

**INFORMED CONSENT IN COMMERCIAL SPACE TRANSPORTATION SAFETY**

**Dr. George C. Nield**

Federal Aviation Administration  
Office of Commercial Space Transportation (FAA/AST)  
Washington, DC, United States, george.nield@faa.gov

**Nathan Johnson**

Federal Aviation Administration  
Office of Commercial Space Transportation (FAA/AST)  
Washington, DC, United States, nathan.a.johnson@faa.gov

**Jim Duffy**

Federal Aviation Administration  
Office of Commercial Space Transportation (FAA/AST)  
Washington, DC, United States, jim.duffy@faa.gov

**John Sloan**

Federal Aviation Administration  
Office of Commercial Space Transportation (FAA/AST)  
Washington, DC, United States, john.sloan@faa.gov

In 2004, the U.S. Congress passed the Commercial Space Launch Amendments Act (CSLAA), which gave the U.S. Federal Aviation Administration (FAA) clear authority to regulate commercial human space flight. The new law did not allow the FAA to regulate the safety of those people onboard the space vehicles, as is done today in the aviation industry. Instead, the law contained an important provision that required only the informed consent of the onboard crew and passengers. Essentially, occupants must state in writing that they understand that the U.S. Government has not certified the space launch or reentry vehicle as safe and be informed of the risks of the vehicle they are boarding and others like it. The Congress stated that “the regulatory standards governing human space flight must evolve as the industry matures so that regulations neither stifle technology development nor expose crew or space flight participants to avoidable risks as the public comes to expect greater safety for crew and space flight participants from the industry.”

The FAA issued regulations to carry out the CSLAA in 2006. The FAA regulations require the space launch operator to inform the space flight participants and the crew in writing about the hazards and risks associated with the space flight. The regulations also require the operator to inform space flight participants and crew about the historical safety record of all U.S. launch or reentry vehicles that have carried people onboard. There are additional regulations for crew qualification and training, a waiver of claims against the U.S. Government, and training of space flight participants. The level of detail in the information that the operator must provide participants and crew in order to satisfy these regulations has not yet been established.

This paper will examine the roles and responsibilities of the FAA and the commercial space transportation industry for meeting U.S. law and regulations about informed consent. For countries interested in adopting U.S. commercial space transportation law and regulations, or in attracting U.S. launch operators to their spaceports that will be FAA-licensed, the informed consent regime is an important factor in understanding the risk.

## **I. Introduction & Origins of Informed Consent for Human Spaceflight**

In 2004, the U.S. Congress passed the Commercial Space Launch Amendments Act (CSLAA), which gave the U.S. Federal Aviation Administration (FAA) clear authority to regulate commercial human space flight.<sup>1</sup> The timing of the law was no coincidence, as that same year SpaceShipOne became the first private human spacecraft to launch and return safely, offering the proof of concept for a new industry.<sup>2</sup> Because this was a new industry, Congress chose to allow the industry to develop with government oversight limited to the safety of the public, and not the persons on board, except in limited circumstances.

Instead, the law contained an important provision that required only the informed consent of the onboard crew and passengers. The Congress stated that “the regulatory standards governing human space flight must evolve as the industry matures so that regulations neither stifle technology development nor expose crew or space flight participants to avoidable risks as the public comes to expect greater safety for crew and space flight participants from the industry.”<sup>3</sup>

Members of Congress debated if new regulations should protect people onboard. The prevailing approach, as expressed by Representative Sherwood Boehlert, chairman of the House Committee on Science, likened the new industry to adventure travel and not that of an airline for passengers: “... [T]his industry is at the stage when it is the preserve of visionaries and daredevils and adventurers. These are people who will fly at their own risk to try out new technologies. These are people who do not expect and should not expect to be protected by the government.”<sup>4</sup>

The FAA issued regulations to carry out the CSLAA in 2006.<sup>5</sup> The FAA regulations require the space launch operator to inform the space flight participants and the crew in writing about hazards and risks associated with the space flight. The regulations also require the operator to inform space flight participants about the historical safety record of all U.S. launch or reentry vehicles that have carried people onboard. There are additional regulations for crew qualification and training, a waiver of claims against the U.S. Government, and training of space flight participants.

The level of detail in the information that the operator must provide participants and crew in order to satisfy these regulations has not yet been established.

As commercial space flight providers anticipate flying participants, the industry will begin developing examples of how to provide informed consent. This paper will examine the roles and responsibilities of the FAA and the commercial space transportation industry for meeting U.S. law and regulations about informed consent.

