Guidelines for Handling Crisis Situations with Research Participants

It is important to provide recommendations and establish guidelines for working with research participants who may be in a crisis situation. This could include, but is not limited to, being severely depressed or suicidal, shock of receiving a positive pregnancy or drug test, learning about a serious incidental finding, or disclosing physical or sexual abuse to themselves or others while participating in a research study. This document is not meant to be all inclusive or to cover every possible scenario, and it should be used as a reference guide for understanding what steps must be taken to protect research participants and abide by state and federal laws. The guidance is focused on voluntary participation in research studies and not a clinical setting, which may have different regulations and requirements.

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Key Important Phone Numbers:
  • Adult Protective Services Statewide Intake: 866-654-3219 or 505-476-4912
  • CYFD’s Statewide Central Intake child abuse hotline: 1-855-333-SAFE [7233] or #SAFE from a cell phone
  • UNM Police- Non-Emergency & Security Escort: 277-2241
  • Fire/Ambulance/Police Emergency: 911
Potential Harm to Self or Others

BACKGROUND (including statutes and definitions):

- If you suspect an adult is being abused, neglected, or exploited, call Adult Protective Services Statewide Intake, toll free at 866-654-3219 or 505-476-4912.
- In New Mexico, every person who knows or has reasonable suspicion that a child is being abused or neglected must report the matter immediately to CYFD’s Statewide Central Intake child abuse hotline (1-855-333-SAFE [7233] or #SAFE from a cell phone), or to law enforcement or the appropriate tribal identity. See the section below on Abuse or Neglect (page 6) for specific definitions.

N. M. S. A. 1978, § 32A-4-2 (Effective: May 18, 2016).

CONSIDERATIONS:

- It is the PI’s responsibility to establish a protocol-specific plan for dealing with potential information that may be discovered or disclosed during the study.
- PIs are responsible for ensuring the safety of their research participants and staff. If it is anticipated that the study may involve sensitive results or disclosure or harm to self or others (i.e. BDI, BASC-2, SCID), it is recommended that research staff are appropriately trained and a study specific checklist or plan be developed using this guideline, including who is available to speak with the participants.
- PIs need to provide additional precautions when dealing with minor participants, ensuring it is clear to the parents and the minor what information will or will not be shared with the parents/guardians.
- If the participant resides on a reservation then local authorities may have limited jurisdiction. As part of triaging the situation, determine if the individual lives on tribal land so the appropriate agency may be contacted for support. CYFD Tribal Liaison: 505-827-7612 (cell: 505-412-0093), Department of Health (505) 827-2627, Department of Health Tel: (505) 827-2627. Please refer to the following document for Navajo Nation contact information for Law Enforcement, Shelters (safe home for women and children), suicide crisis line, hospitals and health clinics, counseling for mental health and substance abuse, domestic violence, rape crisis center, child protection, victim advocate and family violence prevention, legal services, etc: http://www.sanjuancounty.org/documents/Victim%20Advocate%20-%20Navajo%20Nation%20Resources.PDF
- Resources and contact information provided in this document are for participants in the Albuquerque/New Mexico areas. If your study has participants in other states, a reference document should be provided for those sites.

ASSESSMENT of participants who are severely depressed or suicidal:

- Always follow the protocol-specific plan, if one exists.
- Alternatively, use the following guidelines:
If a participant discloses intent to harm themselves, use Agora recommended prompt questions to determine if threat is imminent (see Suicide Risk Assessment Checklist attachment).
- Do you have a plan to kill yourself (none, vague, detailed)?
- Do you have (access to) the means to kill yourself (not sure, easy access, has now)?
- Are you thinking of suicide today (unidentified, less than 48 hours)?

If risk level is high, contact the study PI immediately, or your clinical contact if your study team has a designated person for such situations.
- The PI or Clinician will make a determination on whether to call police or escort the person to the UNM emergency room or other appropriate facility.

If the threat of harm is not imminent, you may:
- Assist in making a safety plan (including asking if you can contact them the following day to check in),
- Provide information for the Agora Crisis Center or other resource sheet, as appropriate.
- Offer a private space to call the Agora Crisis Center while on site (866-HELP-1-NM or 505-277-3013).
- Call UNM Psychiatric Emergency Services (PES) at 505-272-2920 for assistance.
- If there is an ongoing concern and the individual decides to leave without taking action, the non-emergency police line may be called for a “well check visit” if you know the participant’s residence address.

FOLLOW-UP/REPORTING:

- If a participant discloses child abuse or neglect or intent to harm others, contact your PI and the clinical contact immediately.
  - The PI and Clinician will make a determination on whether information provided requires mandatory reporting and if appropriate will make a report to police, CYFD or tribal authorities.
  - Follow guidance under Abuse or Neglect (page 6) of this document for specific reporting and documentation details.

- Follow up:
  - If appropriate, let the participant know you would like to contact them the following day to check in;
    - ALWAYS document the incident, including who was involved/consulted and outcome in a research progress note, which should be kept in the participant study file;
    - Documentation must include details for good faith reporting and should be stated as “Basis for good faith reporting includes…..”
    - PI must determine whether individual should be (or stay) enrolled in study;
    - PI must determine whether to report to IRB (unexpected, involve risk of harm to self or others, possibly related to the research).
• If study takes place outside of New Mexico, state laws should be checked for appropriate reporting requirements.

RECOMMENDED CONSENT FORM CONFIDENTIALITY LANGUAGE FOR MANDATORY REPORTING DISCLOSURES:

• You should understand that if the investigators learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, we will report that information to the proper authorities.

