

National Aeronautics and
Space Administration
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Lyndon B. Johnson Space Center
Houston, Texas
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July 22, 2013

Reply to Attn of: SD-13-081

TO: SA/ Chairman, JSC Institutional Review Board

FROM: SD211/ISSMP Project Scientist

SUBJECT: Revision to IRB On-Orbit Consent Process

Included in this memo is a revision to the on-orbit consent process for crewmembers to participate in research investigations during their missions. The issue was discussed with representatives from the NASA International Space Station Medical Projects, the Space and Clinical Operations Division and the chairman of the NASA JSC Institutional Review Board. An agreement to revise the on-orbit consent process was reached as follows:

The IRB acknowledges that potential scientific experiments may not be identified or offered to crewmembers before flight. Under these circumstances, it is acceptable for a crewmember to be contacted while on orbit. The International Space Station Medical Projects (ISSMP) together with the Principal Investigator of the proposed research study will provide the investigation requirements/informed consent briefing to the crewmember. Questions regarding the investigation may be addressed directly to the ISSMP and the Principal Investigator.

The Flight Surgeon may participate in the informed consent briefing and at a minimum will be provided the technical and operational requirements of the study. The Flight Surgeon will be prepared to discuss the investigation with the on-orbit crewmember just as they would preflight. Medical questions or concerns from the crewmember may be resolved directly with the Flight Surgeon. Crewmember consent via e-mail or verbal consent in such a situation will stand in place of the usual signed informed consent. The crewmember's flight surgeon may serve as witness and may sign the informed consent as his/her proxy, if requested by the crewmember. It is understood that all programmatic approvals for adding the experiment/activity will be in place prior to approaching a crewmember, as well as IRB/HRMRB approval of the addition to a crewmember's complement.

We are requesting JSC IRB committee review of this request and implementation upon approval and posting to the JSC IRB Website (<http://irb.nasa.gov/>).

A handwritten signature in blue ink, appearing to read "Clarence Sams".

Clarence Sams, Ph.D.
National Aeronautics and
Space Administration