

1 **Policy Appendix II: Financial Disclosure Policies for the DRCR Network**

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4 The policy will be reviewed for potential revisions at least annually by the Executive Committee.

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6 **A. Financial Disclosure Policy Overview**

7 Based on U.S. Public Health Service regulations (42 CFR Part 50 Subpart F), the DRCR
8 Network has developed a policy to promote objectivity in research by establishing a policy that
9 provides a reasonable expectation that the design, conduct, and reporting of DRCR Network
10 research is free from bias resulting from investigator financial conflicts of interest. For the
11 purposes of this policy, the term “investigator” means any member of the DRCR Network who is
12 expected to disclose financial interests.

13 Investigators are expected to be discriminating in the selection of outside commitments in order to
14 avoid impairment of the Network’s reputation as a leading research entity within the ophthalmic
15 community. Investigators should avoid commitments that could compromise the basic scholarly
16 independence and freedom of action that are central to the Network.

17 Investigators at an institution without a Financial Conflict of Interest Policy that have elected to
18 follow the Jaeb Center for Health Research (JCHR) Financial Conflict of Interest Policy are
19 required to be trained on the JCHR Financial Conflict of Interest Policy. The DRCR Network
20 policy is consistent with and complimentary to the JCHR IRB Conflict of Interest Policy
21 (https://wiki.jaeb.org/SOP/index.php/Conflict_of_Interest). Training must occur no less than
22 every four (4) years and whenever the JCHR COI SOP is revised with major changes.

23 **B. Definitions**

24 **1. Institutional Responsibilities**

25 *Institutional responsibilities* refers to the responsibilities related to the investigators position.
26 These may include professional responsibilities such as teaching, consulting, research,
27 professional practice, institutional committee membership, and service on panels such as IRBs or
28 Data and Safety Monitoring Boards.

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30 **2. Significant Financial Interest**

31 A *significant financial interest (SFI)* consists of one or more of the following interests of the
32 investigator (or those of the investigator’s spouse and dependent children):

- 33 • With regard to any publicly traded entity, a *significant financial interest* exists if the
34 value of any remuneration received from the entity in the 12 months preceding the
35 disclosure and the value of any equity interest in the entity as of the date of disclosure
36 exceeds \$5,000.00. For purposes of this definition, remuneration includes salary and
37 any payment for services not otherwise identified as salary (*e.g.*, consulting fees,
38 honoraria, paid authorship); equity interest includes any stock, stock option, or other
39 ownership interest, as determined through reference to public prices or other
40 reasonable measures of fair market value.

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- With regard to any non-publicly traded for-profit entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000.00. A SFI also exists when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest) in a non-publicly traded entity.
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

49 In addition, an SFI exists whether remuneration is paid directly to the investigator OR to the
50 investigator's institution/legal entity on the investigator's behalf.

51 The term *significant financial interest* does not include the following types of financial interests:

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- Salary, royalties, or other remuneration paid by Jaeb Center for Health Research (JCHR) to the investigator if the investigator is currently employed or otherwise appointed by JCHR, including intellectual property rights assigned to JCHR and agreements to share in royalties related to such rights;
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Employee does not directly control the investment decisions made in these vehicles.
 - Income from seminars, lectures, or teaching engagements sponsored by
 - a Federal, state, or local government agency,
 - an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - an academic teaching hospital,
 - a medical center, or
 - a research institute that is affiliated with an Institution of higher education;
 - Income from service on advisory committees or review panels for
 - a Federal, state, or local government agency,
 - an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - an academic teaching hospital,
 - a medical center, or
 - a research institute that is affiliated with an Institution of higher education.

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73 **2. Financial Conflict of Interest**

74 A SFI is considered to be a *financial conflict of interest (FCOI)* if it could directly and
75 significantly affect the design, conduct, or reporting of research. See section D for DRCR
76 Network policy on avoiding FCOI.