“When a researcher obtains a Certificate of Confidentiality, the subjects must be told about protections afforded by the Certificate and any exceptions to those protections - i.e., the circumstances in which the investigators plan to disclose, voluntarily, identifying information about research participants (e.g., child abuse, harm to self or others, etc.). This information should be included in the informed consent form unless a research subject is no longer actively participating in the project so amendment of the informed consent would be impractical. The researchers should eliminate provisions in consent form templates that may be inconsistent with the Certificate protections (such as references to disclosures required by law, since the Certificate enables researchers to resist disclosures that would otherwise be compelled by law).” NIH CoC.

REFERENCES/APPENDIX:

NIH Certificates of Confidentiality: https://humansubjects.nih.gov/coc/index

New Mexico Indian Affairs Department – State of New Mexico Tribal Liaisons http://www.iad.state.nm.us/tribal_liaisons.html

New Mexico Indian Affairs Department – New Mexico Pueblos Contact List: http://www.iad.state.nm.us/pueblos.html

Navajo Nation contact information for Law Enforcement, Shelters (safe home for women and children), suicide crisis line, hospitals and health clinics, counseling for mental health and substance abuse, domestic violence, rape crisis center, child protection, victim advocate and family violence prevention, legal services, etc: http://www.sanjuancounty.org/documents/Victim%20Advocate%20-%20Navajo%20Nation%20Resources.PDF
### Suicide Risk Assessment Checklist

**Participant ID:** __________________________

**Visit:** ____  baseline = 00

**Date:** _ _/_ _/_ _  

**Site:** ____________

<table>
<thead>
<tr>
<th>Prompt Questions</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you thinking of suicide today?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Have you thought about suicide in the last two months?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Have you ever attempted to kill yourself?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL OF RISK:</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Method</strong></td>
<td>Not sure</td>
<td>Pills</td>
<td>Firearm</td>
</tr>
<tr>
<td></td>
<td>Unidentified</td>
<td>Auto</td>
<td>Currently intoxicated</td>
</tr>
<tr>
<td></td>
<td>Other: _________</td>
<td>Hanging</td>
<td>Other: _________</td>
</tr>
<tr>
<td><strong>Plan</strong></td>
<td>None</td>
<td>Vague</td>
<td>Detailed</td>
</tr>
<tr>
<td><strong>Means</strong></td>
<td>Not sure</td>
<td>Easy access</td>
<td>Has now</td>
</tr>
<tr>
<td><strong>Intent</strong></td>
<td>Vague</td>
<td>Preparing</td>
<td>Attempt in progress</td>
</tr>
<tr>
<td><strong>Timeline</strong></td>
<td>More than 48 hours</td>
<td>Unidentified</td>
<td>Less than 48 hours</td>
</tr>
<tr>
<td><strong>Prior Attempts</strong></td>
<td>None</td>
<td>Once</td>
<td>Multiple</td>
</tr>
<tr>
<td><strong>Prior Attempt Timeline</strong></td>
<td>&gt;1 year ago</td>
<td>6-12 months</td>
<td>&lt;6 months</td>
</tr>
</tbody>
</table>

Can person promise to stay safe?  
Yes  
No  

If Yes, for how long?  

### Safety Plan

<table>
<thead>
<tr>
<th>Safety Contacts:</th>
<th>Counselor/Therapist?</th>
<th>If no, referrals should be offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe/No use of drugs/alcohol?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Will person disable the means?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Other resources (short/long term)?  

What will ease their pain?  

Is the event reportable to the IRB?  

Follow up contact with participant?  
Yes  
No  

Date/time/method/initials:

### Notes/comments:
Abuse or Neglect (including minors)

BACKGROUND (including statutes and definitions):

N. M. S. A. 1978, § 32A-4-2 - Effective: May 18, 2016

§ 32A-4-2. DEFINITIONS:

As used in the Abuse and Neglect Act (definitions below are not comprehensive and sections have been removed for brevity – please see full statute list if the definitions below do not address situation):

- **“Abandonment”** includes instances when the parent, without justifiable cause:
  - left the child without provision for the child’s identification for a period of fourteen days; or
  - left the child with others, including the other parent or an agency, without provision for support and without communication for a period of:
    - three months if the child was under six years of age at the commencement of the three-month period; or
    - six months if the child was over six years of age at the commencement of the six-month period;

- **“Abused child”** means a child:
  - Who has suffered or who is at risk of suffering serious harm because of the action or inaction of the child’s parent, guardian or custodian;
  - Who has suffered physical abuse, emotional abuse or psychological abuse inflicted or caused by the child’s parent, guardian or custodian;
  - Who has suffered sexual abuse or sexual exploitation inflicted by the child’s parent, guardian or custodian;
  - Whose parent, guardian or custodian has knowingly, intentionally or negligently placed the child in a situation that may endanger the child’s life or health; or
  - Whose parent, guardian or custodian has knowingly or intentionally tortured, cruelly confined or cruelly punished the child;

- **“Neglected child”** means a child:
  - Who has been abandoned by the child’s parent, guardian or custodian;
  - Who is without proper parental care and control or subsistence, education, medical or other care or control necessary for the child’s well-being because of the faults or habits of the child’s parent, guardian or custodian or the failure or refusal of the parent, guardian or custodian, when able to do so, to provide them;
  - Who has been physically or sexually abused, when the child’s parent, guardian or custodian knew or should have known of the abuse and failed to take reasonable steps to protect the child from further harm;
- Whose parent, guardian or custodian is unable to discharge that person’s responsibilities to and for the child because of incarceration, hospitalization or physical or mental disorder or incapacity; or
- Who has been placed for care or adoption in violation of the law; provided that nothing in the Children’s Code shall be construed to imply that a child who is being provided with treatment by spiritual means alone through prayer, in accordance with the tenets and practices of a recognized church or religious denomination, by a duly accredited practitioner thereof is for that reason alone a neglected child within the meaning of the Children's Code; and further provided that no child shall be denied the protection afforded to all children under the Children’s Code;

