

MEG CORE FACILITY

National Institute of Mental Health

Bethesda, MD 20892-1059

VARIANCE / PROCESS IMPROVEMENT REPORT

Variance Reporting: To be filled out within 24 hours by the person(s) witnessing an event to report the occurrence(s) or variance(s) to normal operations, policies, procedures, and practices involving any users, subjects / patients and / or equipment. If any injury involved notify Lab Director immediately.

QA/QI Instructions: To make recommendation(s) for quality assurance / improvement indicate details of the proposed improvement in the description section.

Check all that apply; Fill out sections A-N; where not applicable indicate N/A

Section I.

A. **Variance** **QA/QI**

B. Status: (✓ all that apply)

- 1. Subject
- 2. Patient
- 3. Equipment
- 3. Other _____

C. Variance Date: ____/____/____ **Variance Time:** _____ am / pm

Witnessed by: _____
 Witnessed by: _____
 Witnessed by: _____

D. Description of Variance / Description of Improvement: (attach another page if necessary)

E. Injury To Person: *Report all subject, patient or staff injuries to the MEG Core Director immediately.

- N/A
- No Injury
- Inconsequential injury or effect
- Consequential (Possible temporary injury or effect)
- Serious / (Possible minor permanent injury or effect)
- Severe / (Possible major permanent injury or effect)
- Seizure / Possible Seizure
- Medical Emergency: _____

F. Damage to Equipment: If any damage has been sustained discontinue use. Place an "Out of Service/Do not use" sticker on the equipment.

- N/A
- None
- Minor Damage / Inconsequential damage
- Consequential (Possible temporary damage)
- Serious / (Possible minor permanent damage)
- Severe / (Possible major permanent damage)
- Other _____

G. Equipment Malfunction: * Discontinue use and place an "Out of Service" sticker on the equipment. If there is an injury contact the Lab Director immediately.

- N/A Unknown
- Malfunction
- Malfunction with injury
- Other _____

H. Use Related: If there is an injury contact the Lab Director immediately.

- N/A Unknown
- Not clean
- Improper use
- Not properly maintained
- Previous user changed settings
- With injury
- Other _____

I. Electronics Problem:

- N/A DSQ Electronics command failure
- No LEDs
- Slow Boot
- Flashing yellow LED
- Fails to boot
- DSQ Configuration read error
- Other _____

J. Acq Problem:

- N/A
- Failure to start / launch Acq
- During localization at beginning of collection
- During localization at end of collection
- During collection
- Other _____

K. Maintenance Related:

- N/A Unknown
- Maintenance not done
- Other _____

L. Other:

- N/A Unknown
- Policy/procedure/practice variance
- _____

M. Whom Notified:

- Director Staff Scientist System Analyst Research Asst. Lab Manager / Tech No one available
- Other _____

Reported by: _____ Phone Number: _____ Date Reported: _____

N. Action:

Section II. (To be complete by MEG Staff)

Priority: Urgent Important Routine

Outcome / Result of Investigation:

Recommendations / Possible Solutions:

Process Improvement / Measures Implemented To Prevent Reoccurrence:

Investigator: _____ **Date:** _____

Classification Code (Check all that apply):

Acq / Electronics / Equipment / Damage / Injury / Maintenance / User / Other