

## USP Commitment to Confidentiality

USP is an independent, standards-setting organization with nearly 200 years of experience working with expert volunteers and various stakeholders to facilitate the development and finalization of public standards. USP understands that third parties that seek to collaborate or partner with us on public standards possess data that they consider to be proprietary and confidential.

USP has significant experience with the receipt and protection of confidential information. To address the concerns typically covered in confidentiality agreements, USP has established policies and procedures that provide the highest safeguards to confidential information submitted by third parties. These policies and associated handling procedures represent best practices employed by USP to protect third party confidentiality while facilitating development and finalization of a public standard. Due to these safeguards, USP does not generally enter into confidentiality agreements with individual companies.

USP's overarching organizational policies are found in our [Code of Ethics](#), which applies to our staff and volunteers. These policies reflect our strong commitment to confidentiality and are implemented through specific rules and procedures as described below.

### Confidentiality Policy

Our Confidentiality Policy ([USP Code of Ethics, pages 12-13](#)) requires the following individuals to maintain the confidentiality of all information designated as such by a third party:

- USP Board members ([Rules of Business Practice for the 2015-2020 USP Board of Trustees, sec. 2.03](#))
- Expert volunteers, namely:
  - Expert Committee members ([Rules and Procedures of the 2015-2020 Council of Experts, sec. 2.06\(a\) and \(b\)](#))
  - Expert Panel members, where confidentiality is required ([Rules and Procedures of the 2015-2020 Council of Experts, sec. 2.06\(b\), 5.05\(b\)](#))
- Government liaisons<sup>1</sup> ([Rules and Procedures of the 2015-2020 Council of Experts, sec. 6.02](#))
- USP staff (Employee Handbook)

USP Board members, expert volunteers, and government liaisons must sign confidentiality agreements reflecting these obligations and requiring them to safeguard any and all information deemed confidential.

### Classification and Handling of Confidential Information

Third party information is presumed confidential unless otherwise indicated by USP staff. USP is a secured facility, and staff use best practices in the secure storage of confidential information on our network. Further, confidential information is clearly marked as such in the limited cases in which such information is shared (e.g., in materials shared with USP expert volunteers). Expert volunteers are requested to receive and send any confidential electronic

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<sup>1</sup> Government liaisons are representatives from the U.S. Food and Drug Administration (FDA) or other federal or state governmental agencies in the U.S., or from government agencies in other countries. They participate in USP's standards-setting process, but do not vote on USP standards.

communications from a private email address, not shared with or accessible to their employer or any other third party ([Rules and Procedures of the 2015-2020 Council of Experts, sec. 2.06\(a\)](#)).

### **Document Disclosure Policy**

USP protects third party confidential information to the fullest extent permitted by law. USP staff begins every expert meeting by reminding our expert volunteers and government liaisons of their confidentiality obligations. Under our Document Disclosure Policy ([Document Disclosure Policy; Code of Ethics, pages 7-8](#)), we do not release confidential information to requesting parties.

USP's confidentiality policy and procedures do not apply when a third party's information is required to be disclosed by law, regulation, rule, act or order of any governmental authority or agency, such as identifying country of origin on USP reference materials ([USP Guideline for Submitting Requests for Revision to USP-NF General Information for All Submissions, Part C](#)). Nevertheless, we are committed to pursuing reasonable efforts to protect third party confidential information even when faced with a compelled disclosure request.

### **Intellectual Property Policy**

There are many types of data protected by third party intellectual property rights that USP does not need to access for the purpose of developing a public standard. For instance, we rarely need access to information about patented manufacturing technologies or product formulations. Before submitting sensitive information to USP, we recommend working with a USP staff contact to narrow down the data set such that you will not need to disclose any more confidential information than is absolutely necessary to meet the goals of your collaboration or partnership with USP.

Under our Intellectual Property Policy ([USP Guideline for Submitting Requests for Revision to USP-NF General Information for All Submissions, Part C; Code of Ethics, pages 19-20](#)), USP respects intellectual property rights and uses its best efforts to adhere to all applicable laws regarding protection of intellectual property. However, USP is not responsible for the protection or enforcement of intellectual property rights in the U.S. and elsewhere. Additionally, because USP's standards are intended to be public standards available for the use and benefit of all parties, USP requests that third parties disclose whether any portion of the data shared with us is subject to patent or other sponsor-held intellectual property rights.

In cases where patented methods, procedures or materials required for compendial tests and assays are proposed, USP may seek assistance from the sponsor in obtaining clearance or license for use by any persons seeking to use or apply a USP public standard incorporating such method, procedure or material, and may consider other approaches to avoid publishing a public standard that includes material protected by third party intellectual property rights. USP reserves the right to indicate in a resulting public standard whether methods or procedures are subject to third party intellectual property rights.