- “Physical abuse” includes but is not limited to any case in which the child exhibits evidence of skin bruising, bleeding, malnutrition, failure to thrive, burns, fracture of any bone, subdural hematoma, soft tissue swelling or death and:
  - There is not a justifiable explanation for the condition or death;
  - The explanation given for the condition is at variance with the degree or nature of the condition;
  - The explanation given for the death is at variance with the nature of the death; or
  - Circumstances indicate that the condition or death may not be the product of an accidental occurrence;

- “Sexual abuse” includes but is not limited to:
  - Criminal sexual contact
  - Incest or criminal sexual penetration
    - As those acts are defined by state law;

- “Sexual exploitation” includes but is not limited to:
  - Allowing, permitting or encouraging a child to engage in prostitution;
  - Allowing, permitting, encouraging or engaging a child in obscene or pornographic photographing; or
  - Filming or depicting a child for obscene or pornographic commercial purposes, as those acts are defined by state law;

CONSIDERATIONS:

- It is the PI’s responsibility to establish a protocol-specific plan for dealing with potential information that may be discovered or disclosed during the study.
- PIs are responsible for ensuring the safety of their research participants and staff. If it is anticipated that the study may involve sensitive results or disclosure of abuse, neglect, (or other cases covered by the Children’s Code) it is recommended that research staff are appropriately trained and a study specific checklist or plan be developed using this guideline, including who is available to speak with the participants.
• PIs need to provide additional precautions when dealing with minor participants, ensuring it is clear to the parents and the minor what information will or will not be shared with the parents/guardians.

• If the participant resides on a reservation then local authorities may have limited jurisdiction. As part of triaging the situation, determine if the individual lives on tribal land so the appropriate agency may be contacted for support. CYFD Tribal Liaison: 505-827-7612 (cell: 505-412-0093), Department of Health (505) 827-2627, Department of Health Tel: (505) 827-2627. Please refer to the following document for Navajo Nation contact information for Law Enforcement, Shelters (safe home for women and children), suicide crisis line, hospitals and health clinics, counseling for mental health and substance abuse, domestic violence, rape crisis center, child protection, victim advocate and family violence prevention, legal services, etc: http://www.sanjuancounty.org/documents/Victim%20Advocate%20-%20Navajo%20Nation%20Resources.PDF

• Resources and contact information provided in this document is for participants in the Albuquerque/New Mexico areas. If your study has participants in other states, a reference document should be provided for those sites.

ASSESSMENT:

- If a participant discloses child abuse or neglect or intent to harm others, contact your PI and the clinical contact immediately.
  - The PI and Clinician will make a determination on whether to report to police, CYFD or tribal authorities.
  - In cases where reporting is required, it does not need to be done immediately while participants are still on site unless it is an emergency. The urgency of reporting should be evaluated and only imminent danger situations need to be reported right away to law enforcement.
  - If the participant is a minor and discloses they have been or are being abused or have intent to harm others, it is important to consider the details of the information provided. There is no time limit on reporting and events that have happened years in the past may still be significant. Individual events may seem minor, but that shouldn’t be the sole determining factor for deciding to report an event since other reports may already exist. The younger the minor the more caution needs to be taken to ensure the protection of that child. The circumstances should determine what needs to be reported – i.e. even if an event is quite old, if the event is significant (ex: sexual abuse) if the minor still has regular contact with the individual then err on the side of reporting.
  - If a minor participant discloses his/her parent/guardian is the abuser, then consider who is with the participant at the research visit and who lives with the participant. If there is imminent danger, then 911 should be called and the study team should ensure they have reliable contact information and a current/valid physical location for where the
participant lives in case they leave the site. Additionally, participants may not be held against their wishes at the research site, however in some cases it may be appropriate to “stall” if PI or authorities need to be contacted. Prior to a participant leaving the site, attempt to verify/obtain the location they are headed to in case a police “well check” is warranted.

- For less urgent disclosures, follow standard procedures to evaluate the situation with the PI and Clinician to determine what should be reported and make any reports in a timely manner.

**FOLLOW-UP/REPORTING**

- Follow up:
  - If appropriate, let the participant know you would like to contact them the following day to check in;
  - ALWAYS document the incident, including who was involved/consulted and outcome in a research progress note, which should be kept in the participant study file;
  - Documentation must include details for good faith reporting and should be stated as “Basis for good faith reporting includes…..”
  - PI must determine whether individual should be (or stay) enrolled in study;
  - PI must determine whether to report to IRB (unexpected, involve risk of harm to self or others, possibly related to the research).
  - If study takes place outside of New Mexico, state laws should be checked for appropriate reporting requirements.

**RECOMMENDED CONSENT FORM CONFIDENTIALITY LANGUAGE FOR MANDATORY REPORTING DISCLOSURES:**

- **You should understand that if the investigators learn about abuse of a child or elderly person or that you intend to harm yourself or someone else, we will report that information to the proper authorities.**

“When a researcher obtains a Certificate of Confidentiality, the subjects must be told about protections afforded by the Certificate and any exceptions to those protections - i.e., the circumstances in which the investigators plan to disclose voluntarily, identifying information about research participants (e.g., child abuse, harm to self or others, etc.). This information should be included in the informed consent form unless a research subject is no longer actively participating in the project so amendment of the informed consent would be impractical The researchers should eliminate provisions in consent form templates that may be inconsistent with the Certificate protections (such as references to disclosures required by law, since the Certificate enables researchers to resist disclosures that would otherwise be compelled by law).” NIH CoC.
GUIDELINES for focused interview questions:

- **Questions about physical abuse:**
  - Have you ever been hurt by someone taking care of you?
    - How did that happen?
    - Have you ever been taken to the hospital/emergency room because you were hurt?
    - How did that happen?

