	10-24-2022
12 Week Follow-up	_____	11-27-2022	12-04-2022
6 Month Follow-up	_____	03-05-2023	03-13-2023

Verification of Index COVID-19 Test Date

The CDC requires that all Index COVID test dates are verified within +/- 1 day. If the site is unable to verify this date on the testing verification form, select the following reason:



Verification of Self-Reported Records

MOP 6.0

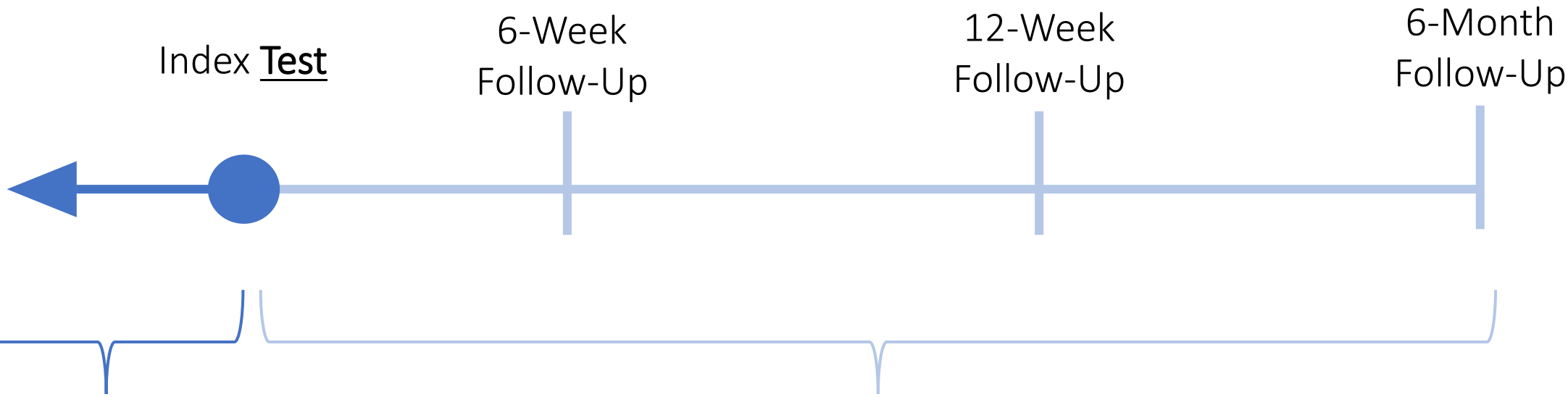
COVID-19 Testing

COVID-19 Vaccinations

Health Care Utilization

Vaccine Verification

MOP 5.7.3



All COVID-19 vaccine doses received prior to index test are reported by participant **and verified** by study staff

All COVID-19 vaccine doses received after index test may be reported by participants on follow-up surveys but are **not required to be verified.**

Vaccine Verification

MOP 5.7.3

COVID-19 vaccination prior to index COVID test must be verified using at least one of the following sources:

1. Medical record of the occupational health/employee health or health system (bulk reporting from employee health clinical will be sufficient for source verification);
2. Medical record of the primary care physician or other vaccination center; or
3. State or federal vaccine registry (state Immunization Information System, Vaccine Administration Management System, or other vaccination registry).
4. Letter documenting trial arm allocation if participant was in a vaccine study

