

Johns Hopkins faculty and other Johns Hopkins personnel whose inventions may be licensed or optioned to startup entities often have questions about applicable Johns Hopkins University and Johns Hopkins Medicine policies and procedures regarding participation in JHU activities related to the startup, especially regarding the ability to conduct research that may relate to the licensed IP or the startup. As an inventor of technology licensed to a startup, you should be aware of the items below and address them as early as possible, especially if you are engaged in or plan to propose any research, regardless of the funding source.

The guidance below also applies to Johns Hopkins faculty and personnel who are founders or have other financial interests in startups, even if they are not inventors. Complying with these policies and procedures can be complex and is an ongoing process. You are urged to contact the offices listed below with any questions.

1. IMPORTANT TOPICS FOR FACULTY AND OTHER INVENTORS WHOSE IP IS LICENSED TO STARTUPS

License Negotiations with the Startup

- Johns Hopkins Technology Ventures (JHTV) is the JHU office that negotiates licenses to JHU intellectual property.
- Please refer to ventures.jhu.edu for more information about licensing JHU IP.
- Please note that JHU personnel who have financial interest in a startup may not be involved in or try to influence business negotiations between JHU and the startup. Instead, a member of the startup who has no ties to JHU or JHHS must negotiate the license with JHTV. The JHU personnel must also recuse themselves from related purchasing decisions.

Sponsored Projects and Collaborative Research

- The following offices negotiate sponsored research agreements (SRAs) of all types for JHU faculty projects, including basic science, pre-clinical, and clinical research: School of Medicine - [Office of Research Administration](#); all other divisions - [Johns Hopkins University Research Administration \(JHURA\)](#).
- Startups can support research at JHU directly with their own funds or can apply for certain governmental programs such as SBIR or STTR grants, where the award is paid to the startup and then may flow down to JHU under a contract subject to the program's terms and conditions.
- In certain circumstances, the School of Medicine may accept a reduced overhead rate for preclinical research funded by qualifying startups. Please contact the appropriate research administration office to learn whether this option is available.
- Inventors may have conflicts of interest related to research supported by a startup, so a non-conflicted investigator may be required for such projects. (See **Conflict of Interest** section below.)

Material Transfer Agreements (MTAs)

- Materials may only be transferred to an outside entity under a material transfer agreement (MTA). When the transfer relates to a sponsored research agreement signed by ORA, the MTA must be signed by the ORA or JHURA, depending on the school in which the responsible faculty member has a primary appointment. When the transfer does not relate to a sponsored research agreement signed by ORA or JHURA, the MTA must be signed by JHTV.
- Terms regarding material transfer may be included within a comprehensive SRA.
- Human biospecimen samples may only be transferred in compliance with the Johns Hopkins Medicine Biospecimen Transfer Policy and in furtherance of an academic research collaboration between JHU and the requesting entity. Agreements for a research collaboration involving the transfer of previously collected human samples should be generated by the research administration office responsible for the school in which the requesting faculty member has a primary appointment.
- Generally speaking, specimens are only shared with commercial entities as part of a research collaboration conducted under an SRA. As such, the terms regarding specimen transfer are usually included as part of a comprehensive SRA; in such cases, a separate MTA for the specimens is not needed.
- To request a transfer of human biospecimens, please refer to the JHM policy on [Transferring Human Biospecimens to Outside Organizations](#).

