

Huntington Study Group (“HSG”) Conflict-of-Interest Guidelines and Disclosure Requirements

In the form of Frequently Asked Questions (FAQs)

This document provides details about the conduct and conflict-of-interest disclosure requirements for all those involved in clinical trials, research, studies, initiatives, or other projects with HSG or its wholly owned subsidiary HSG Clinical Research, Inc. (“HSGCR”). For purposes of these FAQs, we will refer to HSG and HSGCR together as “HSG”. The same requirements will apply to you notwithstanding if HSG or HSGCR is the contracting party.

HSG requires that all individuals working for, with, or on behalf of HSG on clinical trials, studies, projects, initiatives, or any other effort sponsored by or affiliated with HSG, maintain the **highest degree of integrity and level of personal and professional standards of conduct, including disclosure of potential conflicts as described in this policy.**

It cannot be emphasized enough –conflicts are not inherently wrong or bad. Having a conflict does not necessarily mean that there has been or will be bias. However, **all conflicts must be disclosed.** It is **your responsibility** to self-report all conflicts. Action(s) can often be taken to ensure conflicts are properly managed.

This document contains information related to business, scientific and other conflicts as described below. There is a separate policy for directors and officers and a limited group of employees regarding certain fiduciary conflicts of interest. That policy relates to a specific universe of conflicts that are regulated by New York law. If that policy applies to you, you will receive a copy of that policy. There is a common disclosure form for both policies and there is a separate disclosure form for study-related conflict disclosures.

Please read all of the information below and reach out to Kristin Keyes (kristin.keyes@hsglimited.org) if you have any questions.

What is the purpose of the HSG Conflict of Interest (“COI”) Guidelines and Disclosure Requirements (the “Guidelines”)?

- The purpose of the Guidelines is to make our Conflict of Interest and Disclosure Requirements and processes as clear and easy as possible for everyone to understand and follow.

Who do the Guidelines apply to?

- These Guidelines apply to all individuals, including HSG members, working for, with, or on behalf of HSG. For the purposes of this document, we will refer to such individuals as **“Involved Persons.”**
- For example, these Guidelines apply to you **and define you as an Involved Person** if:

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You are working on an HSG clinical trial, study, project, or initiative in any capacity (individually or through your employer), **AND one or more of the following apply to you:**

1. You are working on an HSG clinical trial or study that HSG is conducting under an agreement with a pharmaceutical company or other organizational sponsor, **and/or**
2. You are working on a project or initiative that is under an agreement or business arrangement between HSG and an organization or entity, **and/or**
3. You are an HSG director, officer, employee, Executive Committee Chair, Co-Chair, or Member, Advisory Council Chair, Co-Chair, or Member. (As described above, directors officers and certain employees are also subject to the rules and processes described in HSG’s Fiduciary Conflict of Interest Policy.)

What if I’m not sure if these Guidelines apply to me?

- If, after reading this document, you are not sure if these Guidelines apply to you, please contact Kristin Keyes at kristin.keyes@hsglimited.org.

What is a Conflict-of-Interest for the purpose of these Guidelines?

- A conflict-of-interest occurs when an HSG Involved Person is participating in an HSG activity with an entity with whom HSG has a contractual and/or business relationship (for the purposes of this document we will use the term “Involved Company” to describe such entities) **and** has a separate nonfinancial relationship with that Involved Company. This relationship may conflict with the service of the individual because (i) it could significantly impair the individual’s objectivity, or (ii) it could create an unfair competitive advantage for any person or organization.
- Examples of a conflict-of-interest resulting from a personal financial and/or nonfinancial interest at HSG are as follows:
 - An involved person as a financial conflict-of-interest that must be disclosed if that person has a compensation arrangement with or an ownership interest in an Involved Company.
 - An Involved Person has a nonfinancial conflict of interest that must be disclosed if they have an arrangement with an Involved Company that could impact their career advancement or professional standing.

Why is HSG concerned about conflicts-of-interest?

- HSG has an ethical and professional responsibility to uphold and preserve scientific objectivity and integrity.

What are the duties of Involved Persons?

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- HSG Involved Persons participating in HSG clinical trials, research, studies, advisory councils, committees, working groups, projects, or other initiatives with HSG, **have a duty to act first and foremost in the best interests of HSG.**

What are some examples of the specific roles I may have as an HSG Involved Persons?

- Individuals participating in an HSG trial or study and are paid for their participation by HSG through their institution, such as principal investigator, site investigator, and coordinator are Involved Persons.
- Individuals participating in an HSG trial or study and are paid for their participation directly by HSG such as steering committee member, statistician, consultant, data safety monitor, and medical monitor are Involved Persons.
- Individuals serving on designated HSG advisory councils, committees, or working groups or involved in an HSG initiative. HSG staff will let you know if your work in these roles makes you an Involved Person and requires you to submit any conflict-of-interest disclosure forms.
- Again, you are an Involved Person if you are working for, with, or on behalf of HSG or in any way.

What conduct is expected by HSG Involved Persons?