Vaccine Verification

MOP 6.2

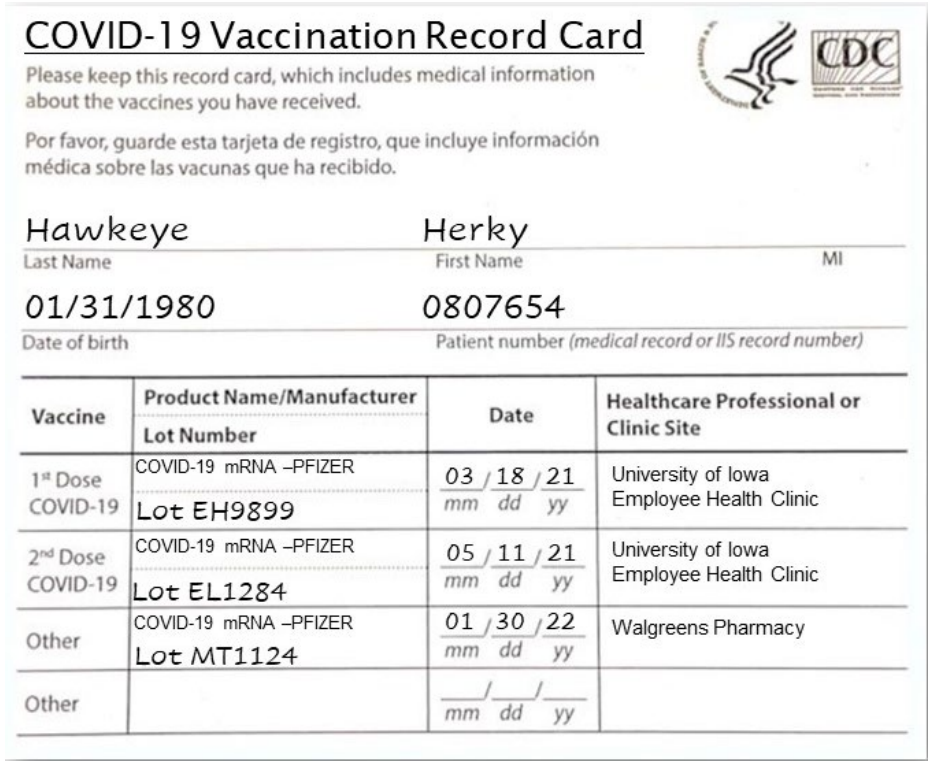
For participants that provide source documents that provide vaccine verification, the document must include the following:

1. Identifying information about the organization that administered the vaccine
2. Participant identifier (Name)
3. Date of administration of the vaccine(s)
4. Manufacturer or product name of the vaccine administered
5. Lot number recorded if known *but not required* *If lot unknown, enter "9999"*

****Complete a separate form for each vaccine dose administered**

Vaccine Verification

MOP 6.2



COVID-19 Vaccination Record Card

Please keep this record card, which includes medical information about the vaccines you have received.

Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Hawkeye — Last Name
Herky — First Name
MI

01/31/1980 — Date of birth
0807654 — Patient number *(medical record or IIS record number)*

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1st Dose COVID-19	COVID-19 mRNA –PFIZER Lot EH9899	03/18/21 mm dd yy	University of Iowa Employee Health Clinic
2nd Dose COVID-19	COVID-19 mRNA –PFIZER Lot EL1284	05/11/21 mm dd yy	University of Iowa Employee Health Clinic
Other	COVID-19 mRNA –PFIZER Lot MT1124	01/30/22 mm dd yy	Walgreens Pharmacy
Other		___/___/___ mm dd yy	

University of Iowa Hospitals and Clinics (UIHC)
200 Hawkins Dr.
Iowa City IA 52242
United States of America

COVID-19 Vaccination Record

as of September 20, 2022

Rabbit, Rodger DOB: 04/04/1975

COVID-19 vaccination complete (3 of 4)

Dose 1 administered on December 14, 2020

Name:	COVID-19, mRNA 12+ yo (PFIZER) 30mcg/0.3mL
Manufacturer:	Pfizer, Inc
Lot #:	EH9899
Location:	University of IA Employee Hlth Clin

Dose 2 administered on January 7, 2021

Name:	COVID-19, mRNA 12+ yo (PFIZER) 30mcg/0.3mL
Manufacturer:	Pfizer, Inc
Lot #:	EL1284
Location:	University of IA Employee Hlth Clin

Dose 3 administered on September 28, 2021

Name:	COVID-19, mRNA 12+ yo (PFIZER) 30mcg/0.3mL
Manufacturer:	Pfizer, Inc
Lot #:	EW0172
Location:	University of IA Employee Hlth Clin

Vaccine Verification: non-vaccination

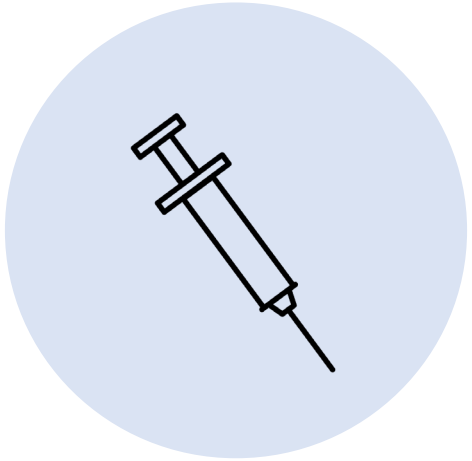
MOP 5.7.3.1

- All sites must have process to verify the absence of vaccination in patients who report they did not get the COVID-19 vaccine
- Site specific plans to verify: search local employee health or state vaccine registry
- To record verification, create a new vaccine verification form
  - "What is this participant's vaccination status?" → No vaccine