Human Subject Research/IRB Issues

- All activities that qualify as human subjects research must receive prospective approval by a JHU Institutional Review Board (IRB).
- IRB approval is contingent upon the review and management of any investigator or institutional conflicts of interest. The IRB is charged with ensuring any conflict of interest (COI) management provisions related to the study (e.g. formulation of an independent data and safety monitoring board (DSMB) and disclosure of conflicts in the consent form for participants) are implemented before the study is approved or promptly upon identification of a new conflict during the course of an existing study.
- Investigators who have financial interests related to a human subjects study must identify the interests when they agree to participate in the study within the electronic IRB application. Under COI and IRB policy, investigators with certain significant financial interests that relate to the human subjects research may be limited in their roles in the research. For example, they may be barred from serving as principal investigator (PI) or serving as investigational new drug application/investigational device exemption holder (IND/IDE holder) for technology in which the startup has an interest. Conflicted faculty members may also be limited on obtaining consent, evaluating participant eligibility or assessing safety events.
- When human subjects research is conducted in collaboration with a start-up or company that has licensed the technology, individuals at that company who propose to engage in human subjects research must seek their own IRB review or request to rely on the JHM IRB for the proposed research. Additional guidance is available:
 - [Office of Human Subjects Research - Institutional Review Board](#)
 - [Institutional Review Board](#)
 - [Homewood Institutional Review Board](#)

Transfer of Data/Data Trust/Data Use Agreements

- Data may be shared with third parties in order to advance the University's nonprofit mission.
- The preferred mechanism for sharing data is through a collaborative research arrangement, without transfer of ownership and with data use limited to the proposed collaborative research. Various offices at JHU are involved in the review of proposed sharing of JHU data with third-party entities. Depending on the data type, this may include JHTV; research administration offices (ORA or JHURA); for human subjects data, the Institutional Review Boards; and for JHM patient data, the JHM Data Trust
- Requests by third parties (including startups) to receive JHM human subject research data must be reviewed by the relevant JHU Institutional Review Board. If the request includes patient data or JH plan member data, JHM Data Trust review may also be required. JHM data may not be shared for purely commercial purposes, and the JHM Data Trust may require that data be accessed within the JHM secure environment.
- The Data Trust may choose not to release data for research to evaluate a commercial product if the faculty member serving as PI has significant financial interests in the commercial product. The conflicted faculty member may serve in other roles on the study team.
- Once a faculty member/investigator leaves JHU, access to protected health data is limited to IRB-approved research collaborations. Such collaboration requires a Data Use Agreement approved by the Office of Research Administration as well as IRB approval of the departing faculty member's new employer or a reliance agreement with the SOM IRB. Review more information on [processes for departing faculty members here](#).
- Guidance on [research collaborations is available here](#).

Conflict of Interest/Conflict of Commitment/Office of Policy Coordination (OPC)

- Faculty members and investigators conducting research at and under the auspices of the university are required to [disclose their outside activities and interests](#), including financial and fiduciary interests in startup companies and licensees for institutional review. Faculty members who propose to have roles as advisors, consultants, officers, or board members in startup companies must disclose these activities as well. They will be reviewed for potential conflict of interest and conflict of commitment.
- Disclosures should be made as early as possible, even before a license agreement with the startup is finalized.
- All disclosures must be submitted electronically via the online disclosure system, JHU [eDisclose](#).
- For additional information, SOM inventors may contact policy@jhmi.edu. KSAS and WSE inventors should contact HCOI@jhu.edu. SPH inventors should contact mschakne@jhu.edu.
- Outside activities and financial interests are reviewed by the Dean's office of the faculty member's primary appointment and by the Dean's office where any related research takes place.
- Acceptance of outside financial interests or outside activities may limit the ability of a faculty member to conduct research at the university.
- For additional information, review our [Overview of Outside Interests webpage](#).

Use of Johns Hopkins Facilities/Equipment

- Johns Hopkins facilities (labs, conference rooms) and equipment may not be used by startup companies or faculty inventors, founders, or consultants acting on behalf of startup companies. Rare exceptions may be granted only if there is a formal written agreement between JHU and the company.
- Off-campus startup lab and office facilities can be leased through [Johns Hopkins Technology Ventures](#).

Involvement of Trainees, Lab Members, and Other Employees

- In some cases, students or trainees are inventors of technology that is licensed to a startup company.
- Students, trainees, and employees must disclose their licensing-related financial interests via eDisclose if they are participating in research at Johns Hopkins that relates to the licensed technology.
- Faculty inventors may not recruit students, trainees, lab members, or other employees who are not inventors of the licensed technology to work in their startup companies.
- [Disclosure requirements for specific affiliations and roles are set forth here](#).

