**Cause of RASHes in the ED**

**“CRASHED” Project**

Subtitle: Examining the Prevalence, Clinical Characteristics, and Treatment of Mpox in U.S. Emergency Departments Participating in *EMERGE*ncy ID NET

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**MANUAL OF OPERATING PROCEDURES**

**Version 3.0**

**August 15, 2023**

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# Key Personnel and Contact Information

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# 2.0 Summary of Project Design and Objectives

|  |  |
| --- | --- |
| Project Purpose | We propose to conduct Mpox surveillance in the emergency department (ED) setting, which is unique in being broader-based and more likely to reach medically disadvantaged and socially vulnerable groups than surveillance for Mpox among recognized high-risk individuals presenting to sexually transmitted infections (STI), HIV, and LGBTQ+ clinics. This project may suggest that Mpox has been largely eradicated, or possibly resurged and/or that risk factors have evolved, which would impact ongoing public health efforts to control the spread of this infection. Our results will justify additional systematic efforts to conduct US ED surveillance through coordinated networks, such as *EMERGE*ncy ID NET. |
| Project Design | This will be a two-phase project with the first phase beinga 1-monthpilot project conducted at 2 Los Angeles EDs to develop, test, and refine data collection methods followed by a second phase that will be a 6-month large scale national surveillance project conducted at *EMERGE*ncy ID NET sites.  Patients age >3 months presenting with a pustular, vesicular, crusted, or ulcerated skin rash will be enrolled and consented in the ED. During the ED visit, the site coordinator will record responses from the participant and their treating clinician about the participant’s illness, and the participant will be asked to allow collection of specimens obtained by swabbing the rash(s) (i.e., 2 swabs). The site coordinator will also obtain between two and four digital pictures of the rash sites that are swabbed. Participants ages ≥16 years of age will also be asked to complete a self-administered questionnaire about their sexual orientation, gender identity, and recent sexual behavior. After the ED visit, the site coordinator will review and abstract data from their medical record about their visit and outcomes. The site coordinator will contact the participant at 45 days to ask them about the outcome of their illness and healthcare utilization. For participants who test positive for Mpox during the project period, the site coordinator will conduct another medical record review at 45 days to capture additional healthcare utilization. Participants who test positive for Mpox and still have symptoms at 45 days will be called again at 90 days to ask about any additional healthcare utilization and the site team will conduct another medical record review at 90 days. |
| Participant Population | The project will enroll ED patients age ≥3 months who present for evaluation of a skin lesion that is pustular, vesicular, crusted, or ulcerated. This approach will allow the inclusion of populations that may have been underrepresented in Mpox surveillance, including women, children, homeless, immigrant, minorities, and individuals with low-income. |
| Duration of Participant’s Participation | The duration of participation is 45 days for most participants but for those that test positive for Mpox and still have symptoms at 45 days, they will participate for 90 days, although the actual project-related time spent by the participant in those 90 days will be about one hour. |
| Duration of project enrollment | The first phase of the project will be initiated in April 2023 and will continue for one month. The second phase of the project involving the other sites will be initiated in June 2023 and will continue for six months in order to capture US community Mpox activity in 2023. |

# 3.0 Screening and enrollment

Site coordinators or assistants will screen for eligible patients by reviewing the emergency department (ED) and if feasible also the urgent care (UC) electronic health record tracking board for patients who may meet inclusion and exclusion criteria (see below). **Patients presenting to the ED or UC with chief complaint of rash, skin lesion, skin ulcer, Mpox or sexually transmitted infections, should be screened.** **Also, patients who have chief complaints that include fever, chills, and pain in oral, genital, or anal area should be screened (review nursing or triage notes) to see if they also have a rash/lesions.**

In addition, posters will be displayed, if possible, in the ED and UC doctors’ room with inclusion criteria and the site team’s contact information for clinicians to call if they encounter an eligible patient. **Any posters or flyers used should refer to this as a “Rash” project, not Mpox project, to ensure this project encompasses broad surveillance of rashes and to eliminate any clinician bias.** If sites are able, they may display posters/flyers directed at patients in the ED waiting area to notify their doctor or nurse if they have a rash.

All sites must maintain a Screening Log (see section 3.2). All patients that have any rash should be entered into the Screening Log. Each site will set up their screening hours depending on their site staff’s ability. Site teams should backscreen to look for missed patients with rash during off hours. If they are admitted and potentially qualify for the project, the site team can approach the patient in the hospital for enrollment if their treating clinician approves. If they have already been discharged, note them on the Screening Log.

## 3.1 Eligibility criteria

Site coordinators or assistants will contact the treating provider if they identify a patient that meets criteria to ask if the patient can be approached for enrollment. Even if the provider does not think the rash is related to Mpox infection the site coordinator should still approach and enroll the patient if they meet eligibility criteria (see section 3.1.3 for additional guidance on eligibility).

### 3.1.1 Inclusion criteria

Whether the patient is being admitted or discharged, they can be enrolled, but they must meet the following inclusion criteria:

1. Patients age >3 months who present with one or more qualifying lesions that appears pustular, vesicular, crusted or ulcerated

The site coordinator only needs to verify with the provider if the skin lesions are pustular, vesicular, crusted or ulcerated.

### 3.1.2 Exclusion criteria

Patients who are enrolled must not meet any of the following exclusion criteria:

1. Prior enrollment in this project

Site coordinator should verify by searching site’s screening and enrollment log to make sure the patient has not been enrolled previously.

1. Any records flagged “break the glass” or “research opt out”

If your site uses Epic for electronic medical records (EMR), then “break the glass” is a privacy tool used in Epic to prompt users to enter a reason why they need to access a record that has been marked sensitive. These sensitive records should not be accessed, and these patients should not be approached. Other EMRs, e.g., Cerner may have a similar privacy feature and should be handled similarly.

It is possible that patients who present to the ED or UC with a rash, may have been a victim of rape or sexual assault. These patients can still be enrolled if the treating clinician approves their approach, but they should be reminded that they may choose to decline answering any of the questions.

1. Speak a language other than English or Spanish

Patients must be able to speak English or Spanish at enrollment so they can respond to questions required for completion of data collection forms and complete the self-administered survey with site coordinator assistance (e.g., if patient cannot read but is willing to have the study coordinator read the questions and responses to them) if warranted.

1. Unable to provide consent

For children >3 months their parent or legal guardian will provide consent by signing the consent form. Children who are able to provide assent will do so.

1. Only have lesion(s) > 2cm in diameter. Note: Ignore surrounding erythema when determining lesion size.

If a patient only has one lesion, then site coordinator should confirm that the lesion diameter is not >2cm. Patients with one or more lesions larger than 2 cm may still be enrolled, given that there are qualifying lesions that are ≤ 2 cm. However, only the lesion(s) that are ≤ 2cm in diameter should be swabbed and photographed for this project.

1. Duration of rash >4 weeks

Patients should not be enrolled if their rash is chronic.

### 3.1.3 Clarification on Determining Eligibility

The best way to determine if a patient may qualify, is to call the treating provider and ask if the lesion(s) are pustular, vesicular, crusted or ulcerated. A vesicular lesion is a fluid-filled blister. Patients who are suspected of having shingles, herpes, or hand, foot and mouth disease could qualify if their lesion(s) meet inclusion criteria. Although rarely, some patients might have ulcers in their mouth only, and should be included.

