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Reporting Abnormal Research Laboratory Values	#1	10 OCT 2025	

Revision History		
Version No.	**Effective Date**	**Description**

Purpose

This Standard Operating Procedure (SOG) establishes the process for identifying, documenting, and reporting abnormal laboratory values discovered during the conduct of research studies. It ensures timely notification of clinically significant findings to appropriate research personnel and research participants as appropriate.

This SOG is not meant to replace protocol-specific laboratory guidelines. Sponsor provided documents should be used as the primary source of guidance. However, this SOG may serve to clarify definitions, and recommended courses of action when protocol guidance is absent, ambiguous, or requires supplemental interpretation or for unfunded or non-sponsored projects who often lack support and sponsor provided lab manuals.

Scope

This SOG applies to all study personnel involved in collecting, processing, reviewing, or analyzing laboratory data in clinical research studies. It covers all laboratory tests performed as part of approved research protocols.

Definitions and Acronyms

Abnormal Value: Any laboratory result that falls outside the established reference range for that test.

Clinically Significant: An abnormal finding that suggests a disease process or poses risk to the participant's health. It may require medical evaluation or intervention, but is not immediately life-threatening.

Critical Value: An abnormal result that indicates a pathophysiological state at such variance with normal that it is life-threatening unless prompt action is taken.

Principal Investigator (PI): The individual responsible for the conduct of the research study.

PD: Protocol Deviation(s)

Responsibilities

Principal Investigator:

- Overall responsibility for ensuring participant safety
- Establishing study-specific criteria for abnormal values that require reporting if not provided by the study protocol
- Reviewing and evaluating abnormal laboratory values
- Determining appropriate follow-up actions
- Initial and dating all laboratory reviews within 3-5 days of receipts

Study Coordinator/Research Nurse

- Initial review of all laboratory reports, ensuring that report is complete, accurate and that no pages are missing
- Flagging and reporting abnormal values according to the study protocol or this SOG in the absence of clear direction from study protocol
- Documenting all actions taken in response to abnormal values
- Communicating abnormal values and course of action as needed, to study participants as indicated by the Principal Investigator

Laboratory Personnel

- Immediate notification of critical values to the research team
- Providing complete and accurate laboratory reports
- Maintaining appropriate documentation of all testing procedures

Procedure

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1. **Identification of Abnormal Values: All laboratory results must be reviewed within 24 hours of receipt.**
   - 1.1. Compare each result to the laboratory's reference range if unable to determine by report the criticalness of the results
   - 1.2. Flag any value outside the reference range as abnormal. Typically, laboratory reports will already flag abnormal values.
   - 1.3. Classification of abnormal values:
     - 1.3.1. Low abnormal (L):
       - 1.3.1.1. Definition: A result below the reference range.
       - 1.3.1.2. Clinical Relevance: Not typically concerning unless persistent or correlated with symptoms.
     - 1.3.2. Clinically Significant Low Abnormal (L) with clinical context:
       - 1.3.2.1. Definition: A result significantly below the reference range
       - 1.3.2.2. Clinical Relevance: May require medical evaluation or monitoring.
     - 1.3.3. Critically Low Abnormal (LL or L*):
       - 1.3.3.1. Definition: A result significantly below the reference range, indicating a potentially life-threatening condition.
       - 1.3.3.2. Clinical Relevance: Requires immediate medical attention
     - 1.3.4. High abnormal (H):
       - 1.3.4.1. Definition: A result above the reference range
       - 1.3.4.2. Clinical Relevance: May be benign depending on context
     - 1.3.5. Clinically Significant High Abnormal (H):
       - 1.3.5.1. Definition: A high abnormal result that may indicate a disease process or health risk.
       - 1.3.5.2. Clinical Relevance: May require medical evaluation or monitoring
     - 1.3.6. Critically High Abnormal (HH or H*)
       - 1.3.6.1. Definition: A result significantly above the reference range, indicating a potentially life-threatening condition.
       - 1.3.6.2. Clinical Relevance: Requires immediate medical attention.

2. **Reporting Timeline**

Category	Urgency	Reporting Timeframe
Critical (HH/LL)	Immediate, life-threatening	Within 30 minutes to 1 hour
Clinically Significant (H/L)	Potentially serious	Within 24 to 72 hours
Abnormal (H/L)	Mild deviation	Within 3-5 days

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3. Investigator Notification Process

3.1 For critical values:

- Contact PI Immediately by text or secure email
- If PI is unavailable, contact designated back up investigator immediately
- Document time of notification, response and follow up in subject's chart.

3.2 For abnormal and significantly abnormal values:

- Securely email PI with subject line "Abnormal Lab Value – Subject ID and Protocol Number.
- Include the participant ID, copy of abnormal labs report.
- Document time of notification, response and follow up in subject's chart.

3.3. For normal values

- Forward lab report to investigator for review and ensure it is reviewed within 3-5 days of receipt.
- Ensure lab report is initialed and dated by investigator and file in the participant's research chart.

4. **Participant Notification:** All follow up notes (action items) must be documented on the actual lab report. The lab report should include the PIs' initials and date of review.

4.1. PI determines if participant notification is required based on clinical significance.
4.2. Critical values: Participant must be notified immediately with clear follow-up instructions provided by the PI.
4.3. Clinically significant values: Notify participant with 3-5 days with clear follow-up instructions if action is needed. If not action needed, may notify at next study visit or within 14 days of results whichever is sooner.
4.4. Abnormal values: Notify participant within 7-14 days or may be discussed at next scheduled visit if.

5. **Follow-Up Actions**
   5.1. PI will determine appropriate follow-up actions, which may include:
      5.1.1. Repeat testing to confirm results.
      5.1.2. Referral to primary care provider or specialist.
      5.1.3. Immediate medical intervention.
      5.1.4. Modification of study participation status (e.g. withdrawal, IP adjustment, etc.) as per study protocol and/or consultation with medical monitor.
   5.2. All follow-up actions must be documented in the participants' research record
   5.3. All laboratory reports must be reviewed by the investigator and must be initialed and dated on the date of the review. If review was completed via email, then a copy of the email with the PI's acknowledgment and follow-up instructions should be printed and file along the laboratory report.
   5.4. Resolution of abnormal values must be tracked and documented.

Documentation

The following must be documented for all abnormal lab values:

- Date and time of result receipt
- Person who first identified the abnormal value
- Classification of severity (this may be available on the lab report itself)
- PI's assessment and recommended actions
- Date and time of participant notification (if applicable)
- All follow0up actions taken and their outcomes
- Resolution status

Documentation Location

- All documentation must be maintained in the subject's research chart.
- Critical values must also be documented in the Adverse Event log as described in the study protocol.

References

- Clinical Laboratory Standards Institute (CLSI) Guidelines
- Good Clinical Practice (GCP) Guidelines
- Code of Federal Regulations 21 CFR Part 50, 56, 312
- Institutional Review Board Policies and Procedures
- Study specific Laboratory Manual

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Document Approval

- Name and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By: Date:

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Insert Name and Title

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