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ORGANIZING FOR SCIENCE PARTICIPATION ON THE INTERNATIONAL SPACE STATION[1]

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Abstract

On January 14, 2004 the President of the United States announced an exciting national vision for space exploration that includes extending human presence across our solar system. To meet this goal, he announced a plan for the current Shuttle and International Space Station (ISS) that includes completing construction of the ISS by the year 2010 and returning the Shuttle to flight, also until 2010. These programs and a new crew exploration vehicle will support the long-term goal of returning to the Moon by 2020, to live and work, and then to launch human missions to Mars, and beyond. In order to achieve this far-reaching vision for people in space, President Bush emphasized the need to research the effects on humans of the space environment, including radiation and weightlessness. This life sciences research has long been an important element of both the Shuttle and ISS programs. The paper focuses on the life sciences mission of the ISS and the legal mechanisms being employed by several space agencies, including the National Aeronautics and Space Administration (NASA), the European Space Agency (ESA), the Canadian Space Agency (CSA), the Japan Aerospace Exploration Agency (JAXA), the German Aerospace Center (DLR), the French Centre National d'Etudes Spatiales (CNES), and the National Space Agency of Ukraine (NSAU) to maximize science opportunities and international cooperation.

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[2] The views expressed herein are those of the authors and may not reflect the views of the National Aeronautics and Space Administration or the United States of America. Louis H. Ostrach, Ph.D., Program Executive, and Justin E. Tilman, International Program Specialist assisted in the preparation of this paper.

Introduction

The National Vision for Space Exploration provides a bold roadmap for our future — wherein humans and robots return to the Moon and venture onward to Mars and beyond. NASA's success in mitigating the negative effects of the space environment on humans traveling long distances, and eventually living and working in space is a critical hurdle toward achieving the vision. Duly noted in the Vision Statement are these life sciences challenges that are before us today.

> For human explorers to undertake lengthy research trips on other worlds, they will have to maintain their health in environments that possess higher radiation and lower gravity than Earth and that are far from supplies and medical expertise. Research aboard the International Space Station and at various laboratories on Earth is critical to understanding the effects of space environments on the human body, developing techniques for mitigating these hazards, minimizing the logistical burden of supporting humans far from Earth, and addressing remote medical emergencies. NASA plans to complete assembly of the Space Station, including international partner elements, by the end of the decade. NASA will also augment its bioastronautics research program with the goal that Space Station research on other worlds will be complete by 2016.[3]

In April 2004, consistent with the vision, NASA transformed itself into a streamlined organization better suited to carry out its mission. The Office of Biological and Physical Research (OBPR), which was responsible for the agency's life sciences programs became part of the newly created "Exploration Systems Mission Directorate" established to advance current capabilities in human and robotic exploration. Equally important is the work of the Space Operations Mission Directorate that manages the International Space Station (ISS) and Space Shuttle programs.

The ISS provides an ideal platform for advancing human understanding of life sciences because it has been continuously occupied since its first crew of 3, Expedition 1, arrived on November 2, 2000. Once complete, the ISS will consist of research platforms, including "three international pressurized research laboratories, multi-user, discipline-specific research facilities, multidisciplinary EXPRESS Racks[4]; four external truss sites for payloads that require exposure to the space environment, as well as additional exposed facilities on the Japanese and European modules; a 2.5 meter centrifuge to provide artificial gravity for gravitational research; and supporting equipment for power generation and operations..."[5] The ISS biology research facilities planned and in place are impressive and include an advanced animal habitat for rats and mice; habitat holding racks; a European Modular Cultivation System for cells, small organisms, and plants; a variety of equipment to support cell and tissue culture research; a Human Research Facility to support medical monitoring and research; separate life sciences and microgravity sciences gloveboxes; and a fluids and combustion facility.

[3] NASA, The Vision for Space Exploration 15 (February 2004).

[4] "Expedite the Processing of Experiments to the Space Station" racks contain standard interfaces that allow multidisciplinary payloads quick and standard access to ISS resources.