If a patient has only one lesion, even though it may not be considered a rash, the patient can still be enrolled if the one lesion meets the definition of pustular, vesicular, crusted or ulcerated. However, patients with a skin abscess or a diabetic foot ulcer would not qualify.

Although most allergic reactions and eczema cause a maculopapular rash, the site coordinator should still contact the treating provider to determine if any of the lesions of the rash are pustular, vesicular, crusted or ulcerated. If a patient comes in mainly for an unrelated complaint, but also has a rash that fits the inclusion criteria, we can still consider the patient for enrollment.

## 3.2 Screening Log

All patients presenting to the ED and UC with any rash should be added to the Screening Log. Even if the site coordinator has clarified with the provider that the rash is not pustular, vesicular, crusted or ulcerated, these patients should still be included on the log. The screening log will be numbered consecutively and will include the following column headers: date of ED presentation, patient’s medical record number (MRN), patient’s name, if enrolled (yes or no). If not enrolled, the reason for not enrolling or ineligibility should be recorded, e.g., declined participation, missed by site team, out of site team coverage hours, or specific inclusion/exclusion criteria that excluded them. If a participant refuses to sign the Medical Records Release of Information Form (see section 3.6) or does not want a photograph of their lesion taken, they can still be enrolled. If a participant refuses to be contacted for the Telephone Follow-up, they can still be enrolled, however the site coordinator should try to probe to find out the reason why and record on the log. If enrolled, the Project Identification (ID) number should be recorded (see section 3.7).

**Figure 1. Sample Screening Log**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Log – IDNET Mpox surveillance - OVUCLA** | | | | | | | |
| **Screening ID** | **ED date** | **MRN** | **Last Name** | **First Name** | **Enrolled (Y/N)** | **Reason for not enrolling** | **Project ID** |
| 1 | 3/28/2023 | 123456 | Doe | Jane | N | Rash not pustular, vesicular | N/A |
| 2 | 4/1/2023 | 567890 | Patrick | Saint | Y |  | OVMP001 |
| 3 | 4/2/2023 | 789909 | Bunny | Easter | N | Declined to participate | N/A |
| 4 | 4/4/2023 | 234435 | Rabbit | Peter | N | Outside SC coverage hours | N/A |
| 5 | 4/6/2023 | 234234 | Man | Bat | Y |  | OVMP002 |

## 3.3 Patient Approach

When approaching the patient, the site coordinator should introduce themselves, and explain they are part of the team at the hospital gathering data for a Mpox public health project being funded by the Centers for Disease Control and Prevention. Since there is some social stigma associated with Mpox infection and we will ask some deeply personal questions, it is important that the site coordinator approaches the patients with sensitivity and without judgement. The site coordinator should further explain that enrolling in the project does not necessarily mean that the doctors suspect the patient has Mpox. Furthermore, the patient should be told we would like to take a picture of and a swab of the rash today to perform a Mpox test for project purposes. If the Mpox result is positive and they are not getting a Mpox test as part of their regular care, the patient will be notified of their positive result in about 2-4 weeks.

Patients should be informed that if they agree to participate, they will be asked questions about their medical and social history. In addition, for any patient >16 years of age, they will be asked personal questions about their gender identity, recent social behavior and sexual practices which may make them feel uncomfortable. They can choose to decline answering any of these questions. The patient will not be asked these questions verbally. Instead, they will be asked to complete these questions via paper or electronically on a tablet or using their phone.

Patients should be informed that they will be contacted in 45 days via telephone to see if their symptoms are improving. An additional telephone call may be made in 90 days which will be determined by the outcome of their symptoms on the 45-day call. This project allows approaching patients who are incarcerated, but this will be site specific depending on local and state laws. Finally, let the patient know that they will be compensated for their time with $25 today and $25 each for follow-up contacts.

When approaching a patient, the site team should have the following documents and materials ready in English or Spanish as applicable:

1. Informed consent form (section 3.4)
2. Assent form (section 3.5)
3. Release of Medical Records Form (section 3.6)
4. Participant pre-printed Project ID Labels for photos and rash swabs (section 5.1)
5. Ipad/tablet to take pictures and to administer Enrollment Survey (for participants who prefer to use a tablet or their phone for survey responses).
6. Rash swabs
7. Participant Contact Information form (section 4.1.1)
8. Enrollment data form (section 4.1.2)
9. Enrollment Survey form (for participants who prefer to use paper for survey responses; section 4.1.3)
10. Other site-specific required documents/materials (e.g., ruler if useful for clinician measurements,
11. Participant compensation (e.g., cash, gift card, etc.; section 6.0)

## 3.4 Consent

All patients >18 years of age enrolled in the project will provide written informed consent to participate, or the written consent of a legally authorized representative (LAR), if applicable. After the site coordinator or investigator explains the project to the patient, they will give them the written informed consent form and allow them ample time to read it over and discuss it with their family member, friend or LAR. Elements of the consent include explaining the project procedures, potential risks and benefits of participating and protection of confidentiality. The rights and welfare of the patients should be protected by emphasizing to them that they will still be able to receive medical care at the facility if they decline to participate in the project. The patients should have the opportunity to inquire about details of the project and to decide whether or not to participate. All questions should be answered to the satisfaction of the patient or LAR. Prior to participation, the written informed consent form should be signed and personally dated by the participant or LAR, and by the person who conducted the informed consent discussion.

For Spanish speaking patients, site coordinators who speak fluent Spanish will approach them about the project so they can communicate effectively with these patients. If no Spanish speaking site coordinator is available, the site coordinator will utilize a Spanish speaking healthcare worker who is available or use the appointed translation service that is offered by the institution.

The consent form will be available in English and Spanish. Patients who do not speak English or Spanish cannot be enrolled in the project. Once the participant/LAR has signed the consent, the site coordinator will provide a copy of the signed consent to the participant/LAR. Another copy will be scanned into the participant’s EMR.

## 3.5 Assent

Children age ≥ 8 and <18 years must provide assent prior to participating, which means they agree to take part. They may also dissent, which means they do not agree to take part. To take part in the assent process, the child must be mature enough to understand the project and what is required of them. For this project, children >8 years of age should be given an opportunity to provide assent.

The site coordinator or investigator will explain the project to the child in a language that can be understood by the child, in English or Spanish. If no Spanish speaking site coordinator is available, then the site will utilize the institution’s translation service. If the child can read and write, a copy of the written assent form should be given to the child in their preferred language (English or Spanish). Ample time should be given for the child to read it over and discuss it with their parent(s) or LAR. The child should have the opportunity to inquire about details of the project and to decide whether or not to participate. All questions should be answered to the satisfaction of the child. Prior to participation, the written assent form should be signed and personally dated by the child. A copy of the signed assent form will then be provided to the child/participant and another copy will be scanned into the participant’s EMR.

Additionally, the child’s parent/LAR must provide written informed consent prior to the child’s participation. Therefore, the site coordinator must follow the steps above in Section 3.4. to make sure that the child’s parent/LAR goes through the written informed consent process. The parent will sign on the “Authorized representative” line of the ICF. The child does not sign the ICF, only the parent. This applies to all parents/LARs of children <18 years of age being enrolled. This is regardless of if the child is mature enough and able to provide assent.