- **Questions about sexual abuse:**
  - Has anyone made you do anything that you feel uncomfortable about?
    - What have you learned about “good touch/bad touch?” How did you learn that?
    - What would you do if someone were trying to touch your private areas?
    - What if it was someone that you know?

- **Questions about neglect:**
  - What kind of things make you scared when you are at home?
  - What does the word “discipline” mean to you?
  - How was your mother disciplined when she was growing up? How about your dad?
    - What is discipline like for you? Your brothers or sisters?
    - How do you think kids should be disciplined if they do something bad?
    - Who is at your house when you come home from school (when you get up in the morning, go to sleep at night)?
    - Who helps you get ready for school?
    - What do you think you are worth as a person?
    - Are there times when you feel bad about yourself? How does that happen?

REFERENCES/APPENDIX

- NIH Certificates of Confidentiality: https://humansubjects.nih.gov/coc/index
- New Mexico Indian Affairs Department – State of New Mexico Tribal Liaisons http://www.iad.state.nm.us/tribal_liasons.html
- New Mexico Indian Affairs Department – New Mexico Pueblos Contact List: http://www.iad.state.nm.us/pueblos.html
- Navajo Nation contact information for Law Enforcement, Shelters (safe home for women and children), suicide crisis line, hospitals and health clinics, counseling for mental health and substance abuse, domestic violence, rape crisis center, child protection, victim advocate and family violence prevention, legal services,
etc:  http://www.sanjuancounty.org/documents/Victim%20Advocate%20-%20Navajo%20Nation%20Resources.PDF
## Abuse/Neglect Assessment Checklist

<table>
<thead>
<tr>
<th>Participant ID:</th>
<th>Visit: ____ baseline = 00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: <em>/</em>/<em>/</em>___</td>
<td>Site: ________</td>
</tr>
</tbody>
</table>

**Prompt Questions**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ever been hurt by someone taking care of you?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If yes, how did that happen?</td>
<td>Details:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever been taken to the hospital/emergency room because you were hurt?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>If yes, how did that happen?</td>
<td>Details:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has anyone made you do anything that you feel uncomfortable about?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>What have you learned about “good touch/bad touch?” How did you that?</td>
<td>Details:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What would you do if someone were trying to touch your private areas?</td>
<td>Details:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the participant a minor?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Any concerns for abuse, neglect or other reportable case?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Will participant stay in study?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Is the event reportable to the IRB?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Follow up contact with participant?</td>
<td>Yes</td>
<td>No</td>
<td>Date/time/method initials:</td>
</tr>
</tbody>
</table>

**Notes/comments:**
Positive Test for Pregnancy, Drugs or Communicable Diseases

BACKGROUND (including statutes and definitions):

Reporting of contagious diseases:

NM Stat § 24-1-15 (2013) Section 24-1-15

https://nmhealth.org/publication/view/regulation/372/
7.4.2.13 New Mexico Administrative Code

Minors of any age may seek treatment/consent in New Mexico for:

- Sexually Transmitted Diseases (STD’s) NMSA 1978, § 24-1-9
- Human immunodeficiency virus (HIV) testing, including required counseling regarding test results NMSA 1978, § 24-2B-3
- Pregnancy and all pregnancy related care NMSA 1978, § 24-1-13; NMSA 1978, § 24-1-13.1
- Family Planning NMSA 1978, § 24-8-3
- Non-invasive initial behavioral health evaluations and verbal therapy of less than two calendar week duration NMSA 1978, § 32A-6A-14(B)

CONSIDERATIONS:

- It is the PI’s responsibility to establish a protocol-specific plan for dealing with potential information that may be discovered or disclosed during the study.
- PIs are responsible for ensuring the safety of their research participants and staff. If it is anticipated that the study may involve sensitive results, including pregnancy, STDs or drug use, it is recommended that research staff are appropriately trained and a study specific checklist or plan be developed using this guideline, including who is available to speak with the participants.
- PIs need to provide additional precautions when dealing with minor participants, ensuring it is clear to the parents and the minor what information will or will not be shared with the parents/guardians.
- If minor is under the age of 14 or a disabled teenager then a positive pregnancy test may be considered a case of neglect or abuse that is reportable. In these cases, if possible, inquire for information regarding who the father may be, how old the father is, and if there is a relationship between the parents. Additionally, if the father is more than four years older than the minor then it may also fall under reportable mandates. For cases where neglect or abuse may be possible in the case of teenage pregnancy, refer to section B (Abuse or neglect (including minors)) for evaluation and reporting guidelines.
- Resources and contact information provided in this document is for participants in the Albuquerque/New Mexico areas. If your study has participants in other states, a reference document should be provided for those sites.
• **Always follow the protocol-specific plan, if one exists.**

• Alternatively, use the following guidelines:
  - If a pregnancy or drug test is inconclusive, the test should be repeated.
  - If a repeat test is inconclusive, or clearly positive, determine whether the staff feel comfortable discussing a positive result with the participant, otherwise contact other trained study team members who are comfortable in this role. If assistance is needed, privately call the clinical contact, the study PI or other trained individual (per protocol-specific plan) for guidance on the steps to take next. The clinical contact will speak to the participant about the results, or will let the RA know the best way to proceed.
  - If a drug or pregnancy test is inconclusive or positive, ask the participant if there is any possibility why their test may be positive (i.e., unprotected sex, dietary supplements, medications etc).
  - Under no circumstances should a female with a positive pregnancy screen complete an MRI scan.
  - For a positive drug or STD test, follow study specific protocol for who is allowed to continue with the scan, who needs to be rescheduled or removed from the study. If there is any question about a participant being impaired by drugs or alcohol, they should not be consented and/or complete any study procedures.
  - For any positive drug or pregnancy test:
    - Ask the participant if it is ok if someone from the study team follows up with them in a day or two to see if they have any questions or need any additional information.
    - Give the participant the Pregnancy Resources or the Drug/Alcohol Referral sheet and ask them if they have any questions or need anything.
    - Remind the participant that no one involved with the project will let anyone know about the results of their pregnancy or drug test or why they did not complete a scan. Inform the participant that they are welcome to discuss what happened today with whomever they would like, but that the study team will strictly maintain their privacy on their results. Finally, let them know that they are welcome to give the study contact (trained individual) a call if they have any questions or concerns.
    - For minor participants - ALWAYS remember that the information obtained during these tests should only be shared with the child/adolescent and should NEVER be shared with parent without direct consent of child. Ask the child/adolescent if they would like help discussing a positive test result with their parent or guardian. Determine whether the study team member feels comfortable in this role, otherwise contact other research team members who do feel comfortable discussing a positive result.
In the case of mandatory communicable disease reporting, inform the participant only and follow standard procedures for state reporting. Information regarding required disclosures should be in the consent form if any testing completed falls under this category (see reference section below). If study takes place outside of New Mexico, state laws should be checked for appropriate reporting requirements.