[5] NASA, Science and Technology Research Directions for the International Space Station 7 (January 1, 2000). http://commercial.hq.nasa.gov/files/ISS_Res_Dir_Jan_2000.pdf

International Space Life Sciences Working Group

In order to maximize utilization of the facilities and platforms on the ISS and to advance science, in March 1990, the International Space Life Sciences Working Group (ISLSWG) established itself.[6] It is a multilateral planning and coordinating group of ISS space agencies engaged in space life sciences research. The purpose of the collaboration is to "identify the mutual interests and programmatic compatibilities of the various agencies; enhance communication and unity among and between the participating space life sciences communities around the world; and enable a more complete coordination of the international development and utilization of space flight and special ground research facilities."[7] Members include NASA, CSA, ESA, JAXA, Centre National d'Etudes Spatiales (CNES) of France, Deutsches Zentrum für luft-und Raumfahrt (DLR) of Germany and National Space Agency of Ukraine (NSAU). The ISLSWG approach has met with great success in terms of the caliber of science, avoidance of duplicative activities, and diversity of its participants. The ISLSWG legal framework provides insight into how this coordinated approach has been accomplished and is further explained in this paper.

ISLSWG Approach

The ISLSWG approach was further defined in an April 1996 Protocol document.[8] ISLSWG provides cooperative access to life sciences flight resources (e.g., instruments, facilities, crew time, electrical power) provided by each party to its life sciences research program through a coordinated international recruitment, review and sponsored selection process implemented by the group. The process is designed to achieve the highest quality peer reviewed science available internationally. Specifically, the ISLSWG process requires: [1] coordinated announcements of opportunity that are issued simultaneously from each agency, on an annual basis[9] and include standardized materials, such as instructions, description of the flight opportunities, flight hardware and available resources, review processes and evaluation criteria; [2] review of all proposals forwarded from the sponsoring agencies by an international peer review scientific panel designated by the space agencies; [3] international technical review of proposals to determine feasibility and risk; and [4] a uniform scoring scale. Based on scores provided by the two panels, each space agency prepares a final candidate list from which it negotiates with its agency counterparts to discuss final selection, including consideration of international teaming arrangements, where feasible, to expand the opportunity for participation to a wider group of scientists and strengthen space research in life sciences. The final selection balances hardware and resource availability and individual agency contributions to the international space life sciences research program.[10]

Announcement of Flight Opportunities

To date there have been five research announcements issued through the ISLSWG process – in 1996, 1998, 1999, 2001 and 2004.[11] Announcements are released

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[6] International Space Life Sciences Strategic Planning Working Group Charter (March 15, 1990), *sub nom.* International Space Life Sciences Working Group. http://spaceresearch.nasa.gov/research_projects/islswg.html.

[7] http://spaceresearch.nasa.gov/research_projects/international.html.

[8] CNES/CSA/DARA/ESA/NASDA/NASA Protocol on the International Approach to Life Sciences Recruitment, Review and Selection for the International Space Station, International Space Life Sciences Strategic Planning Working Group 1 (April 12, 1996).

[9] Research announcements were made in 1996, 1998, 1999, 2001 and 2004.

[10] Protocol, *supra*, at 1.

[11] http://research.hq.nasa.gov/code_u/nra/current/NRA-04-OBPR-01/index.html (2004). http://peer1.nasaprs.com/peer_review/nra/01_OBPR_03.html (2001).

simultaneously by each agency, with uniform scoring rules, however, each space agency ultimately decides the specific areas of interest for its own solicitation notice. In addition, a space agency may have national policies or procedures that differ from other partner policies and dictate the content of a particular space agency's solicitation. For example NASA requires that all research involving human subjects adhere to NASA Policy Directive 7100.8D issued by NASA's Chief Health and Medical Office[12] to protect human beings. NASA's most recent "NASA Research Announcement" was focused on fundamental space biology and biomedical research and countermeasures. Participation was open to "all categories of organizations, industry, educational institutions, other nonprofit organizations, NASA laboratories and other Government agencies."[13] In response to these coordinated announcements, principal investigators submit proposals for experiments that are sponsored by their national space agency. Teaming arrangements are encouraged and may include co-investigators from other countries provided that funding is available from that country.