## 3.6 Medical Record Release of Information

All participants will be asked to sign a Medical Record Release of Information Form (RIF). If a participant refuses to sign the RIF, they can still be enrolled. By signing this form, the participant is giving authorization to the site team to access their health records from another facility. The participant should be asked to sign a blank RIF after the consent form has been signed. If participant is a minor, the parent/LAR should sign on the witness line and the minor does not sign the form. The site coordinator should explain to the participant that the RIF will only be used if the participant goes to another healthcare facility to get care related to their current rash in the next 90 days and they have a positive Mpox test in the next 90 days. It will then be submitted to that healthcare facility to obtain the participant’s medical records. If the participant does not test positive for Mpox at enrollment or thru the 45 days after enrollment, the RIF will not be used and will be destroyed by the site team.

## **3.7 Enrollment and Assigning Project ID**

Once the participant has agreed to participate, and the consent and if applicable the assent, and the release of information forms have all be signed, then a Project ID number can be assigned. Once a Project ID is assigned, the participant is considered enrolled in the project. The Project ID is a unique alphanumeric number comprised of 4 letters and 3 numbers. The first 4 letters will be site specific as follows:

|  |  |
| --- | --- |
| BSMP | Baystate Medical Center |
| CSMP | Cedars-Sinai Medical Center |
| OVMP | Olive View-UCLA Medical Center |
| HCMP | Hennepin County Medical Center |
| JHMP | Johns Hopkins Hospital |
| TUMP | Lewis Katz School of Medicine at Temple University |
| OHMP | Oregon Health & Science University Hospital |
| RRMP | Ronald Reagan UCLA Medical Center |
| UIMP | University of Iowa |
| UMMP | University of Mississippi Medical Center |
| NMMP | University of New Mexico Hospital |
| MKMP | University of Missouri-Kansas City |
| VWMP | Valleywise Medical Center |

The 3 numbers following the first 4 letters will begin with 001 and increase chronologically for each participant. For example, at Olive View-UCLA Medical Center the first participant enrolled will have a Project ID of OVMP001, and the second participant will have a Project ID of OVMP002, etc.

# 4.0 Data Collection

After consent, and if applicable assent, is obtained, site coordinators will complete an Enrollment form, which consists of questions for the clinician and the participant. At the enrollment visit, participants >16 years of age will also be asked to complete a self-administered survey (Enrollment Survey) on paper or mobile device which asks more personal questions about their gender identity, recent social behavior, and sexual practices. At Day 45, participants will be contacted by a site coordinator by phone (and if necessary, by email or text) to ask about any additional Mpox or STI testing, any health care utilization related to their rash, and their symptoms. If the participant tests positive for Mpox at enrollment thru Day 45 and still reports symptoms at Day 45, they will be contacted again at Day 90 to ask about any additional health care utilization related to their Mpox through 90 days.

In the header on each page of the data collection forms, the site coordinator should make sure the “Project ID” is filled out for the specific participant. Site coordinators should review the forms after visit completion to ensure the forms are completely filled out and accurate. Below is a list of all the forms. The sections following contain more detailed information about each form.

List of forms:

1. Participant Contact Information form (section 4.1.1)
2. Enrollment Data form (section 4.1.2)
3. Enrollment survey (completed by participant; section 4.1.3)
4. Baseline EMR review form (section 4.2)
5. Test results and Follow-up Form (section 4.4.1)
6. Telephone Follow-up Form – Day 45 (section 4.4.2)
7. Healthcare Utilization Form (section 4.4.4)
8. Specimen shipment form (section 7.0)

## 4.1 Enrollment Visit – Day 1

The date the participant/LAR signs the written informed consent will be considered Day 1, the Enrollment visit. On Day 1, the site coordinator will need to complete the Participant Contact Form and Enrollment Data Form. If the participant is ≥16 years old, the site coordinator will ask the participant to complete the Enrollment Survey.

### 4.1.1 Participant Contact Form

To ensure high retention rates, it is important that the site coordinator collect complete information on the Participant Contact Form. The details include name, address, phone numbers, email address and information from a secondary contact (i.e., spouse, child, parent etc.), to use only in cases when the participant is not reachable after multiple attempts. Site coordinators should emphasize the importance to participants of answering and returning all calls from the site team, so that complete data can be captured for this project.

If the participant does not have a phone, but lives with someone who does, they can still be enrolled. If the participant is homeless, and there is no way for the project team to contact them (i.e., they do not have a phone and do not live with anyone who does), they can still be enrolled. The site coordinator should find out if the homeless participant is staying at a shelter so that the name and phone number of the shelter can be collected. The site coordinator should provide the site team’s phone number to the homeless participant and explain to them to call the site coordinator during the Day 45 window.

If the participant is incarcerated, the site coordinator will not be able to obtain a phone number for the participant, but can ask if they have a phone number for an alternate contact where they can be reached assuming they will be released in 45 days. If the prisoner does not know when he/she will be released, the site coordinator can still enroll even if there is a high probability that follow-up may not be completed.

### 4.1.2 Enrollment Data Form

Responses from the participant and clinician interview will be recorded on the Mpox Enrollment Data Form by the site coordinator. If the participant is <15 years of age, then the survey is complete after question #36. Ask the participant if they would like to provide any feedback on the questions. In the comments at the end of the form include the feedback that was provided*.* If the participant is >16 years of age, then the Enrollment Survey (Section 4.1.3) will also need to be completed.

Clinician questions

When feasible, ask the clinician the 9 questions on page 1. The following is clarification of some questions:

Question #4. How many lesions are present? \_\_\_\_\_\_ # of lesions

Prompt the clinician to count or provide an estimate of the number of lesions. They must provide a numerical value, i.e, “>20” or “many” is not acceptable. If participant has 3 lesions, but only 1 lesion qualifies as meeting the description of crusted, the total number of lesions which is “3” should be entered, not “1”. However, if any of the lesions are chronic (>4 weeks), then they should not be counted.

Question #7. Estimate the approximate diameter of a typical lesion: \_\_\_\_ cm

The word “typical” is included for cases when the patient has many lesions, so we can give the clinician some direction that they should provide a measurement of the most representative lesion of the stage of active infection. If there is only one lesion, then just enter the diameter of that one lesion. The diameter of a typical lesion does not have to be <2cm. The participant still qualifies to be enrolled if most lesions are <2cm. The clinician can use a ruler to measure the diameter of a typical lesion, but using a ruler is not required. The clinician can give their best guess. They must provide a single numerical value, i.e., a range like “5-7cm” is not acceptable.

Question #9. Please circle location(s) of lesions.

The clinician should circle all the alphanumeric characters on the diagram that represent the closest area to where all the skin lesions are located on the participant. For a rash that is located under the nose, use ”3O” for the location.

If participant is already admitted to the hospital when approached and enrolled, the site team will need to figure out and facilitate a plan for the site PI or a proxy to assess the participant to answer the Clinician questions as soon as possible.

Participant questions

The next set of questions will be asked by the site coordinator to the participant or parent/LAR, if the child is too young to provide answers. Before interviewing the participant, the site coordinator should remind the participant that if they prefer not to answer certain questions, they can choose to skip them.