## **II. FAA Regulations for Informed Consent**

In passing the CSLAA, Congress mandated two separate levels of informed consent for crew and for the space flight participant. For crew, the law only asked that the holder of a launch or reentry license or permit inform, in writing and before contracting or agreeing to employment, that “the United States Government has not certified the launch vehicle as safe for carrying crew or space flight participants.”<sup>6</sup> For the space flight participant, the law included the same provision, and more. First, it asks the holder of a launch or reentry license or permit to inform, in writing and prior to receiving compensation, “about the risks of the launch or reentry, including the safety record of the launch or reentry type.”<sup>7</sup> Second, the law also asks that the space flight participant provide “written informed consent to participate in the launch and reentry.”<sup>8</sup> These requirements were incorporated in the new regulations published in 2006.

Title 14, Chapter III (Commercial Space Transportation, Federal Aviation Administration, Department of Transportation) of the U.S. Code of Federal Regulations (CFR), Part 460.9, is titled “Informing Crew of Risk,” and includes the same language as the law, requiring a pre-employment disclosure that the launch vehicle is not certified by the United States Government as safe for carrying crew or space flight participants.<sup>9</sup>

Part 460.45 is titled “Operator informing space flight participant of risk,” and elaborates on the original language of the law by enumerating multiple factors required to adequately inform a space flight participant.<sup>10</sup> For instance, in order to inform a space flight participant of “the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type,” the operator “must disclose in writing” the following factors “in a manner that can be readily understood [...] with no specialized education or training” - “(1) [...] each known hazard and risk that could result in a serious injury, death, disability, or total or partial loss of physical and mental function; (2) that there are hazards that are not known; and (3) that participation in space flight may result in death, serious

injury, or total or partial loss of physical or mental function.”<sup>11</sup>

Additionally, the operator must inform on “the safety record of all launch or reentry vehicles that have carried one or more person on board, including both U.S. government and private sector vehicles [including] - (1) the total number of people who have been on a suborbital or orbital space flight and the total number of people who have died or been seriously injured on these flights; and (2) the total number of launches and reentries conducted with people on board and the number of catastrophic failures of those launches and reentries.”<sup>12</sup>

The operator must also inform on the safety record of its own vehicle, covering “launch and reentry accidents and human space flight incidents that occurred during and after vehicle verification [including] – (1) the number of vehicle flights; (2) the number of accidents and human space flight incidents; and (3) whether any corrective actions were taken.”<sup>13</sup>

Aside from requiring that the information be given in an easy to understand manner, the operator must also inform the space flight participant that they “may request additional information regarding any accidents and human space flight incidents reported,” and before flight give them an opportunity “to ask questions orally to acquire a better understanding of the hazards and risks of the mission.”

Finally, in order to document the space flight participants’ informed consent, they must provide that consent in writing, including (1) identifying the specific launch vehicle, (2) the statement that the participant understands the risk and is voluntarily aboard the launch vehicle, and (3) be signed and dated by the participant.<sup>14</sup>

Because the standard for informing crew is minimal in comparison to informing the space flight participants, the majority of these regulations were issued in an effort to enumerate and make clear to the industry what factors were involved to adequately inform space flight participants. However, the procedures for actually gathering and distributing that information have yet to be developed.

### **III. Untested Attributes of Informed Consent**

#### Defining the Risks and Hazards

While Congress identified space transportation as “inherently risky,” the legislation did not state

definitively what the risks are.<sup>15</sup> The regulations manage to elaborate on the risks, by identifying the outcome of “serious injury, death, disability, or total or partial loss of physical and mental function.”<sup>16</sup> As for the source of risks, several studies have been performed to identify potential causes of harm to space flight participants.

A 2008 study conducted for the FAA identified two categories of potential risks to human space flight, differentiating between physical and psychological hazards.<sup>17</sup> The sources of physical hazards included high decibel noise, loss of pressure, high G-forces (sustained acceleration), high or low temperature, high radiation levels, physical impact trauma, exposure to toxic chemicals, and adverse composition of the cabin atmosphere. The study also identified the mission phase and/or failure mechanism that could cause the hazards, and the potential physical effects.<sup>18</sup>

Psychological response hazards include claustrophobia, excitement, agitation, fear, motion sickness, vertigo or loss of bearing or balance, and rapid pulse or increased blood pressure.<sup>19</sup>