ISLSWG Strategic Plan

The current ISLSWG Strategic Plan sets out two specific goals, namely "strengthen space research"; and "enhance knowledge and information exchange." Thus, ISLSWG extends beyond the provision of flight opportunities for ISS life sciences, the focus of this paper. The plan also identifies guiding principles for the international strategy, including the following:

> · Promote the highest quality scientific investigations, consistent with the particular constraints defined by a research opportunity;
>
> · Preserve the autonomy of each of the member space agencies by participating in cooperative activities;
>
> · Optimize the utilization of scarce resources by avoiding unnecessary duplication of equipment, by sharing equipment and flight opportunities, and by cooperating with all members whenever possible; and
>
> ·Recognize that access to space is a precious resource and that it should be shared among members whenever feasible to maximize science return.[14]

Finally, the plan provides an implementation strategy for member agencies to achieve each goal. Some of the elements of the strategy for the first goal of strengthening space research include: regular sharing of information through formal working group meetings and workshops; promotion of international space research opportunities; standardization of space flight investigations; optimization of the use of existing hardware and ground facilities, and use of common terms to enhance effective communication in the space life sciences community.[15]

For the second goal of enhancing knowledge and information exchange, the plan provides: wide dissemination of space life sciences programs and results; exchange of graduate and post graduate students, archiving of space flight data and publication of the availability of such data, a uniform approach to data and

http://research.hq.nasa.gov/code_u/nra/current/NRA-99-HEDS-02/index.html (1999).
http://research.hq.nasa.gov/code_u/nra/current/NRA-99-HEDS-03/index.html (1999).
http://research.hq.nasa.gov/code_u/nra/current/NRA-98-HEDS-02/index.html (1998).
http://research.hq.nasa.gov/code_u/nra/current/NRA-96-HEDS-04/index.html (1996).

[12] NASA Policy Directive 7100.8D, Protection of Human Research Subjects (May 31, 2002).

[13] NASA Research Announcement 04-OBPR-02, Research Opportunities for Flight Experiments in Space Life Sciences 3 (January 15, 2004).

[14] ISLSWG, International Strategic Plan for Space Life Sciences, 4 (June 1995; rev. 1, draft July 4, 2003).

[15] *Id.*

bibliographic archiving; conduct of meetings and use of other means, including policies for facilitating information exchanges, collaboration and leveraging of resources.[16]

Agreement Structure for Space Flight Investigations/Umbrella Arrangement

The legal structure that provides ISS flight opportunities for the ISLSWG-selected investigations was designed to be easy to implement. This was accomplished by an umbrella arrangement concluded in September 2002 between NASA, ESA, NASDA and CSA (umbrella arrangement).[17] The arrangement provides the general principles and terms that were developed through the Charter, Protocol, Strategic Plan, and Implementation Plan -- foremost among them -- the international solicitation, review and selection process. Equally important, the umbrella arrangement defines the other central tenets of the ISS partner cooperation including exchange of data and goods, data rights, intellectual property, liability, and consultation and settlement of disputes, discussed in more detail, below. Finally, because the umbrella arrangement applies to all ISLSWG-sponsored flight investigations, once an experiment or study is approved, the only legal document that is required among the relevant parties is an exchange of letters summarizing the specific nature of the experiment; identifying the parties providing the flight opportunity; sponsoring the flight experiment; and performing the lead management function. This avoids having to negotiate all the legal terms every time an experiment is selected and also simplifies the review cycle internally and the level of authority required for signature.