The following is clarification on some of the questions:

Question #12. Race (check one)  
 American Indian/Alaska Native  
 Asian  
 Native Hawaiian or Pacific Islander  
 Black or African American  
 White  
 Mixed Race (please elaborate in comments)  
 Declined to Answer

Several participants may not consider themselves as belonging to one of the Race options listed. In that case, “Mixed Race” can be chosen, and in Question #12a., the specific race or nationality that the participant identifies with can be entered here, even if the participant is only of one race.

Question #19. Have you traveled outside of this city in the last three months?

City is defined as the larger metropolitan city or county that the participant lives in, e.g., Los Angeles for Olive View-UCLA, RR-UCLA and Cedar Sinai medical center sites.

Question # 25. Are you using PrEP (Pre-Exposure Prophylaxis) to prevent HIV?

If participant does not have HIV, and for adults who do not take PrEP as a preventative measure, mark “No.” Do not leave it blank.

Question#27b. Mpox or “monkeypox” vaccine:  Yes  No

We expect that participants will know if they received the Mpox vaccine. If there is a participant that is unsure, then leave the question blank and note in Comments section that participant wasn’t sure.

Question #27b1. If yes, select below:   
 Imvamune/JYNNEOS, date of administration: \_\_\_/\_\_\_/\_\_\_\_  
 Imvanex/ACAM2000, date of administration: \_\_\_/\_\_\_/\_\_\_\_  
 Unknown Mpox vaccine, date of administration: \_\_\_/\_\_\_/\_\_\_\_

If participant is not sure of date of administration, leave the date of administration blank and note this in the comments section.

Question #28a. If Yes, what was approximate date of diagnosis? \_\_\_/\_\_\_/\_\_\_\_

We expect that the participant will be able to remember the year of diagnosis of their prior Mpox infection. If participant is only aware of month and year of diagnosis, then prompt participant to estimate the date even if it is their best guess.

Question #36. Have you or your child attended a large music festival or crowded social event in the last one month?

We do not want to quantify “large” (i.e., number such as >1000 for a festival or >100 for a graduation). We want the participant to decide if they were at such an event that they would consider “large.” For example, a graduation may involve hugs with 30 contacts, and a music festival may include 10,000 attendees and no contact at all. Therefore quantifying “large” does not capture the activity that occurred at the event.

At the end of the Enrollment Form there is a section “For site coordinator to complete” where the site coordinator will record confirmation that the rash swabs and images were obtained. Collection of at least one rash swab for testing is required for the project. Use the figure to look up the location code of where the swab was taken from and enter the code into the fields “Location A” and “Location B.” If only one rash swab was collected inadvertently, then for “Location B” leave it blank and in the comments section write “second rash swab not obtained.” This information will also be entered into the REDCap. If the site team is unable to get at least one swab, please notify the Clinical Coordinating Center (CCC) as soon as possible for instructions. Collection of the images is not required, e.g., if the participant is not comfortable with you taking the pictures, but recommended.

### 4.1.3 Enrollment Survey

Participants >16 years of age will be asked to answer more personal questions about their gender identity, recent social behavior, and sexual practices on the Enrollment Survey form. To ensure privacy of answers, the survey will be self-administered by the participant. The site coordinator should ask the participant if they prefer to complete the survey on paper, a tablet provided by the site, or using the participant’s personal mobile phone. The site coordinator should remind the participant that they can choose the “decline to answer” option on any questions that they do not feel comfortable answering. They should also be reminded that at the end of the survey they can provide any feedback in the comments section. The site coordinator should be easily accessible (e.g., stand outside the door or nearby) while the participant is completing the survey, so that if any questions arise, they can help answer them.

If the participant prefers to complete the paper form, the site coordinator should fill out the Project ID at the top of page 1, and then hand over the survey and a manilla envelope to the participant. After the participant has completed the form, they should be instructed to insert the completed survey into the manilla envelope and then hand over to the site coordinator. For those who complete the paper form, the site coordinator should inform them that if they answer “No” to question #5, they can stop; they do not need to proceed any further with the survey. After stepping out of the room with the participant’s survey, the site coordinator should review the completed survey to make sure all questions are answered including checking the response to question #5 to determine if no further questions should have been answered. Review answers to make sure participant did not select “Decline to answer” and another option for a question. If any answers or missing data need to be clarified, the site coordinator should follow-up with participant before they are discharged. However, if the participant has already been discharged then the site coordinator should call the participant in the next few days to get clarification.

If the participant prefers to use the tablet or their own phone, the site coordinator will:

1. Log into Redcap on the tablet.
2. Create a record in REDCap for the participant by clicking **“Add/Edit Record”** and entering their project ID into the “**Enter a new or existing Record ID” field.** This step will create the record and take you to the Record Home Page
3. Click on the **“Enrollment Survey Form**” button for that record and which will take them to the Enrollment Survey
4. If the participant wants to complete the survey form on the tablet, the site coordinator will go to “**Survey Options**” located on the top right corner of the form and click “**Log Out and open survey**.” This will open the survey in a completely separate REDCap page. This way, the participant will not be able to see any other record.
5. If the participant prefers to complete the survey form on their phone, the site coordinator will go to “**Survey options**” and click “**Survey Access Code plus QR code**” which will take you to a page with a QR code that the participant can scan and access their survey.

If the participant is Spanish speaking, there is an option to choose “English” or “Spanish” at the start of the survey. The site coordinator should facilitate and ensure the participant chooses their appropriate language. After the survey is completed in REDCap, the site coordinator should step out of the room, log into REDCap and check that the participant did not simultaneously select “Decline to answer” and another option for any of the questions.

If participant is <16 years old, then there is no need to complete the Enrollment Survey, but in order to complete the record in REDCap, type "Pediatric participant" in the comments section of the Enrollment survey and mark as complete.

**Question-specific clarifications**

Question #3. In the last three months, have you?  
 Binged alcohol (5 drinks or more for men, 4 drinks or more for women   
 on one occasion)  
 Used tobacco products (cigarettes, vape, chew, etc.)  
 Used cannabis products  
 Injected any drugs  
 Used stimulants/uppers: Ecstasy, Molly, Ketamine, GHB,   
 Methamphetamine, Cocaine, etc.  
 Used downers: Fentanyl, Heroine, Prescription opioid pills (Percocet,   
 Vicodin, OxyContin, Methadone, Morphine, etc.)  
 Used “poppers”  
 None of the above  
 Decline to answer

If participant is unsure what “poppers” are, the site coordinator should explain that they are a liquid drug that give people an instant high and relaxes their muscles when inhaled/sniffed. Other names for it are amyl nitrate, butyl nitrate, VCR cleaner, and liquid gold. If participant is taking a prescribed drug (i.e., Adderall), then do not check the option for “Used stimulants/uppers.” The question is referring to illicit use of stimulants.

## 4.2 Baseline EMR Review Form - Day 5-7

Approximately 5-7 days after the Enrollment visit, the site coordinator should fill out the Baseline Electronic Medical Record (EMR) Review Form.

### 4.2.1 Baseline Electronic Medical Record Review Form

The site coordinator should access the participant’s EMR from the Day 1 visit and abstract the pertinent information to complete the Baseline Electronic Medical Record Review form. If the participant was admitted to the hospital on Day 1, then question #4 on this form, asking about medication(s) at discharge, should be answered once the participant has been discharged.