Verification of Self-Reported Records

MOP 6.0

COVID-19 Testing



COVID-19 Vaccinations

Health Care Utilization

Health Care Utilization Verification

MOP 5.7.4

***Index Date Definition**

1. Start of symptoms (symptomatic cases and controls)
2. Index test (asymptomatic controls)

Health Care Utilization Verification

MOP 5.7.4

Health Care Utilization to Include:

- Inpatient or observation hospital admission
- ED, urgent care, or other unscheduled clinic visits (excluding visits for mental health)
- Outpatient clinic appointments (only in relation to current symptoms of COVID-19 infection)

Health Care Utilization to EXCLUDE:

- Admissions to skilled nursing facilities, rehabilitation, long-term care, post-acute care
- Inpatient or outpatient visits for mental health
- Visits for testing only (no corresponding clinical evaluation)
- Telehealth visits

Health Care Utilization Verification

MOP 5.7.4

Records abstraction

- Participants will receive a ROI form when they report utilization of health care in baseline survey
- Source documents should be uploaded into REDCap. They must be uploaded as a single document for each encounter
- Each health care encounter will have an associated verification form.
- Note! emergency department visits and inpatient hospitalizations count as separate encounters, *even if the patient is admitted to the hospital through the ED*

Clinic notes
Emergency department record
Hospital admission notes
Radiology reports
Lab results
Vitals signs
Vaccination records
Medication lists
Problem list

Health Care Utilization Verification

MOP 6.3

6.3 Medical Records/Health Care Visit Record Verification

Please complete a different form for every health care encounter. This includes creating a separate form for an emergency department visit resulting in a hospital admission.
Encounters for testing alone only need to be verified on the testing form.

ALPHANUMERIC IDENTIFIER	DATA FIELD OR QUESTION	INSTRUCTIONS FOR DATA COLLECTOR
GENERAL INFORMATION		
mv2274	Record reviewer, name and affiliation	**Required.** Free text. Record your (the reviewer's) HawkID used to log into REDCap
mv4473	Medical records regarding health care visits	Required for participants who sought outpatient care or required COVID-19 treatment. Request the medical records from every qualified visit which includes: 1) Any acute inpatient or observation hospital admission (for any cause) from 14 days prior to the onset of symptoms through 14 days after the onset of symptoms. Comprehensive medical records for all hospital admissions should be included (including but not limited to admission note/H&P, daily provider and nursing progress notes, procedure notes, consult notes, discharge summary, vital sign summaries, lab and imaging results, and

Medical Records Abstraction – MOP Resources

MOP Appendix E.

Table 1. Common Immunosuppressants

GENERIC NAME	TRADE NAME
5-FLUOROURACIL (5-FU, FLUOROURACIL)	EFUDEX, FLUOROPLEX, CARAC, ADRUCIL
6-MERCAPTOPURINE (6-MP, MERCAPTOURINE)	PURINETHOL
ACTINOMYCIN-D (DACTINOMYCIN)	COSMEGEN
ADALIMUMAB	HUMIRA
AFATINIB	GIOTRIF
ALDESLEUKIN (INTERLEUKIN-2)	PROLEUKIN
ALEMTUZUMAB	CAMPATH
ALTRETAMINE	HEXALEN
ANTI-THYMOCYTE GLOBULIN	THYMOGLOBULIN, ATG, ATGAM
ARSENIC TRIOXIDE	TRISENOX, ARSENOX
ASPARAGINASE	ERWINAZE, CRISANTASPASE, ASPARAGINASE MEDAC, CIDEROLASE, ONCASPAR, SPECTRILA
ATEZOLIZUMAB	TECENTRIQ
AXITINIB	INLYTA

REDCap Reports to Track Medical Record Abstraction

MOP 5.7.5

1. Medical records to request
2. Medical records requested but not received
3. Medical records abstractions to complete
4. Vaccine verification
5. Testing verification

Questions for DCC?

MOP 5.7.6

- Record item number for the question (e.g. ef4242)
- Record survey number for participant (e.g. 134)
- Email: EmergencyIDNet-Prevent@uiowa.edu

Data Abstraction Certification Quiz

MOP 7.5.1

- All study personnel that will be completing data abstraction must take and pass the Data Abstraction Certification Quiz
- **80% required to pass**
- https://uiowa.qualtrics.com/jfe/form/SV_8hM8WBS8EHBXG1U