Relationship to the ISS IGA and MOUs

The ISS Intergovernmental Agreement (IGA) between the Partner States[18] and the Memoranda of Understanding (MOUs) between the space (cooperating) agencies[19] cover the "detailed design, development, operation and utilization"[20] of the ISS. Article 9 of the IGA addresses utilization and prescribes rights based on provision of user elements,[21] which is described more fully in the MOUs. Much has been written to date about this legal structure, so this paper does not include a general evaluation.[22] Of importance to this discussion, however, is an understanding that the IGA/MOU responsibilities only cover "complete basic functional outfitting"[23] and, therefore, do not include specific responsibilities for providing research equipment or otherwise conducting scientific utilization programs. The ISLSWG arrangement is not an implementing arrangement as defined in Article 4 of the IGA. Therefore, the specific terms of any utilization arrangements (ISLSWG foremost among them) may vary provided that: [1] the arrangements are consistent with the IGA/MOUs; and [2] the IGA/MOU partner responsibilities that apply

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[16] *Id.* at 5.

[17] Arrangement among the Canadian Space Agency, the European Space Agency, the National Aeronautics and Space Administration of the United States of America, and the National Space Development Agency of Japan concerning International Space Life Sciences Flight Experiments on the International Space Station (September 30, 2002). (*hereinafter*, Umbrella Arrangement).

[18] Agreement Among the Government of Canada, Governments of Member States of the European Space Agency, the Government of Japan, the Government of the Russian Federation, and the Government of the United States of America Concerning Cooperation on the Civil International Space Station (January 29, 1998).

[19] Memoranda of Understanding between, respectively, NASA and CSA, NASA and ESA, NASA and the Government of Japan Concerning Cooperation on the Civil International Space Station (January 29, 1998).

[20] IGA, *supra*, at Article 1.1

[21] *Id.* at Article 9.

[22] For a good discussion of the ISS IGA and MOUs, *See* A. Farand, The Space Station Cooperation Framework, ESA Bulletin 94 (May 1998). http://esapub.esrin.esa.it/bulletin/bullet94/FARAND.pdf
Also, *See* Edward A. Frankle, Legal Aspects of Space Station Utilization, IISL-99-.1.03 (October 1999).

[23] MOU, *supra*, at Article 3 § 3.2.

more broadly are incorporated in full, including the cross-waiver of liability; customs and immigration; treatment of data and goods in transit; intellectual property; and language requirements.[24]

By way of explanation, Article 19 of the IGA, "Exchange of Data and Goods" describes the rights and obligations among the ISS partners while the umbrella arrangement describes those rights between a partner and its ISS user. The specific terms for the exchange of data and goods under ISLSWG must be found in the provisions of the umbrella arrangement. A partner may have overlapping responsibilities as a signatory under Article 19 of the IGA (where it is acting within its responsibilities under the MOUs and implementing arrangements) and under the separate terms of the ISLSWG arrangement, some of which may occur concurrently. Whereas Article 19 does not dictate the content of provisions in partner utilization agreements concerning transfer of data and goods among the partners themselves or to third parties, it does require partners to protect marked data given to them, through a cooperating (space) agency, from any user under a utilization agreement. This approach provides the necessary protection of data across the ISS program and builds in flexibility to enhance protections required specifically in utilization agreements, as appropriate.

Data Rights

Data rights are an important element of any collaborative scientific undertaking. The ISLSWG approach is consistent with international practice. Principle investigators and their teams are given a period of a year to publish resulting scientific or technical data, which should be accomplished as soon as practicable. All access to the data provided to other parties involved in the experiment/investigation — the party providing the flight opportunity, sponsoring the flight experiment, and providing lead management — may not negatively affect first publication rights. In return, the three other parties involved in the experiment/investigation (unless roles are duplicative, in which case there would be fewer than three other parties with access to the data) are granted a royalty free license under copyright (if applicable) to reproduce, distribute and use the published reports.[25]