## 4.3 Mpox Test results

Rash swabs will be shipped approximately every two weeks to the central laboratory, the UCLA Microbiology Laboratory located in Los Angeles, CA (see Section 7.0). The CCC will receive test results from the central laboratory (UCLA Microbiology Lab) after they have completed testing weekly. The CCC will send the results to each site after their review. When they receive these results from the CCC, the site coordinator will enter the participant results on the Test Results and Follow-up Form in the “Enrollment Test Results” section (see Section 4.4.1).

## 4.4 EMR Review and Telephone Follow-up – Day 45

Approximately 45 days (+/- 10 days) from the Enrollment visit the site coordinator should fill out the Test Results and Follow-up Form and the Telephone Follow-up Form. All participants will be called on Day 45 (+/- 10 days) regardless of if their Mpox test results were positive or negative. The site team should make at least 6 attempts to contact the participant starting at the beginning of the window. To improve the chance of reaching the participant, the site team will attempt their calls at different times of day (morning, midday and evening), and on weekends if possible. If the site team is unable to reach the participant after 3 attempts, then they should send the Follow-up survey by email or text to the participant (see section 4.4.3). If the site team is still unable to contact them by email, text or phone, the site team should contact their alternate contacts. All call, email and textattempts should be recorded on a log similar to the one below:

Table

Description automatically generated

If no attempts are made to contact the participant, the site PI should be notified immediately, and the site team should be retrained on procedures.

### 4.4.1 Test Results and Follow-up Form

The Test Results and Follow-up Form will be used throughout follow-up to record the results of the Mpox test received from the central laboratory, results of any additional Mpox testing through 45 days and to help track the follow-up requirements (e.g., if they require a 90 day follow-up) and prompt the site teams when to complete a Healthcare Utilization Form when relevant. Thus, the form should be completed at the following timepoints:

1. Upon receipt of participant’s Enrollment Mpox test results from CCC (see Section 4.3)
2. At 45 days, after telephone follow-up and EMR review is completed
3. If participant tested positive for Mpox and reported symptoms at 45 days, it should be updated again at 90 days.

If only one rash swab was shipped to the central lab then on the form under “Location B,” you would mark “specimen not sent to lab,” and in the comments section write, “second rash swab not obtained.”

The mpox test results will be emailed to the site as an excel file. Here is an example of what it will look like:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Receive Date** | **Project ID** | **Location** | **Location# and Description** | **Collection Date** | **Test Date** | **OPXV** | **MPXV** | **Rnase P** |
| 5/2/23 | OVMP001 | A | 17L (left thigh) | 4/6/23 | 6/1/23 | Negative | Negative | 20.7267 |
| 5/2/23 | OVMP001 | B | 17L (left inner thigh) | 4/6/23 | 6/1/23 | 37.368 | Negative | 28.2892 |

|  |
| --- |
| **Legend** |
| Positive |
| Indeterminate |
| Negative |

The “OPXV” is the general orthopox target (including mpox and many other orthopox viruses). The “MPXV” is the specific target for mpox. The “Rnase P” is the internal positive control target. It should always be positive (shaded green) for all the specimens to ensure that the PCR is working.

If you have an “Undetermined” result listed in OPXV or MPXV columns, it means negative (shaded gray); there was no PCR signal. If you have a numerical value listed in the OPXV or MPXV columns that is the Cycle threshold (Ct) value. If the Ct value in the OPXV or MPXV columns are shaded pink, it means indeterminate result. If the Ct value in the OPXV or MPXV columns are shaded green, it means positive result. An mpox positive result would need to be shaded green for all three targets (OPXV, MPXV, and Rnase P).

**Prior to calling the participant,** the site coordinator should review the participant’s EMR AND enrollment form. The purpose of the EMR review is to determine if they had another health care visit since the Day 1 index visit. For participants who tested positive for Mpox at Enrollment, the site coordinator should review the provider notes to see if the visit was related to Mpox. For participants who did not test positive for Mpox at baseline, the site coordinator should review their EMR to determine if they had a positive Mpox test since their Enrollment visit. The purpose of reviewing the EMR prior to the telephone call is to aid the participant in recalling relevant healthcare visits and testing, e.g., they may have returned to the hospital’s urgent care and not remembered what the visit was for and whether they got a test. In these cases, the site coordinator can help remind them of relevant visits when conducting the telephone interview. Also, the study coordinator should review the participant’s enrollment form prior to conducting the telephone interview so they can prompt them for questions 2a (remind them of the number of days they reported having the rash at that time) and question 3 (remind them about their other symptoms reported at enrollment).After reviewing the EMR and the participants enrollment form, the site coordinator should call the participant to conduct the Telephone Follow-up (see Section 4.4.2)

After completing the Telephone follow-up, the site coordinator should complete the section “45-Day Follow-up – all participants” section from the “Test Results and Follow-up form.”The following is clarification to some of the questions on the form:

Question #2. Did the participant receive an additional MPox test after enrollment and through the 45-day follow-up?   
 No/No records available  
 Yes  
 2a. If yes, record result: Indeterminate Negative Positive  
 If yes, record location: \_\_\_\_\_\_

If during the Telephone follow-up the participant reports they did have an additional Mpox test done elsewhere, and they are still waiting for the results, then the site coordinator should follow-up with the participant at a later time to obtain the results for question #2a. If site coordinator is unable to reach the participant after multiple attempts and there is no record of additional Mpox test in the EMR, then select “No/No records available.”

Question #3. For participants with a positive MPox test through 45 days, did the participant receive additional tests and/or health care visits after enrollment?  
 Not applicable participant does not have a positive MPox test through Day 45  
 No/No records available  
 Yes  
 3a. If yes, how many total visits: \_\_\_\_\_   
 *complete health care utilization form*

If the participant never had a positive Mpox test through the Day 45 Telephone follow-up, check “Not applicable participant does not have a positive Mpox test through Day 45,” even if they did visit a health care facility for their initial rash. If the participant had a positive Mpox test at Enrollment, and they did visit another health care facility, but the visit was not related to Mpox, then check “No/No records available.” If site coordinator is unable to reach the participant for their telephone follow-up after multiple attempts, then question #3 should be answered based on their review of the EMR.

Question #4. For participants with a positive MPox test through 45 days, did the participant still report having symptoms?  
  Not applicable participant does not have a positive mpox test through day 45  
  Telephone follow-up not done  
  No  
  Yes (if yes, complete 90 day follow-up telephone call and EMR review)

If the participant did have a positive Mpox test through Day 45 then the response should match what the participant reported for question #3 on the Telephone Follow Up Form. If participant does still report having symptoms, then select “Yes” and follow-up with participant at Day 90 Telephone Follow-up (see Section 5.4). If you checked “not applicable, “telephone follow-up not done,” or “No” to #4, you are done with follow-up for this participant. You can check “not applicable” for #5.

If site team is unable to reach the participant for their Telephone follow-up after multiple attempts, check “Telephone follow-up not done.”

### 4.4.2 Telephone Follow Up Form

This form is used to conduct the Telephone follow-up interview at Day 45 (+/- 10 days) and is available in English and Spanish. Question #1 must be completed for all participants, even if you are unable to complete the follow-up call.