Purchase, Testing or Other Implementation of Invention at Johns Hopkins Facilities (including the Johns Hopkins Health System)

- Johns Hopkins inventors must be recused from decisions, discussions, and voting on contracts and agreements between the Johns Hopkins University or the Johns Hopkins Health System and the startup company. This includes sponsored research agreements, license agreements, and purchasing or procurement agreements, among others. See, among other resources, the [JHM Policy on Interaction with Industry](#). For JHSPH, [visit here](#).
- Inventors may not introduce their licensed inventions into use or practice at any Johns Hopkins lab or other facility without independent review and decision-making regarding the needs of the unit and absent a formal agreement between Hopkins and the company.

Development/Fund for Johns Hopkins Medicine

- Philanthropic gifts in support of research may not be directed to specific projects with expected deliverables to the donor. If a company wants to support a specific research project with specific deliverables, the arrangement must be structured as a sponsored research agreement. [Visit here for details](#).
- If the donor of a charitable donation has a financial interest in research supported by the donation, an institutional or individual conflict of interest may exist. Conflicts of interest that result from charitable donations are managed in substantially the same manner as conflicts of interest that arise from other scenarios.

Publicity/Use of Name

- The name “Johns Hopkins” and related insignia, marks and logos are trademarked by Johns Hopkins University and the Johns Hopkins Health System. Generally speaking, third parties (including startup companies who license IP from JHU) are prohibited from using the Johns Hopkins name and other trademarks in advertising and promotional materials.
- The Johns Hopkins use of name policy applies to startup companies, including those in which JHU owns equity.
- Other proposed uses of the Johns Hopkins name and other trademarks must be reviewed and approved in advance.
- For more information about third party uses of the Johns Hopkins name, please refer to brand.hopkinsmedicine.org or brand.jhu.edu/use-of-name.

Studies Using Animal Subjects

JHU animal facilities are not designed to comply with FDA Good Laboratory Practice (GLP) regulations. Animal studies that a startup may want to submit to the FDA in support of drug or device studies may need to be conducted in an external facility that can certify GLP compliance.

2. CHECKLIST FOR INVENTORS WHOSE INVENTIONS ARE LICENSED TO STARTUPS

- Ensure that the startup has its own attorney or a non-JHU officer or other authorized representative to engage with JHU/JHTV on business issues related to the license.
- Promptly disclose through eDisclose any changes in your personal financial or fiduciary relationships with the startup
- Promptly identify in eDisclose whether you are involved in any existing or proposed research that may relate to the startup.
- Properly identify in COEUS whether existing or proposed research may relate to the startup.
- Properly identify in all relevant IRB applications whether existing or proposed research may relate to the startup.
- Refrain from involvement in discussions and negotiations regarding JHU or JHHS purchase of products or services sold by the startup.
- Refrain from involvement in discussions and negotiations regarding proposals for JHU to grant research sub-awards to the startup.

3. KEY CONTACT INFORMATION

» SCHOOL OF MEDICINE

- [Office of Research Administration](#)
- [JHM IRB](#)
- [Data Trust](#)
- [Office of Policy Coordination](#)

» WHITING SCHOOL OF ENGINEERING; KRIEGER SCHOOL OF ARTS AND SCIENCES; SCHOOL OF NURSING; SCHOOL OF EDUCATION; CAREY SCHOOL OF BUSINESS

- [Johns Hopkins University Research Administration \(JHURA\)](#)

» BLOOMBERG SCHOOL OF PUBLIC HEALTH

- [Johns Hopkins University Research Administration \(JHURA\)](#)

» JOHNS HOPKINS UNIVERSITY

- [Johns Hopkins Technology Ventures](#)
- [JHU Office of General Counsel](#)