Policy Number	Policy Owner:	Initial Issue Date:	Approved By:	Revision Number:	Revision Effective Date:
HJF-603	SVP, Program Operations	January 1, 1999	President & CEO	01	October 23, 2018

Scientific Misconduct in Research Policy

1. PURPOSE

HJF is dedicated to fostering and maintaining the highest standards and practices in scientific research conducted by its employees. As such, HJF employees have a duty and obligation to report any concerns they may have regarding an act or acts of scientific research misconduct.

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. **Complainant** (also known as the reporting party) – a person who makes an allegation of Research Misconduct.

3.2. **Inquiry** – information gathering and initial fact-finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

3.3. **Investigation –** the formal examination and evaluation of all relevant facts to determine if misconduct has occurred in accordance with HJF's Internal Investigation policy.

3.4. **Fabrication** – the making up of data or results and the recording or reporting them.

3.5. **Falsification** – the manipulation of research materials, equipment or processes, or the change or omission of data or results such that the research is not accurately represented in the research record.

3.6. **Institution –** the public or private entity, or organization (including federal, state, and other agencies) that is applying for financial assistance from a funding sponsor. The organization assumes legal and financial accountability for the awarded funds and the performance of the supported activities.

3.7. **ORI –** means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for research integrity and research misconduct issues related to PHS supported activities (e.g., grants, contracts, cooperative agreements or proposals).

3.8. **Plagiarism –**the appropriation of another person's or entity's ideas, processes, results or words without giving appropriate credit.

3.9. **Research Integrity Officer (RIO)** –the Institutional official that is responsible for assessing allegations of research misconduct, determining when the allegations warrant Inquiries, and overseeing the Inquiries and Investigations.

3.10. **Research Misconduct** – Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or honest differences in interpretations or judgments of data.

3.11. **Research Record** – means any record of data or results stemming from scientific inquiry, including but not limited to computer files, grants or contracts, laboratory notebooks; physical or electronic notes; correspondence; manuscripts and publications; animal research records; human/animal protocols; human research files (consent forms; case report forms, and patient research files).

3.12. **Respondent** (also known as the subject) **–** the person against whom an allegation of Research Misconduct is directed.

3.13. **Retaliation –** any adverse action taken against an employee in response to a good faith allegation of Research Misconduct.

4. RESPONSIBILITIES

4.1. The Director, Regulatory Affairs is the designated RIO for HJF and has the responsibility for implementation of HJF's policies and procedures on Research Misconduct. The RIO will inform the President & CEO, General Counsel, Chief Ethics and Compliance Officer, and the SVP, Program Operations of the report of misconduct and provide regular updates on the findings and progress. The RIO will seek assistance from other Investigational Leads (as such term is defined in HJF's Internal Investigations Policy) for assistance when needed.

4.2. The General Counsel, Chief Ethics and Compliance Officer and SVP, Program Operations will provide the necessary guidance and support to the Director, Regulatory Affairs during the Inquiry and/or Investigation.

5. POLICY

5.1. HJF is responsible for the quality and integrity of research conducted at and reported from all HJF departments and performance locations.

5.2. All employees having reason to believe that Research Misconduct may have occurred or is occurring must immediately report their concern to the Director, Regulatory Affairs.

An employee may also elect to report concerns anonymously using the HJF Ethics Hotline.

HJF Ethics Hotline: 1-866-687-2321
HJF Ethics Direct: 240-694-4004
Web Reporting: https://hjf.alertline.com

5.3. The employee is responsible for making all allegations in good faith and for cooperating with any Inquiry or Investigation, including complying with reasonable requests to maintain the confidentiality of the Inquiry or Investigation. HJF will comply with all state and federal "whistleblower" laws and laws that govern the protection of persons who make good faith allegations of Research Misconduct.

5.4. The Director, Regulatory Affairs will be the Lead Investigator (as defined in HJF's Internal Investigations Policy) and together with the Chief Ethics & Compliance Officer will assess the information presented to determine whether it constitutes alleged Research Misconduct as defined by this policy and if the allegation is credible.

5.5. If the sponsor of award or awards supporting the applicable research requires notification of Research Misconduct concerns being reviewed at the Inquiry or Investigation level, then that communication will be coordinated by the Director, Regulatory Affairs. Notification to the Institutional Official/RIO where the research is being conducted will also be coordinated by the Director, Regulatory Affairs.

5.6. A finding of Research Misconduct requires that there has been a significant departure from accepted practices of the relevant research community; the misconduct was committed intentionally, knowingly or recklessly and that the allegation has been substantiated following an Investigation.

5.7. The sponsor will be notified of the outcome of an Investigation as specified by the terms and conditions of any applicable award.

5.8. The Office of Research Integrity will be notified if allegations of Research Misconduct arise in connection with a PHS grant or involves PHS funding. (See PHS Final Rule for Research Misconduct is 42 CFR Parts 50 and 93.) The notification to ORI will be made in writing by the Director, Regulatory Affairs.

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.