Questions 8-9 should only be asked to participants who are >16 years of age. Here are some clarifications on some of the questions on this form:

Question #1. Telephone follow-up completed:  
 Yes (proceed to #2)  
 Unable to complete follow-up  
 1a. If unable to complete follow-up specify reason:  
 Participant illness or injury  
 Participant refusal  
 Scheduling difficulties  
 Unable to contact  
 Other (specify):\_\_\_\_\_\_\_\_\_\_

If the site team is unable to complete the follow-up, answer Question #1 and you are done. No further questions need to be completed. If the site coordinator was unable to obtain contact information at enrollment (i.e., homeless, prisoner etc.) then select “Other” and specify that no contact information was collected at enrollment. If the site coordinator fails to make any attempts to contact participant, then select “Other” and specify that no attempts were made.

Question #3. Did all of your (or your child’s) initial symptoms, besides the rash, go away completely? (site coordinator should double-check what symptoms were reported at enrollment)  
 No  
 Yes  
 Did not report other symptoms at enrollment

Decline to answer

Site coordinator should refer to question #32 on the Enrollment Data Form to see which symptoms the participant selected to help trigger their memory. If only some symptoms have resolved but not others, select “No.” Then for question #3a select the symptoms from the list that are still present. Note the symptoms that are selected may match what was selected at enrollment or could be new symptoms that started after enrollment. Mark all that apply at the time of the phone call. If the participant’s initial symptoms have completely resolved, then select “Yes.”

### 4.4.3 Follow-up Survey

If the site team is unable to reach the participant by phone after 3 attempts, the site team should email and/or text the participant the Follow-up survey on or before Day 45 (or as close to that date as possible). The Follow-up survey will be active for 10 days after sending the email invitation or generating the survey link to text. So, the site team should check the survey link for completion and send reminders as necessary during that time. If the participant is Spanish speaking, there is an option to choose “English” or “Spanish” at the start of the survey.

To send the Follow-up Survey by email, follow these steps:

1. Click on the Follow-up Survey link in the participant’s REDcap record
2. Click on “Survey Options” located at the top right of the screen.
3. Choose “Compose Survey Invitation”
4. Under the “Compose message” section, for From email, select your email address and for To email, enter in the participant’s email address.
5. For the Subject heading you can enter “Olive View-UCLA RASH study – please complete your follow-up survey today!” It might be good to include the name of your medical center in the heading so they don’t think it is spam and they are more likely to read it.
6. In the body of the email, please use your own site-specific template. If possible, address the email to the participant using their name, e.g., “Dear Anusha” or Dear “Ms. Krishnadasan,” remind the participant that they enrolled in the study about 6 weeks ago and we just need them to complete a short 5-min survey online, and if they complete it they will receive $25. Finally, include your contact (or your research team’s contact) and phone number in case they have questions.

**DO NOT delete the “survey-link” or the “survey-url” as these are automatically generated by REDCap and are the link to the participant’s record and survey.**

See below screenshot of an example email that was sent to [idnet@ucla.edu](mailto:idnet@ucla.edu). Note how REDCap inserts the survey link and survey url into the received email automatically. You may adjust the text around these links as necessary for your site and participant needs.

A screenshot of a computer

Description automatically generated

1. Click “Send Invitation” and check back on whether the participant completed the survey up through the end of their follow-up window and send reminders if necessary. After sending the email invitation, the survey is active for 10 days only. After 10 days, the participant will be unable to complete the survey.

To send the Follow-up Survey by text, follow these steps:

1. Click on the Follow-up Survey link in the participant’s REDcap record
2. Click on “Survey Options” located at the top right of the screen
3. Click on “Survey Access Code + QR Code” option
4. Send the web address <https://www.ctrc.medsch.ucla.edu/redcap/surveys/> and participant specific code (see screenshot below with information in red box) by text to the participant’s cell phone number.

A screenshot of a computer

Description automatically generated

Note you must enter this into the text manually, so make sure to double check the information before sending it to the participant. Also, include information to the text so the participant does not think it is spam, e.g., “Hi, this is Anusha from Olive View-UCLA Medical Center. I would like to get some follow-up information from you about your rash. Please click on this link and copy and paste the code to take a short 5-minute survey. We will add $25 to your gift card when you complete the survey.

1. Check back periodically to see if the participant completed the survey through the 10 days it is active. Resend reminders if appropriate.

### 4.4.4 Health Care Utilization Form

The Health Care Utilization Form is completed for participants who tested positive for Mpox at enrollment or through the Day 45 follow-up and reported that they sought health care for their Mpox-related illness. There are prompts on the Telephone follow-up form and the Test Result and Follow-up form to complete the Health Care Utilization Form, when applicable. Please complete one form for each health care visit encounter. If the patient was admitted to the hospital, their hospital stay will be considered as one health care visit encounter.

If the participant sought health care at a different facility from the site hospital, then complete the remaining parts of the participant’s pre-signed Release of Information Form that they signed at enrollment (see Section 3.6) with the name of the facility and date(s) of visit and any other required information. Submit this form to the facility to obtain a copy of the participant’s medical records so that the Health Care Utilization Form can be completed.

If site coordinator is unable to obtain records from outside facility, then obtain as much information as possible from participant phone call to complete this form. The following is clarification to two of the questions on the form:

Question #3. Specify dates of care:  
 Start date of care: \_ \_/\_ \_ \_/\_ \_ \_ \_  
 End date of care: \_ \_/\_ \_ \_/\_ \_ \_ \_

If site coordinator is unable to obtain the records from outside facility, and participant is unsure on the exact date(s) of care, then tell participant to give their best guess and record those dates.

Question #6. Did the participant receive Mpox test at this visit? Yes No  
 6a. If yes, note result: Positive Negative/Indeterminate

If site coordinator is unable to obtain the records from outside facility and participate does not know the results of their Mpox test at the time of the call, follow-up with participant at a later time after they are made aware of their results.

## 4.5 Day 90 Follow-up - Day 90

Only participants who tested positive for Mpox at enrollment through Day 45 **and** reported still having symptoms at the Day 45 telephone follow up call will be contacted at Day 90 (+/- 10 days) from the Enrollment visit. There is no separate telephone follow up form for this visit. The site coordinator should just ask the participant question #5 on the Test Results and Follow-up Form (section 4.4.1) to determine if they sought healthcare related to their Mpox illness. Prior to calling the participant, the site coordinator should first review the EMR to see if the participant returned to the site’s hospital for care related to their Mpox illness.

Question #5. Did the participant receive additional test and/or health care visits after day 45? Not applicable  
 No/No records available or unable to contact at 90 days  
 Yes  
 5a. If yes, how many total visits: \_\_\_\_\_\_

If the participant’s additional health care visits were not related to Mpox then mark “No/No records available or unable to contact at 90 days.”

# 5.0 Photograph and Swab of Rash

The site coordinator should consult with the treating clinician or site PI to determine which is the primary site, and for participant’s with ≥2 rash lesions, a secondary rash lesion site. Prioritizing lesions in separate body locations and with material to swab (see section 5.2). If there is only one rash lesion, then the site coordinator should take two rash swabs of that lesion (Location A and B) and two pictures of that lesion (one distant and one up close). If there is more than one rash lesion, the site coordinator will take one swab of the primary lesion (Location A) and one swab of the secondary lesion (Location B) and four pictures, including two pictures distant and up close of the primary lesion (Location A) and two pictures distant and up close of the secondary lesion (Location B). The site coordinator should indicate the location and whether the swabs and pictures were obtained on the participant’s Enrollment Form (section 4.1.2).

