



Policy Number HJF-604	Policy Owner: SVP, Program Operations	Initial Issue Date: October 23, 2018	Approved By: President & CEO	Revision Number: N/A	Revision Effective Date: N/A
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Scientific Publication Policy

1. PURPOSE

The purpose of this policy is to establish HJF’s scientific publication requirements in order to comply with applicable law and funding agreement provisions.

2. SCOPE

This policy applies to HJF, including its wholly or majority owned affiliates and subsidiaries. HJF personnel who manage HJF’s interests in HJF affiliates in which HJF is not the majority shareholder shall ensure that the entity adopts a policy that is substantially similar to this policy. Exceptions to this policy must be approved by the Chief Ethics & Compliance Officer, in consultation with the Legal Department and the Policy Owner.

3. DEFINITIONS

- 3.1. Publication – articles, abstracts, books, case reports, presentations at professional meetings and grant applications.
- 3.2. Corresponding Author – This person takes responsibility for the article or Publication. The Corresponding Author communicates with the journal and is responsible for getting approval from the other authors on the Publication.
- 3.3. Co-Author – A person that collaborates with the Corresponding Author and contributes to the Publication. Co-Authors and Corresponding Authors may be referred to in this policy together as “Authors”.
- 3.4. Acknowledgment – A section in the publication where the Author(s) can thank people that helped with the study/research, preparation of the Publications, or provided technical assistance and/or funding to the Author(s).
- 3.5. Disclaimer – A formal statement denying legal rights or responsibilities; in the context of Publications, this may include a statement that the opinions presented are those of the Author and not of any institution.

4. RESPONSIBILITIES

- 4.1.** The Office of Regulatory Affairs & Research Compliance (“Regulatory Affairs”) has primary responsibility for reviewing all Scientific Publications in which HJF employees are listed on the Publication as an Author.
- 4.2.** The Technology Transfer department is responsible for reviewing Publications that may disclose potentially patentable inventions or other HJF intellectual property.
- 4.3.** The Legal Department is responsible for transferring or assigning copyrights in any Publication. Per HJF’s Patent, Invention and Copyright Policy, Authors do not have authority to assign or transfer copyrights to any publisher.
- 4.4.** HJF Managers and supervisors are responsible for ensuring that this policy is implemented within their respective areas of business.
- 4.5.** All Authors are responsible for complying with this policy.

5. POLICY

5.1. Review of Publication

- 5.1.1.** Any employee that is listed as an Author on a scientific Publication must ensure that (a) he/she is identified as an HJF employee in the Publication (in addition to any other affiliations that may apply); (b) all contractually required Acknowledgments (such as funding Acknowledgments) are included in the Publication; and (c) any necessary Disclaimers are included.
- 5.1.2.** The Publication must have approval from the institution where the Author is located or where the work has been performed. The approving authority varies among institutions (i.e. Public Affairs, Clinical Investigations Department/Institutional Review Board, Department Chair, Dean/President, etc.).
- 5.1.3.** The Author must submit the proposed Publication and evidence of institutional approval to the HJF’s Office of Regulatory Affairs for HJF review and approval via email to HQ_Regulatory_Affairs@hjf.org. Such submission shall indicate whether the Publication includes potentially new or novel concepts, potential inventions, or other intellectual property.

5.2. Approval of Publication

- 5.2.1.** Regulatory Affairs will review the Publication, ensure affiliations are accurate, that any appropriate Disclaimers are included, and that approval from the institution has been received.
- 5.2.2.** If the Publication may include intellectual property disclosures, the Office of Regulatory Affairs will forward the Publication to the Technology Transfer office prior to approving the Publication.

5.2.3. Once approved by Regulatory Affairs (and Technology Transfer, if applicable), Regulatory Affairs will inform the Author of the approval status. If the Publication is for a scientific journal, Regulatory Affairs will direct the Author to the Legal Department for appropriate copyright assignment.

5.2.4. HJF's Legal Department will facilitate the transfer or assignment of copyrights, if applicable.

6. PROCEDURE

Detailed procedures, if applicable, are addressed separately in Standard Operating Procedures that may be issued from time to time in furtherance of this policy.

7. ENFORCEMENT

Failure by HJF employees to comply with this policy may result in disciplinary action up to and including termination of employment.

8. ATTACHMENTS

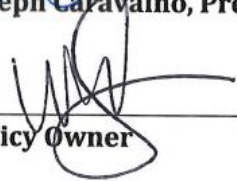
None

9. EFFECTIVE DATE

This policy is effective as of the date set forth above and supersedes all prior policies on the subject matter hereof.



Joseph Carvalho, President & CEO 23 OCT 18



Policy Owner 23 OCT 18