VI. PROTECTION OF HUMAN RESEARCH SUBJECTS

No research on human subjects shall be conducted which could, with reasonable foresight, be expected to jeopardize the life, health, physical integrity, or safety of the subject.

No research procedures shall be undertaken with any ISS crewmember as a human subject without: (1) written approval by the Human Research Multilateral Review Board (HRMRB) and (2) the full written and informed consent of the human subject. Each such approval and consent shall be obtained prior to the initiation of such research, and shall fully comply with the requirements of the HRMRB. The HRMRB is responsible for procedures for initiation of new experiments on-orbit when all consent requirements have been met, but the signature of the human subject cannot be obtained; explicit consent of the human subject will nonetheless be required in all such cases. Subjects volunteering for human research protocols may at their own discretion, and without providing a rationale, withdraw their consent for participation at any time, without prejudice, and without incurring disciplinary action. In addition, approval or consent for any research may be revoked at any time, including after the commencement of the research, by: the HRMRB, the Crew Surgeon, the Flight Director, or the ISS Commander, as appropriate, if the research would endanger the ISS Crew Member or otherwise threaten the mission success. A decision to revoke consent by the human subject or approval by the other entities listed above will be final.

§ 1214.502 Definitions.

(a) Mission Critical Space Systems. The Space Shuttle and other critical space systems, including Space Station Freedom, designated Expendable Launch Vehicles (ELV’s), designated payloads, Shuttle Carrier Aircraft and other designated resources that provide access to space. The Director of each NASA Installation will designate areas associated with these systems that are mission critical space systems areas.

(b) Mission Critical Positions/Duties. Positions/duties which, if performed in a faulty, negligent, or malicious manner, could jeopardize mission critical space systems and/or delay a mission. While this regulation establishes suitability screening requirements which, if met, will allow unescorted access to mission critical space areas, compliance with the requirements does not authorize unescorted access to classified areas by Personnel Reliability Program (PRP) personnel who do not have security clearances.