## 5.1 Photograph of rash

If a participant refuses to have a photograph of the lesion(s) taken, they can still be enrolled. For those that agree to the photograph, the site coordinator should try and adhere to the following preparatory steps:

* Remove any personal identifiers (glasses, jewelry, etc.)
* Pull aside clothing that distracts from the lesion location
* Avoid photo of tattoos, unless they are part of the lesion location
* Attempt to take the photo against a solid/neutral background
* Use natural light if available

Next the site coordinator should fill out the date and location on the photo label and place the sticker on the participant’s skin near the lesions that will be photographed. The first photo should be a distant shot to show the extent of the rash. The second photo should be close up to show the detail of the lesion but try and include some normal skin nearby for comparison. Here is an example of the photo label:

OVMP 001 OVMP 001  
 Date: 3/1/23 Date: 3/1/23  
 Location A: 30 (mouth) Location B: 17R (R thigh)

Keep the body location being photographed either horizontal or vertical in the frame of the ipad/camera to avoid odd angles. Tap on the ipad screen on the lesion you are trying to photograph so that the lighting is adjusted, and the image gets focused.

If there is only one lesion location, then two is the maximum number of photos needed. One distant of Location A and a second one close up of Location A. If there are >2 lesion locations, then 4 is the maximum number of photos needed. One distant of Location A (the primary site) and a second one close up of Location A. Then a third one distant of Location B (the secondary site) and a fourth one close up of Location B.

Picture quality will be poor for participants with oral lesions. If possible, shine an external overhead light or flashlight in the oral area to help with picture quality.

## 5.2 Rash lesion swab collection

The treating clinician or site coordinator (site-dependent) should obtain two rash swabs from each participant. If there is only one rash lesion, then the site coordinator should take two rash swabs of that same lesion, and Location A and Location B on the Enrollment form will be the same. If there is more than one rash lesion, the site coordinator will take one swab of the primary lesion (Location A) and one swab of the secondary lesion (Location B).

Please refer to the Table below for examples of rash lesions and guidance regarding how to decide which lesions to swab.

|  |  |  |  |
| --- | --- | --- | --- |
| **Qualifies patient for study** | **Description of lesion type** | **Photo example** | **Priority** |
| Yes | 1A: Pustular or vesicular with drainage  1B: Pustular or vesicular without drainage  Synonyms – blister, pimple, herpetic, herpes-like | A close up of a person's ear  Description automatically generated with low confidence | Highest priority  Lowest Priority |
| Yes | 1C: Ulcerated, erosive, or crusted  Synonyms - ulcer | A close up of a person's skin  Description automatically generated with low confidence |
| No | 2A: Maculopapular (palpable)  Synonyms – red bump | A close up of a skin  Description automatically generated with low confidence |
| No | 2B: Macular (non-palpable)  Synonyms – red spot | Close-up of a skin with red bumps  Description automatically generated with low confidence |

Notes: Patients are only eligible for the study if they have one or more lesions that appears pustular, vesicular, ulcerative/erosive, or crusted. When collecting the first swab (primary lesion; Location A), choose the lesion that is the most suspicious for Mpox (i.e., nearest to the top of the table). All patients should have two swabs collected. According to CDC recommendations, lesions at different locations and at different stages should be swabbed if that is possible. Refer to the table below for guidance on how to identify the best lesions to swab.

|  |  |
| --- | --- |
| **Description of lesion number, location, and stage** | **Guidance** |
| One lesion | Collect two swabs from same lesion |
| Two lesions | Collect one swab from each lesion (even if second lesion is less suspicious) |
| Two or more lesions, same body location, same stage | Collect swabs from any two different lesions |
| Two or more lesions, same body location, different stages | Collect one swab from most suspicious lesion; Collect one swab from a lesion of a different stage |
| Two or more lesions, different body location, same stage | Collect one swab from a lesion in one location; collect second swab from a lesion in the second location |
| Two or more lesions, different body location, different stages | Collect one swab of the most suspicious lesion in one location; Collect second swab of a lesion from a different location that is at a different stage |

In preparing for the swab collection, the provider or site coordinator should be aware of the following:

* All recommended PPE should be worn (Note: PPE is not needed for every patient being swabbed, unless there is high suspicion of mpox)
* Use the project provided Eswabs
* Vigorous swabbing of the lesion gives higher chance of accurate results
* Specimens that do not contain enough human DNA may lead to inconclusive PCR test results
* Unroofing or aspiration of lesions or using sharp instruments is not necessary nor recommended due to risk of sharps injury
* Do not clean lesion with ethanol or any other disinfectant prior to swabbing

Here are the steps of swab collection of a rash lesion:

1. Hold the swab firmly and avoid touching the swab shaft at least 1” before the tip and the length of the swab shaft that will be submerged in the transport medium.
2. Swipe the swab back and forth on the lesion 2-3 times then rotate and repeat on the other side of the swab at least 2-3 times.



1. Make sure to apply firm pressure which may result in discomfort but is necessary to obtain adequate DNA. Pressure must be firm enough so that the plastic shaft bends slightly.
2. If the lesion ruptures while swabbing, ensure swab collects lesion fluid.
3. If skin material is visible on the swab, then this is adequate collection. However, skin material may not always be visible.
4. Place the swab back within the transport medium vial, fill out the participant specific label and place it on the vial.

The labels are similar to the photo labels (see Section 5.1) except these are specific for storing in ultra-low temperatures. The labels should be filled out the same way they were filled out for the photo labels. After collection, the swabs should be stored in -70°C or lower, however if not available then they can be stored in -20°C.

### 5.2.1 Rash swab not obtained

The site team should obtain two rash swabs from each participant at enrollment. If the team is unable to obtain any rash swab, the participant is not eligible for the project. If the team is only able to collect one rash swab (or they only collect one swab in error), please note this on the Enrollment form by checking “Yes” to rash swab obtained, but for Location B leave it blank and in the comments section write "Second rash swab not obtained." Similarly on the Test results and Follow-up Form #1, for Location B you would check "Specimen not sent to lab" and in the comments section write, "Second rash swab not obtained."

# 6.0 Participant compensation

Participants will be compensated for their time at enrollment, at day 45, and if applicable, at day 90. They will receive $25 for completion of each visit/call. The compensation can be provided by cash, gift card, or check depending on site preference.

Site teams should set up their own site-specific procedures for tracking and disbursement of payments to participants. Ideally, payments should be given to the participant as soon as possible after they complete their enrollment visit and telephone follow-up.

Prisoners should be offered the same compensation as other patients who are enrolled in the project. Both enrolling and compensating prisoners will depend on the site’s local and state laws.