- If participant is in severe distress or if there is concern the person may hurt themself, contact the study PI immediately, or the clinical contact if the study team has a designated person for such situations and follow the protocol for risk of harm to self (above in section A).

**FOLLOW-UP/REPORTING**

- Follow up:
  - Depending on the situation and if the participant gave permission (or expressed a need), consider contacting participant the following day to check in;
  - ALWAYS document the incident, including who was involved/consulted and outcome in a research progress note, which should be kept in the participant study file;
  - PI must determine whether individual should be (or stay) enrolled in study;
  - PI must determine whether to report to IRB of record.

**REFERENCES/APPENDIX**

- Drug and Alcohol Treatment Community Referral List
- Pregnancy Resources List
- Notifiable Diseases or Conditions in New Mexico.
Drug Test Checklist

Participant ID: ____________________ Visit: _____ baseline = 00

Date: _ _/_ _/_ _ _ _ Site: ____________

Version 2/22/2017

Urine Drug Test

Completed? Yes No

Result?
Positive
Negative

Record result as positive or negative:

<table>
<thead>
<tr>
<th>Code</th>
<th>Drug Name</th>
<th>Cut-off Levels</th>
<th>Control</th>
<th>Subject Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>THC</td>
<td>Marijuana</td>
<td>50 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mAMP</td>
<td>Methamphetamine</td>
<td>1000 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPI</td>
<td>Opiates</td>
<td>2000 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>COC</td>
<td>Cocaine</td>
<td>300 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BZO</td>
<td>Benzodiazepines</td>
<td>300 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OXY</td>
<td>Oxycodone</td>
<td>100 ng/mL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This screening device gives you qualitative results only. A positive result will indicate the presence of the drug above the cut-off concentration.

Assay processed by (RA initials):___________

Results provided to participant? Yes No

Is the participant a minor? Yes No

Any concerns for abuse, neglect or other reportable case? Yes No

If positive, will participant stay in study? Yes No

Drug and Alcohol Resources List Provided? Yes No

Is participant safe to leave the site and/or drive? Yes No

Is the result reportable to the IRB? Yes No

Follow up contact with participant? Yes No

Date/time/method/initials:

Notes/comments:
Below is a list of outpatient and inpatient treatment programs in the New Mexico metro area.

**OUTPATIENT:**

**Addictions and Substance Abuse Program (ASAP)**
Evaluation & treatment of alcohol/drug dependence. Outpatient medical detox, methadone, on-site pharmacy, medication management, counseling, & adolescent program.
994-7999, 2600 Yale Blvd SE

**ABQ Metro Central Intake**
Substance abuse referrals for treatments & counseling, recovery services for families w/substance abuse problems, & Physician Assistant on staff for physicals & TB tests.
272-9033, 2650 Yale Blvd SE

**Aliviar Counseling Services (SPANISH SPOKEN)**
Specializes in treating individuals, adolescents & families with chemical dependency problems & other related issues. No one is refused services.
247-4622, 2301 Yale SE

**A New Awakening**
Counseling for substance abuse, domestic violence services, & mental health. Medicaid, AMCI voucher & Premier Care accepted, or cash (call for rates).
224-9124, 600 1st Street SW #200

**Counseling & Therapy (through ABQ Healthcare for the Homeless)**
A psychosocial rehabilitation program emphasizing recovery & group process, excursions, & leadership development.
843-7611, Please call for location.

**Endorphin Power Company**
Outreach, 12-step meetings, meeting space, fitness center, computer center, library, running club, book club, CPR classes, yoga, & housing. For men and women.
268-3372, 509 Cardenas SE (Zuni & Cardenas)

**First Nations Community Healthsource**
Services for persons with co-occurring mental & substance abuse disorders, persons with HIV/AIDS, & DUI/DWI offenders (men & women).
Phone: (505) 262-2481 Hotline: (505) 238-7488, 5608 Zuni Rd SE
**RESIDENTIAL & INPATIENT:**

**Metropolitan Assessment Treatment Services (MATS) formerly Sobering Services**
Recovery treatment and transitional housing program for substance abuse (including individuals with co-occurring disorders). Community development, referrals, & medical, mental health & homeless services. Men & women, 3-5 day social detox for drug & alcohol (NOT a medical detox—NO opiate OR methadone detox or Rx drug detox—see Turquoise Lodge), no smoking facility, **no charge.**
468-1555, 5901 Zuni Rd SE

**Milagro (UNM Hospital)**
Substance abuse prevention and treatment program. Services such as prenatal medical care, childbirth classes, & parenting guidance beginning in pregnancy that continue post-partum. Accept infants & young children w/ their mothers.
925-2493, 2450 Alamo S.E.

