



Policy Number HJF-604	Policy Owner: SVP, Program Operations	Initial Issue Date: October 23, 2018	Approved By: President & CEO	Revision Number: 02	Revision Effective Date: February 12, 2019
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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 and to facilitate the expeditious submission of HJF authors' work for publication.

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 – Scientific articles, abstracts, books, case reports and presentations at professional meetings.
- 3.2. Corresponding Author – This person takes responsibility for the Publication. The Corresponding Author communicates with the publisher or 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 identify 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/agency.

4. RESPONSIBILITIES

- 4.1.** The Office of Regulatory Affairs & Research Compliance (“Regulatory Affairs”) has primary responsibility for reviewing all 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 include potentially patentable inventions or other intellectual property.
- 4.3.** The Legal Department is responsible for reviewing the transfer, assignment, or license of any HJF copyright in a Publication. Per HJF’s Patent, Invention and Copyright Policy, HJF Authors do not have authority to transfer, assign or license HJF copyrights to any publisher or journal.
- 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 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. Please contact HJF’s Office of Regulatory Affairs via email to regulatoryaffairs@hjf.org with any questions regarding these requirements.
- 5.1.2.** The Publication must be submitted to the institution/agency where the Author is located or where the applicable research was conducted, in accordance with the requirements of the applicable agreement.
- 5.1.3.** The Author or applicable program manager must submit the proposed Publication, together with (a) evidence of institution/agency approval, if required; and (b) a completed HJF Form 416 indicating whether the Publication includes potentially new or novel concepts, potential inventions, or other intellectual property, to HJF’s Office of Regulatory Affairs via email to regulatoryaffairs@hjf.org
- 5.1.4.** If institution/agency approval is required and is still pending at the time of submission to Regulatory Affairs, approval may nonetheless be issued, contingent upon receipt of the required approval. However, institution/agency approval must be submitted to Regulatory Affairs when received.

5.2. Approval of Publication

- 5.2.1.** Regulatory Affairs will promptly review the Publication, ensure affiliations are accurate, that any appropriate Disclaimers are included, HJF logos are included

(when applicable) and that any required approval from the institution/agency has been received.

5.2.2. If HJF Form 416 indicates that the Publication includes intellectual property, the Office of Regulatory Affairs will, upon receipt, 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 such approval. If the Publication is for a scientific journal that requires a copyright authorization, Regulatory Affairs will direct the Author to the Legal Department to facilitate the transfer, assignment, or license of copyright, as 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

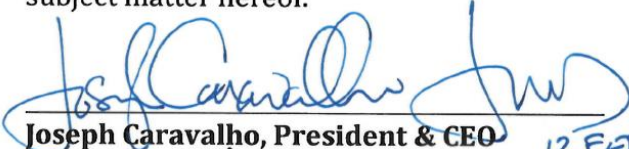
Failure by HJF employees to comply with this policy may result in disciplinary action up to and including termination of employment.

8. ATTACHMENTS

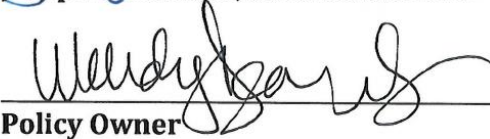
HJF Form 416 – Checklist Review of Research Results Prior to Public Disclosure

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 12 FEB 19



Policy Owner 12 Feb 19



Checklist Review of Research Results Prior to Public Disclosure

This form should be provided with all publications submitted to HJF Regulatory Affairs & Research Compliance for publication authorization. The following checklist will assist HJF in determining whether the Tech Transfer Department should review research findings for intellectual property considerations prior to public disclosure/publication.

Date of Submission to HJF: _____

Publication Title: _____

Contact Name: _____

Contact Phone: _____

Contact Email address: _____

Please check all that apply:

<input type="checkbox"/>	Does the publication contain results from a clinical trial in which data will be made publically available?
<input type="checkbox"/>	Has new software been developed that makes research easier?
<input type="checkbox"/>	Has a molecule/substance been shown to have unexpected results that impact a biological pathway involved in disease?
<input type="checkbox"/>	Has a device been developed which makes patient treatment better (i.e. quicker, more efficient, cheaper etc.)?
<input type="checkbox"/>	Has a diagnostic biomarker or set of biomarkers been identified which associate with a particular disease and/or disease progression?
<input type="checkbox"/>	Has a " biological tool " been developed (i.e. cell-line or plasmid) that might make research activities easier?
<input type="checkbox"/>	None of the above apply.

If you have any questions, please contact us at regulatoryaffairs@hjf.org or 240-694-2067.