Exchange of Data and Goods

This section applies to the transfer of technical data and goods considered necessary by the parties to fulfill their respective responsibilities. It requires each party to facilitate the transfer of all such technical data required for "detailed design, manufacturing, and processing data and associated software necessary for interface, integration or safety purposes.[26] Other technical data or goods — addressing utilization, for example — will also be transferred under the cooperation, and the parties are required to use their best efforts to handle any such requests in an expeditious manner. The furnishing party is required to mark any proprietary, export controlled, or classified technical data with a notice that provides instructions to the receiving party on how the data may be used, including by contractors or other entities. Transferred technical data and goods remain under the ownership of the transferring party and the recipient's rights extend only to use, disclosure and retransfer according to the terms of the accompanying notice.[27]

Intellectual Property

Intellectual property and treatment of inventions is a critical consideration for life sciences activities. This is especially true for ISS where the principle investigation team may be from more than one country, and the science

[24] Umbrella Arrangement, *supra*, at Article 7.

[25] *Id.* at Article 12.

[26] *Id.* at Article 10 § 10.3.

[27] *Id.* at Article 10 § 10.5.

is performed in space, by astronauts of varied nationality utilizing laboratories and facilities provided by several nations. As noted above, the IGA/MOU provisions on intellectual property apply across all partner programs, including utilization activities. This paper will not include a discussion of those rights because they have been considered in depth in a paper prepared by NASA's Office of the General Counsel entitled "Intellectual Property and the International Space Station: Creation, Use, Transfer, Ownership and Protection."[28] Briefly, the main principle governing intellectual property law on the ISS is a "territorial approach based on registry of [ISS] elements... An activity occurring on an element is deemed to have occurred in the territory of the partner of that element's registry."[29] The umbrella arrangement further provides that any joint invention requires consultation to determine the responsibilities and costs of establishing and maintaining patent protection, as appropriate.[30]

Liability and Disputes Resolution

Two other provisions of the ISLSWG arrangement are critical to the partnership, but less important from a programmatic standpoint because they address consequences if the partnership is seriously affected in an adverse manner. The liability scheme, contained in Article 16 of the IGA, applies to all ISS cooperation.[31] A standard approach in cooperative space activities internationally, the risk of loss scheme employs a cross waiver between the parties wherein each party bears its own risk of participation. The waiver does not affect a party and its own related entities, natural citizens, and third parties that have been injured or damaged in some way. For a fuller discussion on the cross-waiver, see NASA's Space Act Agreements Manual,[32] "Liability and Risk of Loss."[33]

Concerning consultations and settlement of disputes, the umbrella arrangement provides that disputes are handled within the program through consultations. The rationale for this approach is that program managers are highly motivated to resolve any disputes and have the requisite understanding and specialized knowledge necessary to be fair. If consultations are unsuccessful, the umbrella arrangement provides that the parties may seek to proceed utilizing some form of dispute resolution, on a consensus basis. However, NASA does not envision a life sciences agreement for a flight experiment/investigation necessitating conciliation, mediation or arbitration for the reasons already stated, above, and because it introduces additional risk and uncertainty into the program.

Conclusion

Understanding how to minimize the negative effects of space on humans traveling long distances, and accomplishing this collaboratively with our international partners is critical to NASA's future plans for sending humans to the Moon, Mars and beyond. A significant step forward is being accomplished through the ISS program and the ISLSWG approach to life sciences, which has proven very successful in providing a structure for achieving maximum scientific benefit. The legal framework, including the ISLSWG Charter, Protocol, Strategic and Implementation Plans, and the Umbrella Arrangement provide a solid basis for a strong cooperation and may offer a model for planning future multinational programs such as those required for implementation of our national space vision.

[28] http://www.hq.nasa.gov/ogc/iss/main.html.
[29] *Id.* at 4.
[30] Umbrella Arrangement, *supra*, at Article 11.
[31] MOU, *supra*, at Article 15.
[32] http://nodis3.gsfc.nasa.gov/1050-1.html.
[33] NASA Advisory Implementing Instructions 1050.1, Space Act Agreements Manual Chapter 1 § 1.2.9 (December 30, 1998).