- As an Involved Person, you have an obligation to conduct HSG trials and studies with the **highest degree of integrity and level of personal and professional standards of conduct, including disclosure of conflicts.**
- As an Involved Person, you must avoid relationships with Involved Companies that compromise your ability to act solely and objectively in the best interests of HSG.
- As an Involved Person, you must act in the public interest and be committed to educate the scientific and Huntington’s disease (“HD”) communities about new developments and progress in research and care.
- In carrying out these activities on behalf of the public interest and HSG, all HSG Involved Persons must take care to ensure there is no disclosure of confidential information or any other information that has the potential to jeopardize the successful outcome of any clinical trial or other research in progress at HSG.

What is an Involved Company?

- An Involved Company is a company that has a relationship with or is working in any capacity with HSG. This includes, but is not limited to, companies involved in clinical trials or companies that have arrangements with HSG such as master services agreements and consulting agreements.

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How do I know if a company is an Involved Company?

- Is it **YOUR** responsibility to understand the relationships you have with companies and whether they are involved with HSG.
- If you are unsure whether a company you have a relationship with is an Involved Company, please contact Kristin Keyes at kristin.keyes@hsglimited.org.

Why do I have to disclose the agreements or arrangements that I have with an Involved Company?

- To allow HSG to identify and manage the risks of an Involved Person, who is required to act in the best interests of HSG, but who also has an incentive to act in the best interests of an Involved Company, and these sets of “best interests” might conflict.
- To protect the scientific integrity and objectivity of all the work and activities of HSG.

What conflicts-of-interest must be specifically disclosed to HSG under this policy?

- Involved Persons must disclose any financial and nonfinancial arrangements from their participation in or knowledge of HSG trials, research, and studies that are in progress.
- Involved Persons must disclose any financial or nonfinancial arrangements received from an Involved Company **by Involved Persons and their immediate family members, including spouses, children, and parents.**

How long does the conflict-of-interest last?

- The conflict lasts until the earlier of:
 1. The publication of the primary, peer-reviewed manuscript, or
 2. When the trial or study steering committee determines that there will be no publication (this only applies if you are working on an HSG trial or study), or
 3. When you are no longer an Involved Person.

Who reports on whether I have a conflict-of-interest?

- **You** must self-report all conflicts. HSG staff will provide you with the appropriate disclosure form on which you must disclose all conflicts of interest that you have or foresee having with an Involved Company.
- Regardless of which form(s) apply to you and at what point you are asked to complete the form, **YOU** are ultimately responsible for disclosing all of your conflicts immediately. To report a new conflict, reach out to the individual(s) at HSG with whom you are working and request a new COI form.

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When must I report on whether I have a conflict-of-interest?

- Involved Persons are required to fill out the disclosure form annually as initiated by HSG staff AND at any point during the year at which the Involved Person’s conflicts change.
- If Involved Persons develop a new relationship with a company that is currently involved with HSG, or if Involved Persons have an existing relationship with a company that becomes involved with HSG, you must update your disclosure form with this new information.

Why is there a separate policy on fiduciary conflicts for directors, officers, and certain employees?

- New York non-profit law regulates a specific universe of conflicts involving directors, officers, and certain senior employees. HSG has established separate rules for these conflicts based on New York and IRS rules.

What is a disclosure form?

- A disclosure form is a document that must be filled out by all Involved Persons. It is used to report all conflicts of interest.

Where do I get the disclosure form?

- HSG staff will provide the disclosure form to you.

How much information do I need to disclose?

- Involved Persons must disclose all financial and nonfinancial sources of support from all Involved Companies.

What happens if I do not disclose a conflict?

- Failure to disclose a conflict of interest is a serious violation of these Guidelines and may lead to dismissal from HSG.

Who reviews my disclosure form?

- Each study’s Steering Committee reviews study-specific Conflict-of-Interest forms.
- The Board of Directors, or a designated committee or department thereof, may also review completed disclosure forms.

What does the reviewing body do with the disclosure form?

- The reviewing party examines all submitted forms to determine if the disclosed conflicts are acceptable to HSG.

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- If the reviewing body determines that the disclosed conflicts are acceptable, the disclosure form is filed and added to the COI tracking list to be updated annually. You as an HSG Involved Person, must keep HSG informed of any changes to the arrangement in the interim until the next annual review.
- If the reviewing body decides that there is potential conflict from the disclosure conflict, it may request more information about the arrangement and initiate further discussion with the HSG Involved Person directly.

If, after collecting all relevant information about the conflict from the Involved Person, the Involved Company, and any other relevant sources of information, the reviewing party determines that the conflict(s) is/are not acceptable, what are the potential outcomes?

- The reviewing body may work with the Involved Persons to determine if the arrangements or relationship can be restructured to minimize or avoid actual or potential conflict.
- If the reviewing body determines that the conflict cannot be avoided, the Involved Persons may be asked to suspend or terminate the activities giving rise to the actual or potential conflict.

For clinical trials, the FDA has specific disclosure requirements based on certain financial thresholds. You are required to abide by the FDA’s requirements, as well as by HSG’s requirements that HSG Members disclose all financial and nonfinancial benefits and investment interests regardless of the financial threshold.

The disclosure of any specific conflict of interest does not mean the HSG Involved Person is automatically prohibited from participating in the activities giving rise to that conflict.

I, _____, hereby attest that I have read this document in its entirety, that I fully understand its contents, and agree to act in accordance with it from this date forward.

Signed

Date