**Salvation Army**
Drug & alcohol residential rehab for Men 21-60.
242-3112, 400 John NE

**Turquoise Lodge (NM Department of Health)**
(SPANISH SPOKEN)
32 bed chemical dependency treatment facility (men & women). Inpatient Medical Detox & Rehab.
841-8978, 5901 Zuni Rd SE

**Crossroads for Women**
A transition program for homeless women with co-occurring addictive and mental health disorders. Help women create safe, secure, and drug free lifestyles for themselves and their children and futures of economic self-sufficiency.
242-1010, 805 Tijeras NW

**Mesilla Valley Hospital**
Psychiatric treatment programs and substance abuse treatment programs for adolescents, adults, and seniors.
800-877-3500, 3751 Del Rey Blvd (Las Cruces)

**St. Martin’s Hospitality Center**
Assisting homeless and near-homeless people by providing resources, opportunities, and hope
242-4399, 1201 3rd St NW

**Victory Outreach**
Helping thousands of people take control of their lives.
843-7930, 1404 Lead Ave SE
**Barratt Foundation**
Helping Women and Children Overcome Homelessness for Over 25 Years
246-9244, 10300 Constitution Avenue NE

**12 Step**

**Alcoholics Anonymous** [www.aa.org](http://www.aa.org)
Albuquerque: 266-1900

Albuquerque: 260-9889

**Cocaine Anonymous** [www.ca.org/](http://www.ca.org/)
Albuquerque: 344-9828

**Marijuana Anonymous** [www.marijuana-anonymous.org/](http://www.marijuana-anonymous.org/)
Santa Fe: 505-690-0749

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**NOTE:** We do not endorse any of the above listed organizations. This referral list is provided to you as a community resource only.
**Pregnancy Test Checklist**

<table>
<thead>
<tr>
<th>Participant ID:</th>
<th>Visit: ____ baseline = 00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 2/22/2017</td>
<td>Date: <strong><strong>/</strong></strong>/_____ Site: ____________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Urine Pregnancy Test Completed?</th>
<th>Yes</th>
<th>No</th>
<th>Pregnant?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat Test Completed?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Was test inconclusive?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Results provided to participant?</td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Is the participant a minor?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Any concerns for abuse, neglect or other reportable case?</td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>If positive, will participant stay in study?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Pregnancy Referral Sources Provided?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Follow up contact with participant?</td>
<td>Yes</td>
<td>No</td>
<td>Date/time/method initials:</td>
</tr>
<tr>
<td>Is result reportable to IRB?</td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Notes/comments:</td>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

*Do not write any participant identifiers on this sheet.*

Once completed, review with the study PI and place the original copy in the participant research file.
American Adoptions
American Adoptions provides adoption services to pregnant women and couples hoping to adopt in all cities in New Mexico, including the major cities of Albuquerque, Las Cruces, Santa Fe, Rio Rancho, Roswell, Farmington, Alamogordo, Clovis, Hobbs, Carlsbad.
http://newmexico.adoption.americanadoptions.com
1-800-ADOPTION

BabyNet
The BabyNet information and referral service (a part of the Information Center for New Mexicans) helps pregnant women and families with small children gain information to access and utilize medical and support services. BabyNet promotes baby wellness by identifying and promoting prenatal and perinatal services as well as helping to reduce the incidence and effects of disabling conditions by educating and providing information.
http://www.cdd.unm.edu/infonet/babynet.html
1-800-552-8195

Bernalillo Council Community
Services offered:
- Emergency contraception information.
- Links to websites for general health and pregnancy information
(505) 975-9667, 1 Civic Plaza NW, 10th Floor

Car Seat Assistance- Trumbull
Family Resource Center
Provides $15 car seats if you come in and get car seat safety training
(505) 256-2005

Care Net Pregnancy Center
Non-profit counseling and pregnancy resource center committed to providing up-to-date information in order to make informed decisions about pregnancy, sexual health, and relationships. Services are free of charge.
www.carenetabq.org
(505) 880-8373, 9809 Candelaria Rd NE

Child Welfare Information Gateway
Resources on all aspects of domestic and intercountry adoption, including adoption from foster care. Includes information for prospective and adoptive parents; information about searching for birth relatives; and resources for professionals on recruiting adoptive families, preparing children and youth, supporting birth parents, and providing postadoption services.
http://www.childwelfare.gov/adoption
1-800-394-3366
County of Bernalillo Public Health Offices
Offers Pregnancy Counseling and Supplemental nutrition program to pregnant women. 
(505) 841-4100, 111 Stanford NE

GRADS – Graduation, Reality, and Duel-role Skills
Services offered:
- Facilitates completion of high school
- Helps teens to understand the importance of prenatal care
- Teaches healthy parenting skills
- Provides the opportunity to earn TECH PREP credit and learn parenting skills while studying child development
- Prepares individuals for work or educational opportunities
info@nmgrads.org
http://www.nmgrads.org

Life Options Academy
Helps teen mothers learn how to pursue careers and teach them life skills.
info@lifeoptionsacademy.org
(505) 265-5522

New Futures, Inc.
Allows teen mothers to bring their children to school with them, and along with their academic coursework, they learn about their parenting responsibilities.
(505) 872-0164, 6110 Bellamah NE

Planned Parenthood
Services offered:
- Abnormal Pap Follow-up
- Annual Exam
- Birth Control without Pelvic Exam
- Birth Control/Family Planning
- Birth Control: Pills, Condoms, Depo-Provera, etc.
- Breast Exam
- Counseling - Birth Control
- Counseling - Pregnancy Options
- Counseling - STD
- Emergency Contraception (EC)
- HIV/AIDS Testing and Counseling
- Male Health Services
- Menopause/Midlife Services
- Norplant Removal
- Post-Abortion Exam
- Pregnancy Testing and Counseling
- Sexually Transmitted Infection Testing & Treatment
• Urinary Tract Infection Diagnosis and Treatment
• Vaginal Infection Testing & Treatment
• Cancer Screening (Pap Test)
• Blood Tests

(505) 265-3722, 3625 Central Ave

NOTE: We do not endorse any of the above listed organizations. This referral list is provided to you as a community resource only.
Notifiable Diseases or Conditions in New Mexico

7.4.3.13 New Mexico Administrative Code

ALL REPORTS INCLUDING ELECTRONIC LABORATORY REPORTS OF NOTIFIABLE CONDITIONS MUST INCLUDE:

- The disease or condition being reported;
- Patient's name, date of birth/age, gender, race/ethnicity, address, patient's telephone numbers, and occupation;
- Physician or licensed healthcare professional name and telephone number; and
- Healthcare facility or laboratory name and telephone number, if applicable.
- Laboratory or clinical samples for conditions marked with [*] are required to be sent to the Scientific Laboratory Division.