# 7.0 Shipping frozen swab specimens

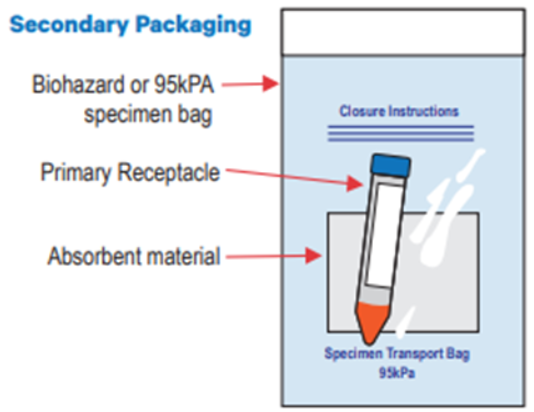
Every two weeks (the 15th and 30th/31st of every month) the swabs that are stored in the site’s freezer will be shipped to the central laboratory. If the 15th, 30th/31st falls on a Friday, Saturday or Sunday, then the swabs should be shipped the following Monday. The CCC will send each site shipping supplies and pre-printed Fedex labels prior to site launch.

All specimens will be shipped to:

Dr. Omai Garner  
11633 San Vicente Blvd, Room 401, Rear Building  
Los Angeles, CA 90049

All project staff shipping swabs should have IATA certification. Here are the steps to package the swabs to be shipped:

1. Place labeled specimen swabs (primary receptacle) into a 95kPa specimen bag (secondary packaging) with absorbent material.



1. Place completed Specimen Shipment Form in the outside pocket of the 95kPa specimen bag.
2. Place some dry ice in the Styrofoam box that is within the durable outer packaging cardboard box.
3. Place the 95kPa specimen bag on top of the dry ice.
4. Add the remaining dry ice on top to fill and completely cover the specimens. At least 7 pounds of dry ice should be filled within the Styrofoam box.
5. Place Styrofoam lid on top, but do not seal with tape.
6. Use packaging tape to securely seal the outer packaging cardboard box.
7. Place “UN3373” and “Biological Category B” and “Dry Ice UN 1845” stickers on the outer packaging box. They must all be placed on the same side of the box.
8. Fill in all information on the “Dry Ice UN 1845” sticker.
9. Place FedEx shipping label on box.
10. Send an email with a copy of the Specimen Shipment Form and the FedEx tracking number to Dr. Omai Garner [ogarner@mednet.ucla.edu](mailto:ogarner@mednet.ucla.edu), [kpathmarajah@dhs.lacounty.gov](mailto:kpathmarajah@dhs.lacounty.gov), and [idnet@ucla.edu](mailto:idnet@ucla.edu) when you send the shipment.

# 8.0 Audit of non-enrolled patients

An audit of non-enrolled but eligible patients will be conducted at each site. The objectives of the audit are to determine our capture rate of eligible patients and to assess whether there is any selection bias in the patient population that agrees to participate in the project, e.g., are patients who are enrolled more or less likely to have Mpox infection compared to those who were not. The capture rate can also help the site team identify issues with their patient screening procedures. Thus, sites should conduct the audit **at least** once a month during their enrollment phase so they can identify any issues early on during surveillance and adjust their screening procedures to improve their capture rates.

No personal identifying information should be collected for the audit. The site team will generate a monthly report of patients presenting to the emergency department who fit the following criteria:

1) Emergency department patient > 3 months of age, **AND**

2) a. Has any of the following ICD 10 ED discharge dx codes

* B00 Herpesvirus
* B01 Varicella
* B02 Zoster
* B03 Smallpox
* B04 Mpox
* B08 Other viral infections characterized by skin and mucous membrane lesions NOS
* R21: Rash

**OR**

b. The treating ED clinician ordered an Mpox test based on a search of Mpox testing from the ED.

For each of the patients that are on this report, confirm by reviewing their EMR that they meet inclusion criteria (ED patients age ≥3 months who present for evaluation of one or more skin lesions that appears pustular, vesicular, crusted or ulcerated) for the project. If there is no mention of rash in the EMR and the patient did not get an Mpox test in the ED, then do not include in the audit.Other rashes to include would be those described as: erosive, blister, pimple, herpetic, herpes-like, ulcer, shingles, zoster, and viral. Note if there is no specification of the type of rash or it is unclear, then do not include it in the audit unless an Mpox test was ordered for that patient**. *It may not be clear which patients meet criteria for inclusion in the audit, so please check with your site PI or main site investigators if you aren’t sure!***

Remove the patients who do not meet inclusion criteria AND the patients that you enrolled from the list. Do not remove patients who had an Mpox test ordered regardless of their rash description or their ICD-10 code. For each patient who met inclusion criteria who you did not enroll and for all patients who had an Mpox test ordered, please fill out the Audit form. Follow the instructions on the form to assign each patient an Audit ID. Finally, enter the information on the Redcap study audit data entry module.

# 9.0 Data Management

All data collected at sites will be entered onto a REDCap created and managed by the UCLA Data Coordinating Center (DCC). No personal identifying information will be entered into the REDCap.

There will be two different databases, one for the main data collection and one for the audit (see Section 8.0).

## 9.1 REDCap Access

Site staff can get access to REDcap by emailing a completed and signed REDcap access form (available on the project website) and their CITI (or equivalent) human subjects training certificate to [lduvergne@mednet.ucla.edu](mailto:lduvergne@mednet.ucla.edu). They will receive a login and instructions on how to access the REDCap from the UCLA REDCap administrator. It is important to login within 9 days of getting this email or the account will be suspended. For *EMERGE*ncy ID NET site staff who already have access to other project REDCaps, email [idnet@ucla.edu](mailto:idnet@ucla.edu) with a list of all staff who will need access to this project.

## 9.2 Data entry and quality assurance

Sites should collect all data on paper forms, except for the Enrollment Survey which can be self-administered by the participant on an iPad or on their phone. The paper forms should be reviewed within 24-48 hours of completion to ensure that they are completed appropriately and contain no missing information. If there is missing information and data can be abstracted from the patient’s EMR, the site coordinator should review the EMR and fill in the information. Data collected on the paper forms should be entered into the REDCap database within 3-4 days of collection.

To identify and minimize data entry errors and streamline the data cleaning process, the DCC requires that data is entered twice for the Enrollment, Baseline EMR review, Telephone follow-up, Test Results and Follow-up and Healthcare utilization forms. If there are discrepancies between the two sets of data entered, the DCC will reach out to the site to resolve them. The data can be entered twice by the same site coordinator or can be entered by two different site coordinators. After initial entry into REDCap, the forms should be marked as “Incomplete.” At least once a week, a site coordinator should be appointed to review all the forms entered into REDCap that week, double-check the data abstracted on the forms and entered into the REDCap, and then after their review, mark the forms as “Complete.” The CCC will be generating reports for review with sites regularly, so it is important for all sites to keep up with the above data entry and checking process on at least a weekly basis.

The site PI or manager must review the first three participant enrollment forms in the first month of the project, to ensure that they are completed appropriately and completely. Approximately 6 weeks after, they should review the three participant’s follow-up forms. If there are consistent errors, the site PI or manager must notify the CCC and make a plan to continue their review of forms to ensure that their site team is collecting data appropriately.

# Appendix A. List of Supplies

Provided by CCC

* Rash swabs
* Project ID labels (for swabs and images)
* Shipping boxes and materials (95kPa specimen bag, labels)
* FedEx Labels

Site should obtain/set up (CCC will not provide)

* Ipad
* Camera (if not using ipad for images)
* Dry ice (for shipments)