A particular launch operator may have a number of risks and hazards that it needs to identify. The regulations also specifically include a provision for requiring the operator to inform the space flight participant that “there are hazards that are not known.”<sup>20</sup> The 2008 study compared the commercial human spaceflight informed consent regime to both medical malpractice law, and commercial recreation and adventure sport.<sup>21</sup>

Within the context of medical malpractice, informed consent has typically served as a defense on behalf of medical providers against patient claims. In that case, it must disclose material risk.<sup>22</sup> Courts may differ on evaluating what constitutes a “material” risk, either relying on what a reasonable provider would disclose, what a reasonable patient would expect to have disclosed to them, or what risk would cause a reasonable patient to change his or her decision to pursue the activity.<sup>23</sup>

Along those lines, the study cited cases in which courts limited the scope of information that would be required to satisfy informed consent. In 1988, a Louisiana court ruled that doctors were not required “to compile long lists of every possible [harm] which could be affected by any given medical procedure,” because an excess of information would not necessarily lead to a better informed patient.<sup>24</sup>

Similarly, in 1995 a Texas court supported a state statute for minimizing required disclosures, by ruling

that doctors could not be expected “to disclose all risks, including those for which the risk is so minimal that it would not influence a reasonable person’s decision.”<sup>25</sup>

Although there is use of informed consent in medical practice, the application by the Congress and FAA of informed consent in commercial space transportation does not make for an equal comparison in part because it does not protect the launch operator from liability and it is required by regulation. Failure to provide informed consent is a violation of FAA regulations.

Gathering Information on Safety Records

The other major portion of informed consent requirements involves historical information on both the safety record of the individual vehicle, and across all human space transportation.

The preamble to 2006 FAA regulations includes a short discussion of whether the informed consent requirement should account for non-U.S. launches as well, with the FAA deciding against it because the information may not always be publicly available and its accuracy would be difficult to verify.<sup>26</sup> An operator may choose to provide additional non-U.S. vehicle information.

The FAA is currently considering making available a continually updated safety record of all human spaceflights within or authorized by the United States for either government or commercial space system operators, including both orbital and suborbital missions.

The following table contains preliminary data on U.S. human space flight history that could be used by U.S. commercial operators to satisfy FAA regulations concerning the human space flight safety record.

Total number of people on suborbital or orbital space flights	1,220
Total number of fatalities or serious injuries on those flights	15 (1.2%)
Total number of launches conducted with people onboard	370
Number of catastrophic failures during those missions	3 (0.8%)

Table 1. U.S. Human Space Flight History  
Source: FAA, April 2013.

The above safety record is an example of what can be provided by the FAA as reference information for use by human space flight operators and space flight participants, and is sufficient to satisfy the regulations; however, it remains the responsibility of the licensed

operators to inform each space flight participant in writing. This would be consistent with discussions accompanying the regulations which suggested that the FAA centralize the collection and communication of this information.<sup>27</sup>

How the totals are calculated is important. Table 1 includes a summary of Mercury, Gemini, Apollo, X-15, Space Shuttle and SpaceShipOne and SpaceShipTwo flights. The data includes one fatality from an X-15 flight, but not fatalities from the Apollo 1 ground test.

The FAA developed a set of ground rules and assumptions for the above table to ensure consistency of data across different mission types. Considerations include: counting repeat trips to space by the same person; definitions of launch, reentry, and suborbital flight and when they begin and end to align with FAA licensing; not counting ground crew or crew of a carrier aircraft; not including people on non-U.S. missions launched or returned outside the U.S.; and not including unpowered drop tests such as by various X-planes, Space Shuttle Enterprise, or SpaceShipTwo.

The requirement for collecting, maintaining, and distributing the safety record of the individual vehicle is levied on the operator. During the rule-making process, various industry representatives suggested that the FAA limit the required information to pre-defined terms like “accidents,” to avoid confusion over what sort of events were necessary to disclose. The FAA therefore made sure the new regulations were comprehensive in the current definitions of launch and reentry accident, as well as adding the term human space flight incident and expanding the scope to include accidents on the ground.<sup>28</sup>

One further clarification made during the rule making process regarded how far back vehicle history information would need to cover. The FAA agreed “that an operator need only disclose its safety record created during and after vehicle verification performed in accordance with § 460.17. This includes all subsequent launches and reentries. Earlier models that predate the verification of the vehicle are not part of the safety record.”<sup>29</sup>

Overall, the rulemaking process worked well in ensuring that the FAA regulations gave clear direction and guidance to operators on what information they would be required to collect and maintain for purposes of informing their customers.

