



HESI eSTAR Committee Best Practices

The HESI Emerging Systems Toxicology for Assessment of Risk (eSTAR) Committee leadership propose the following policies to help clarify committee practices and enhance the efficiency of the Committee operations.

1. Committee Leadership

A. Volunteer Co-Chairs

- Committee to be led by volunteer Co-Chairs. At least one chair will be from the public sector (academe, government, NGO, research institute) and one from the private sector (two public sector chairs is acceptable but not preferable).
- Committee Chairs work with the HESI scientific management staff to provide scientific, strategic, fiscal, and organizational coordination and leadership for the Committee as a whole. Committee Chairs may be asked to serve as spokespersons for the Committee at scientific meetings/workshops and/or in the context of HESI organizational activities.

Process

- Chairs will serve 3-year staggered terms with potential for renewal.
- Incoming Chairs will serve a one year 'vice chair' role to gain experience in the position. After that one year, one of the two sitting Chairs will rotate out of leadership and the Vice-Chair will serve with the existing co-chair.
- Chairs and Chair Elects may be nominated by Committee members, themselves, or staff. Elections will be held via electronic ballot of the committee.

B. Steering Team

- The Committee Steering Team is a collaborative leadership group that helps to achieve the following goals:
 - Ensure communication and synergy across ongoing workstreams within the Committee;
 - Evaluate overall progress towards the Committee mission;
 - Align available resources within the Committee against current or future projects;
 - Serve as an advisory/evaluative body for potential adoption of new WGs or projects; and
 - Promote cohesive and broad communication of the Committee's impact.
- The Steering Team is comprised of all Work Group (WG) leaders, the Committee Chairs, and HESI Staff members supporting the committee. Additional invited experts, including Past Committee Chairs, may be invited to join the Steering Team at the discretion of the current Chairs. WG leaders are expected to report WG progress to the steering team during all scheduled steering team calls and meetings and at annual face to face meetings. To the extent possible, Steering Teams should reflect HESI's commitment to balanced public-private input and participation.
- The Steering Team will meet quarterly via teleconference.

C. *HESI Scientific Program Management Staff*

- HESI's scientific management staff are critical contributors to a Committee's program coordination, stewardship, outreach and communications, resourcing, strategic and scientific design.
- Scientific management staff participate and support all official Steering Team, Committee Work Group, and full Committee work, calls and meetings.

2. **Launching New Scientific Projects and/or New Work Groups (WG)**

General

- WGs allow a Committee to fulfill its mission via the conduct of scientific program work in the form of focused research teams. These teams may conduct *de novo* experimental work, build databases, perform data analyses, develop decision-frameworks and methodology, and/or conduct training and outreach. WGs cover a range of topics of interest to committee participants across sectors (*i.e.* public, private, pharmaceuticals, chemicals, consumer products, etc.).
- Tripartite sector participation is an integral and mandatory component of all HESI programs. All program work is supported and coordinated by HESI management staff.
- The adoption of new initiatives requires strong interest by Committee members, commitment of in-kind and/or financial resources by Committee members to support the proposed study, and sufficient management and coordination resources at HESI. New projects may fall under the auspices of an existing WG or may merit the formation of a new WG.
- **All new proposals should be considered by the Committee Steering Team (and/or full Committee when feasible) as the resources of the program are finite and the adoption of new work streams should be evaluated strategically.**

Criteria for Evaluation

New projects and/or WGs will be evaluated on the following criteria:

- *Scope.* Projects will be assessed for clear alignment with the committee's mission.
- *Anticipated impact of the topic on practice.* Desired areas of impact include (a) promoting efficient and accurate risk assessment; (b) improving the use of systems toxicology to enhance translational or predictive capabilities; and (c) catalyzing impactful and efficient technologies. Projects with the potential to directly impact 'day to day' practice of science will be viewed favorably.
- *Novelty of the topic.* If other scientific groups, workgroups or institutes are working in the same area then the proposal must demonstrate that the proposed efforts will be synergistic, novel, or address an unmet need.
- *Clarity of the proposal.* The proposal should adequately specify the design, resourcing, and anticipated outcome of the project.
- *Potential for success.* The program should have a high likelihood that it will achieve its stated objectives given available time and resources.
- *Resource availability.* Project feasibility will be evaluated in relation to the anticipated direct and indirect resource contributions from the committee members (or other partners), impact on the completion of other ongoing or planned projects within the committee, and overall budget and resourcing for program management.