EMERGENCY REPORTING OF DISEASES OR CONDITIONS
The following diseases, confirmed or suspected, require immediate reporting by telephone to Epidemiology and Response Division at 505-827-0006.

INFECTIONOUS DISEASES

<table>
<thead>
<tr>
<th>Disease/Condition</th>
<th>Disease/Condition</th>
<th>Disease/Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax*</td>
<td>Haemophilus influenzae invasive infections*</td>
<td>Rubella (including congenital)</td>
</tr>
<tr>
<td>Avian or novel influenza*</td>
<td>Measles</td>
<td>Severe Acute Respiratory Syndrome (SARS)*</td>
</tr>
<tr>
<td>Bordetella species (including pertussis)*</td>
<td>Meningococcal Infections, invasive*</td>
<td>Smallpox*</td>
</tr>
<tr>
<td>Botulism (any type)*</td>
<td>Middle East Respiratory Syndrome</td>
<td>Tularemia*</td>
</tr>
<tr>
<td>Cholera*</td>
<td>Plague*</td>
<td>Typhoid fever*</td>
</tr>
<tr>
<td>Diphtheria*</td>
<td>Poliomyelitis, paralytic and non-paralytic</td>
<td>Viral hemorrhagic fever</td>
</tr>
<tr>
<td></td>
<td>Rabies</td>
<td>Yellow fever</td>
</tr>
</tbody>
</table>

OTHER CONDITIONS

- Acute illnesses or conditions of any type involving large numbers of persons in the same geographic area
- Illnesses or conditions suspected to be caused by the intentional or accidental release of biologic or chemical agents*
- Severe smallpox vaccine reaction Suspected foodborne illness in two or more unrelated persons*
- Suspected waterborne illness or conditions in two or more unrelated persons*
- Other illnesses or conditions of public health significance
**Routine Reporting of Diseases or Conditions**

**INFECTIONOUS DISEASES**
Report case within 24 hours to Epidemiology and Response Division by fax at 505-827-0013 or by phone at 505-827-0006; or contact the local health office).

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>Condition</th>
<th>Disease Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arboviral disease</td>
<td>Hansen's Disease/Leprosy</td>
<td>Q fever</td>
</tr>
<tr>
<td>Brucellosis</td>
<td>Hantavirus pulmonary syndrome</td>
<td>Relapsing fever</td>
</tr>
<tr>
<td><em>Campylobacter</em> infections*</td>
<td>Hemolytic uremic syndrome</td>
<td>Rocky Mountain spotted fever</td>
</tr>
<tr>
<td>Chikungunya virus disease</td>
<td>Hepatitis A, acute</td>
<td>Salmonellosis*</td>
</tr>
<tr>
<td><em>Clostridium difficile</em></td>
<td>Hepatitis B, acute or chronic</td>
<td>Shigellosis*</td>
</tr>
<tr>
<td>Coccidioidomycosis</td>
<td>Hepatitis C, acute or chronic</td>
<td>St. Louis encephalitis infections</td>
</tr>
<tr>
<td>Colorado tick fever</td>
<td>Hepatitis E, acute</td>
<td>Streptococcus pneumonia invasive infections*</td>
</tr>
<tr>
<td>Cryptosporidiosis</td>
<td>Influenza-associated pediatric death</td>
<td>Tetanus</td>
</tr>
<tr>
<td>Cysticercosis</td>
<td>Influenza, laboratory confirmed hospitalization only</td>
<td>Trichinellosis</td>
</tr>
<tr>
<td>Cyclosporiasis</td>
<td>Legionnaires' disease</td>
<td>Toxic shock syndrome</td>
</tr>
<tr>
<td>Dengue</td>
<td>Leptospirosis</td>
<td>Varicella</td>
</tr>
<tr>
<td><em>E. coli</em> 0157:H7 infections*</td>
<td>Listeriosis*</td>
<td>Vibrio infections*</td>
</tr>
<tr>
<td><em>E. coli</em>, shiga-toxin producing (STEC) infections*</td>
<td>Lyme disease</td>
<td>West Nile Virus infections</td>
</tr>
<tr>
<td>Encephalitis, other</td>
<td>Malaria</td>
<td>Western equine encephalitis infections</td>
</tr>
<tr>
<td>Giardiasis</td>
<td>Mumps</td>
<td>Yersinia infections*</td>
</tr>
<tr>
<td>Group A streptococcal invasive infections*</td>
<td>Necrotizing fasciitis*</td>
<td></td>
</tr>
<tr>
<td>Group B streptococcal invasive infections*</td>
<td>Psittacosis</td>
<td></td>
</tr>
</tbody>
</table>

**Tuberculosis** *
Report suspect or confirmed cases to NM department of health tuberculosis program by fax at 505-827-0163 or by phone at 505-827-2471 or 505-827-2473: active disease within 24 hours; infection within 72 hours.