## U.S. Export Policy

Commodity Jurisdiction requests approved for Bigelow Aerospace in 2009 and Virgin Galactic in 2012 to move the “spaceflight experience” from the U.S. Munitions List to the Commerce Control List have been given favorable rulings by the U.S. State Department.<sup>30</sup> This means essentially that most non-U.S.-citizen space flight participants can take a ride on U.S. vehicles and receive safety training. The operator would not be considered providing a “defense service” under the International Traffic and Arms Regulations (ITAR).

It is important to note that these determinations do not exempt ITAR controlled vehicle technical information in the context of informed consent and the operator answering safety record questions from space flight participants. Although there is a U.S. review of export and space technology underway related to satellites and spacecraft during 2013, certain suborbital and orbital vehicle technologies would remain on the U.S. Munitions List according to a proposed rule published in the U.S. Federal Register in May 2013. As a result, an operator may be limited in answering ITAR sensitive questions regarding its vehicle.

However, in the preamble to the 2006 regulations, the FAA responded to concerns from industry about the level of detail and proprietary information. The FAA wrote that it “will require only a general system description. An operator only needs to disclose, for example, that a propulsion system exploded, not the details of how the explosion occurred.”<sup>31</sup> In addition the FAA stated “it will not, as originally proposed, require an operator to also describe what corrective actions were taken.”<sup>32</sup>

## Heirs and Estates

One issue regarding the informed consent regulations that has not yet been fully discussed is whether it covers potential legal claims from the heirs and estate of a space flight participant.

In May 2013, the Commercial Space Transportation Advisory Committee (COMSTAC), an industry advisory committee to the FAA, noted in an observation that “while the Commercial Space Launch Act requires that licensees obtain informed consent from their spaceflight participant customers, it does not preclude potential claims from participants and their heirs and estates in the event of a flight incident or accident.”<sup>33</sup> Virginia, Florida, Texas, Colorado, and New Mexico have passed state laws regarding commercial space transportation liability.

## Disclosure of Maximum Probable Loss Information

One provision in the original CSLAA which has not been implemented by regulation is a requirement that the Secretary of the Department of Transportation inform the space flight participant in writing “of any relevant information related to risk or probable loss during each phase of flight” based on information gathered during the required financial responsibility and Maximum Probable Loss (MPL) calculations.<sup>34</sup>

The MPL calculation is a part of the launch or reentry licensing process. The FAA carries out an analysis to determine the value of the maximum probable loss which could result from a licensed activity, and in doing so collects information necessary to reach a conclusion.<sup>35</sup> This analysis often considers factors which could lead to flight failure, a conclusion that would be equally relevant to the safety of a space flight participant.

When a license is issued, the licensee is required to obtain liability insurance, or otherwise demonstrate financial responsibility to compensate for the maximum probable loss which would result from claims by a third party, or damage or loss to Government property.<sup>36</sup>

As stated, this provision of the CSLAA has not been implemented in the regulations because the action is imposed on the FAA, not the licensed operator. However, since the MPL calculation is based on all known hazards and risks that could result from the specific mission and vehicle, this information was determined by Congress to be of sufficient relevance that it needs to be disclosed to the participant as part of the informed consent process.<sup>37</sup>

## **IV. Conclusion**

With the informed consent regime, the Congress has established multiple responsibilities between government, commercial operators, crew, and private participants.

FAA regulations on informed consent state that “an operator must present this information in a manner that can be readily understood by a space flight participant with no specialized education or training” and must disclose in writing for each mission known hazards and risks and “[t]hat there are hazards that are not known.”<sup>38</sup>

As the commercial human space flight industry moves closer to first flights into the known and unknown, the informed consent regime gives industry room to grow and develop.

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## REFERENCES

<sup>1</sup> Commercial Space Launch Amendments Act of 2004, Pub. L. No. 108-492, 118 Stat. 3978 (hereinafter CSLAA).

<sup>2</sup> “SpaceShipOne Flies Again Within 14 Days—Wins \$10M X PRIZE”  
[http://www.scaled.com/projects/tierone/spaceshipone\\_flies\\_again\\_within\\_14\\_days\\_-\\_wins\\_10m\\_x\\_prize](http://www.scaled.com/projects/tierone/spaceshipone_flies_again_within_14_days_-_wins_10m_x_prize)

<sup>3</sup> CSLAA, *supra* note 1.