Process for Launching New Projects

- To propose a new project within an existing WG

- Informal brainstorming/discussion around new project themes and emerging science frequently occurs in the context of working group teleconferences and other interactions among working group members.
- If committee members wish to more formally propose a new project that fits within the scope of an existing WG, they are encouraged to complete a new project template.
- The new project proposal template is a brief two-page (maximum) document that captures key objectives, stakeholders, resources, and impact of the proposed topic. Once completed, this document can be shared with the WG for consideration – proposed leadership and core membership should be identified in the proposal but may be modified as the project progresses;
- If the WG is supportive of the new proposal, the HESI staff will assist in distributing the proposal to the full Committee with a request for input/comment on the content and approach. The proposal, and any critical input elicited from the Committee outreach, should then be submitted to the Steering Team for consideration. The Steering Team may
 - Offer their support for adoption of the proposal within the WG and thus the proposal will be enacted; or
 - Recommend that the topic moves for more extensive discussion by the full Committee to assess whether the topic is impactful for the Committee's portfolio and merits the use of Committee resources; and/or
 - Recommend additional topic/proposal development and refinement for future consideration; or
 - Recommend that the project not be adopted.
- To propose a new WG
 - If a new project concept does not align with an existing WG, members may propose the formation of a new WG.
 - If committee members wish to more formally propose a new project, they are encouraged to complete a new project template.
 - The new project proposal template is a brief two-page (maximum) document that captures key objectives, stakeholders, resources, and impact of the proposed topic.
 - Proposed new WGs must clearly define their scientific aim and a 1-2 year action plan with proposed milestones and deliverables that supports initiation of the WG.
 - Once the proposal is drafted, the HESI staff will assist in the distribution of the proposal to the full Committee.
 - In parallel with submission of the proposal, HESI staff will assist in scheduling a presentation of the proposal by the authors to the full Committee by webinar or at the face to face meeting.
 - Following presentation and review of proposal, Committee members will provide general input/comment on the content and approach.
 - The proposal, and any critical input elicited from the Committee outreach, should then be brought to the Steering Team for consideration.
 - Upon review, the Steering Team may:
 - Offer support of the proposal and disseminate to the full committee membership to request engagement in the proposed WG and to assess level of interest in participation; and/or
 - Recommend more extensive discussion to determine whether the topic is sufficiently impactful for the Committee's portfolio, and to assess whether there is sufficient interest and resources within the Committee; or

- Recommend additional that the proposal needs further development and refinement, and should be reconsidered in the future; or
- Recommend that the project not be adopted.

3. Work Group Leadership/Membership

General

- WGs are populated by members of the Committee. Committee members may opt to participate in any or all of the WGs.
- Each WG should preferably have two co-leaders, one from the public sector and one from the private sector. All WG leaders are de facto members of the Committee Steering Team and will be expected to report progress to the steering team during all scheduled steering team calls and meetings.
- Active participation on a WG is defined as regular engagement in WG teleconferences and/or meetings and providing technical and strategic input and perspectives during the WG's ongoing scientific discussions. It may also include contributing directly to experimental research, data analysis, writing, and/or communicating on behalf of the WG.
- A WG should consist of at least one lead, and at least 5 additional active (core) WG members.
- Progress reports/updates and all other products, including manuscripts, discussion papers, etc. will be available for all eSTAR Committee members via a shared internet workspace (password-protected SharePoint site).

Committing to Work Group Participation

- Members may choose to participate as Core Team members of a WG or as Affiliate members.
- Core WG Members: Participation as a core team member requires a commitment to active and routine participation on calls, meetings, and ongoing research of the team in support of the goals of the WG. Core Team members must be able to commit to making the time for active and substantive work in support of the WG's objectives. These contributions may include direct experimental or analytical work, but can also take the form of providing scientific leadership, contributing actively to technical and strategic discussions, and/or actively conducting outreach on behalf of the team. The Core WG Members are responsible for maintaining the WG action plan and timelines.
- Affiliate WG Members: Committee members may choose to align with a WG as an affiliate member. Affiliates will receive information about teleconferences, meetings, etc. and are anticipated to engage in advisory roles and as occasional contributors.
- At least once annually, HESI staff will poll the Committee members to determine their preferred status for each WG. There is no limit to WG participation and a member's status may differ (Core Team or Affiliate) for different WGs. Members may also join a WG or change status at any time by notifying the WG leads and HESI staff.

4. Travel Reimbursement for Committee Activities

- On an annual basis, the Committee approves a budget that includes limited funding to support selected public-sector scientist travel expenses associated with their active participation in essential Committee-sponsored/supported activities;
- In general, public sector WG leaders and Chairs should anticipate that funding will be available to cover travel/lodging expenses associated with their participation at the committee's annual meeting (in accordance with HESI travel reimbursement policies). These individuals may also be eligible for funding to participate in other Committee-supported events where

their participation is required to meet Committee goals. Other core WG members may also be eligible for funding support if resources are available and prioritized for this purpose.

- The availability of funding to cover travel for other invited speakers, guests to Committee-supported scientific sessions will be a function of available budget and at the discretion of the Committee leadership with counsel from the HESI program management staff.