

The following levels of Medical Monitoring are recognized by the NASA IRB and applicable to research at JSC and in flight:

Level 1

Typically for invasive (e.g. lumbar puncture) or highly provocative procedures (e.g. hypobaric exposure studies) or for protocols that require >85% maximum predicted heart rate or oxygen consumption (VO₂).

When a medical emergency is identified, the emergency medical system should be notified without delay.

A health care provider (Medical Monitor) with current BLS-AED training is required to be present at the time of the research procedure and is actively monitoring the research subject.

At least one other person with current BLS-AED training is present during testing.

Appropriate resuscitation equipment, including an AED, is available in the immediate vicinity of the test.

Advanced life support equipment and personnel (e.g., ambulance/EMT, hospital code team, etc.) are available and within 5-10 min of the testing area if summoned for an emergency. This stipulation is met as long as this activity is conducted during routine operating hours of on-sight EMS services.

Emergency drills are conducted by the investigator team upon initial study approval then prior to each testing session or at least annually.

Protocol Compliance Officer is made aware of the test and emergency drill schedules as appropriate.

Level 2

For procedures that carry less risk than Level 1 procedures, for example those that require sub-maximal aerobic exertion of <85% of maximum predicted heart rate or VO₂.

Health care provider with current BLS-AED training is available by phone or the subject can be transported to the medical clinic within 15 minutes.

Level 3

Typically for minimal risk procedures.

Health care provider is aware of the specific testing and is available for telephone consultation.

N/A: For Minimal Risk procedures that may not require that the Medical Monitor be notified (MML3), an N/A (Not Applicable) MML designation may be appropriate.