<sup>4</sup> Hughes, Timothy and Rosenberg, Esta, “Space Travel Law (and Politics): The Evolution of the Commercial Space Launch Amendments Act of 2004,” *Journal of Space Law*, Volume 31, Number 1, Summer 2005, page 46. Cited from: *The Congressional Record*, H10048-49, daily edition, November 19, 2004.

<sup>5</sup> Human Space Flight Requirements for Crew and Space Flight Participants, 71 FR 75616 (2006-12-15) (hereinafter Regulations). <http://www.gpo.gov/fdsys/pkg/FR-2006-12-15/pdf/FR-2006-12-15.pdf>

<sup>6</sup> Chapter 509 – Commercial Space Launch Activities, 51 U.S.C. § 50905(b)(4)(B).

<sup>7</sup> *Id.*, at (b)(5)(A).

<sup>8</sup> *Id.*, at (b)(5)(C).

<sup>9</sup> Regulations, *supra* note 5.

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*, at §460.45(a).

<sup>12</sup> *Id.*, at §460.45(c).

<sup>13</sup> *Id.*, at §460.45(d).

<sup>14</sup> *Id.*, at §460.45(e)-(f).

<sup>15</sup> 51 U.S.C. § 50901(a)(12).

<sup>16</sup> Regulations, *supra* note 5, at §460.45(a)(1).

<sup>17</sup> Study on Informed Consent for Spaceflight Participants, APT-CFA-230-0001-02F (September 26, 2008) (hereinafter APT Study). [http://www.faa.gov/about/office\\_org/headquarters\\_offices/ast/reports\\_studies/library/](http://www.faa.gov/about/office_org/headquarters_offices/ast/reports_studies/library/)

<sup>18</sup> *Id.*, at Table 1.

<sup>19</sup> *Id.*, at Table 2.

<sup>20</sup> Regulations, *supra* note 5, at §460.45(a)(2).

<sup>21</sup> APT Study, *supra* note 16, at 4-15. For an example of U.S. regulations using informed consent, see CFR 45 Part 46, Public Welfare, Department of Health and Human Services, Protection of Human Subjects. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

<sup>22</sup> *Id.*

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<sup>23</sup> *Id* (citing Margaret A. Berger and Aaron D. Twerski, Uncertainty and Informed Choice: Unmasking *Daubert*, 104 Michigan L. Rev. 257, 270-72 (2005)).

<sup>24</sup> *Id*, at 6 (citing Hondroulis v. John Schumacher, M.D., 521 So. 2d 534 (1988)).

<sup>25</sup> *Id*, at 7 (citing Pennick v. Chritensen, M.D., Pfizer Hospital Group, et al. 912 S.W. 2d 276 (1996)).

<sup>26</sup> Regulations, *supra* note 5, at 75624.

<sup>27</sup> *Id*, at 75625.

<sup>28</sup> *Id*.

<sup>29</sup> *Id*.

<sup>30</sup> Leone, Dan, “Virgin Galactic Granted License Exemption for Spaceflight Experience,” *Space News*, April 11, 2012, <http://www.spacenews.com/article/virgin-galactic-granted-license-exemption-spaceflight-experience>.

<sup>31</sup> Human Space Flight Requirements for Crew and Space Flight Participants, 71 FR 75616 (2006-12-15) <http://www.gpo.gov/fdsys/pkg/FR-2006-12-15/pdf/FR-2006-12-15.pdf>

<sup>32</sup> *Id*.

<sup>33</sup> Chris Kunstadter and Russ McMurry, “Business/Legal Working Group Outbrief” (May 15, 2013) (*available at* [http://www.faa.gov/about/office\\_org/headquarters\\_offices/ast/advisory\\_committee/meeting\\_news/media/2013/may/business\\_legal\\_working\\_group\\_outbrief\\_chris\\_kunstadter.pptx](http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/meeting_news/media/2013/may/business_legal_working_group_outbrief_chris_kunstadter.pptx)).

<sup>34</sup> 51 U.S.C. § 50901(b)(5)(A).

<sup>35</sup> *Id*, at § 50914(c).

<sup>36</sup> *Id*, at § 50914(a)(2).

<sup>37</sup> Regulations, *supra* note 4, at §460.45(a)-(d).

<sup>38</sup> 14 CFR 460.45 (a), (1), and (2), “Operator informing space flight participant of risk.”