**Sexually Transmitted Diseases**
Report to Infectious Disease Bureau - STD Program, NM Department of Health, P.O. Box 26110, Santa Fe, NM 87502-6110
Fax 505-476-3638 or call 505-476-3636.

- Chancroid
- Gonorrhea
- Syphilis
- Chlamydia trachomatis infections
**HIV (Human Immunodeficiency Virus) and AIDS (Acquired Immunodeficiency Syndrome)**
Report to HIV and Hepatitis Epidemiology Program
1190 St. Francis Dr., N1350, Santa Fe, NM 87502
Fax 505-476-3544 or call 505-476-3515

- All CD4 lymphocyte tests (count and percent)
- All confirmed positive HIV antibody tests (screening test plus confirmatory test)
- All HIV genotype tests
- All positive HIV cultures
- All tests for HIV RNA or HIV cDNA (viral load tests)
- Opportunistic infections, cancers, and any other test or condition indicative of HIV or AIDS

**Occupational Illness and Injury**
Report to Epidemiology and Response Division, NM Department of Health
P.O. Box 26110, Santa Fe, NM 87502-6110
Call 505-827-0006

- Asbestosis
- Coal worker’s pneumoconiosis
- Hypersensitivity Pneumonitis
- Mesothelioma
- Noise induced hearing loss
- Occupational asthma
- Occupational burn hospitalization
- Occupational injury death
- Occupational pesticide poisoning
- Occupational traumatic amputation
- Silicosis
- Other illnesses or injuries related to exposure

**Health Conditions Related to Environmental Exposures and Certain Injuries**
Report to Epidemiology and Response Division, NM Department of Health
P.O. Box 26110, Santa Fe, NM 87502-6110
Call 505-827-0006

**Environmental Exposures**

- All pesticide poisoning
- Arsenic in urine greater than 50 micrograms/liter
- Carbon monoxide poisoning
- Infant methemoglobinemia
- Lead (all blood levels)
- Mercury in urine greater than 3 micrograms/liter or
- Mercury in blood greater than 5 micrograms/liter
- Uranium in urine greater than 0.2 micrograms/liter or 0.2 micrograms/gram creatinine
- Other suspected environmentally-induced health conditions

**Injuries**

- Drug overdose
- Traumatic brain injuries
- Firearm injuries
- Fracture due to fall among older adults

**Adverse Vaccine Reactions**
Send copy of report to Immunization Program Vaccine Manager, NM Department of Health, P.O. Box 26110, Santa Fe, NM 87502-6110; fax 505-827-1741

**Healthcare-associated infections**
Acute care hospitals only report through NHSN and confer rights to NM department of health.
Central line-associated bloodstream infections (CLABSI) events *Clostridium difficile* infections

Report all infections, including non-healthcare-associated, within 24 hours to epidemiology and response division by fax at 505-827-0013 or by phone at 505-827-0006
 carbapenem-resistant enterobacteriaceae*; carbapenem-resistant pseudomonas aeruginosa*.

**Cancer**
Report to NM DOH designee: New Mexico Tumor Registry, University of New Mexico School of Medicine, Albuquerque, NM 87131. Report all malignant and in situ neoplasms and all intracranial neoplasms, regardless of the tissue of origin.

**Human Papillomavirus (HPV)**
Report to NM DOH designee: Laboratories report the following tests to the New Mexico HPV Pap Registry, 1816 Sigma Chi Rd NE, Albuquerque, NM 87106
Call 505-272-5785 or 505-277-0266
 Papanicolaou test results (all results) Cervical, vulvar and vaginal pathology results (all results)
 HPV test results (all results)

**Birth Defects**
Report to Epidemiology and Response Division, NM Department of Health
P.O. Box 26110, Santa Fe, NM 87502-6110
Call 505-827-0006

- All birth defects diagnosed by age 4 years, including: Defects diagnosed during pregnancy
- Defects diagnosed on fetal deaths
- Defects found in chromosome testing on amniotic fluid, chorionic villus sampling and products of conception for Trisomy 13, Trisomy 18 and Trisomy 21

**Genetic and Congenital Hearing Screening**
Report to Children’s Medical Services, 2040 S. Pacheco, Santa Fe, NM 87505
Call 505-476-8868

- Neonatal screenings for congenital hearing loss (all results)
- Suspected or confirmed congenital hearing loss in one or both ears
- All conditions identified through statewide newborn genetic screening
- Newborn critical congenital heart defects screenings (all results)
For details online of 7.4.3 NMAC see:

http://www.nmhealth.state.nm.us/nmac/parts/title07/07.004.0003.htm

List of Notifiable Diseases/Conditions in New Mexico revised June 15, 2016
# Communicable Disease Test Checklist

**Participant ID:** ____________________________  
**Visit:** _____ baseline = 00  
**Date:** ___/___/____  
**Site:** ________

<table>
<thead>
<tr>
<th>STD Test Completed?</th>
<th>Yes</th>
<th>No</th>
<th>Positive Result?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat Test Completed?</td>
<td>Yes</td>
<td>No</td>
<td>Positive Result?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Was test conclusive?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results provided to participant?</td>
<td>Yes</td>
<td>No</td>
<td>Initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the participant a minor?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any concerns for abuse, neglect or other reportable case?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If positive, will participant stay in study?</td>
<td>Yes</td>
<td>No</td>
<td>Initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Referral Sources Provided?</td>
<td>Yes</td>
<td>No</td>
<td>Initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment provided via study?</td>
<td>Yes</td>
<td>No</td>
<td>Details:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow up contact with participant?</td>
<td>Yes</td>
<td>No</td>
<td>Date/time: Method: Initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case reported to the NM Department of Health?</td>
<td>Yes</td>
<td>No</td>
<td>Initials:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is result reportable to IRB?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes/comments:**

*Do not write any participant identifiers on this sheet.*  
Once completed, review with the study PI and place the original copy in the participant research file.