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78 **3. Related Research**

79 *Related to DRCR Network research* means an entity that provides funding or support for DRCR
80 Network research or whose financial interest would reasonably appear to have the potential to be
81 directly or indirectly materially affected by the outcome or conduct of the DRCR Network
82 research DRCR Network. Examples include, but are not limited to, companies that hold patent
83 rights for discoveries, drugs or devices being studied in DRCR Network protocols or companies
84 that provide financial or in-kind support for research projects. This term includes companies that

85 compete with any companies that collaborate with the DRCR Network or compete with the
86 manufacturer of the investigational product, if the DRCR Network investigator knows that the
87 financial interests of such a company would reasonably appear to be affected by DRCR Network
88 research. This term also includes any entity acting as the agent of a financially interested
89 company (e.g., a contract research organization). If there is any ambiguity as to whether the
90 company is related to DRCR Network research, the company must be disclosed. In these cases,
91 by examining the company's business and the scope of research conducted by the DRCR
92 Network, the Network Chair and the Director of the Coordinating Center (or Executive
93 Committee, where applicable) will judge whether the investigator's interest is with a "financially
94 interested company".
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96 **C. Reporting Financial Disclosures**

97 **1. Personnel Required to Report**

98 All DRCR Network investigators, coordinators, committee members, and other individuals who
99 are responsible for the design, conduct, or reporting of research (e.g., collaborators or
100 consultants), are required to report financial interests according to this policy (note: throughout
101 the remainder of this document, wherever the term "investigator" is used, it also should be
102 considered as indicative of committee members and other individuals in the Network required to
103 report this information). Being *responsible for the conduct of research* is not the same as
104 performing a study procedure. For instance, a study staff member who conducts visual acuity
105 testing on a study participant is not considered an investigator. Financial interest of an
106 investigator's dependent(s), domestic partner, or spouse also must be disclosed.
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108 In general, clinical site staff other than study investigators and study coordinators are not
109 required to report financial interests according to this policy unless participating on a Network
110 committee (e.g., Writing Committee, Executive Committee, etc.).
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112 **2. Financial Interests to Disclose**

113 All significant financial interests (SFI) from an entity Related to DRCR Network Research must
114 be disclosed. Disclosure is required whether remuneration is paid directly to the investigator OR
115 to the investigator's institution/legal entity on the investigator's behalf. Relationships unrelated
116 to DRCR Network research do not require disclosure.
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118 **3. Frequency of Reporting**

119 Investigators are required to complete the DRCR Network financial disclosure form:

- 120 1) annually, each January,
- 121 2) within 30 days of discovering or acquiring (e.g. through purchase, marriage, or
122 inheritance) a new SFI or a substantial change to an SFI.
 - 123 • A substantial change is defined as when a previously reported SFI increases to a
124 higher category level defined as follows: \$10,000–\$19,999; amounts between
125 \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by
126 increments of \$50,000.

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129 IRB requirements for reporting SFI prior to initiation of a new protocol will be followed.

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131 **4. Disclosure Process Details**

132 Financial disclosures are completed on the DRCR Network study website Financial Disclosure
133 Form.

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135 Financial disclosures are made separately for the following categories:

- 136 • Prospective Clinical or Epidemiological Research Grant – a grant from the entity paid to
137 an organization for the conduct of a prospective clinical study or epidemiologic study that
138 receives IRB approval
- 139 • Basic Science Laboratory Research Grant - a grant from the entity paid to an organization
140 for the conduct of basic science laboratory research
- 141 • Other Research Grant – Investigator-initiated research not meeting criteria above that is
142 conducted for scientific or public health purposes and not considered Work for Hire for
143 the benefit of the company. A research grant in this category should be money that is
144 paid for a specific research purpose with the intent that the results will be reported in a
145 scientific publication. In general this research would be investigator-initiated, would
146 have a budget, protocol, statistical analysis plan, or similar document describing the
147 research and would receive IRB review with either IRB approval of the activity or
148 designation as exempt research.
 - 149 ○ Details (e.g., protocol, statistical analysis plan, IRB approval, or similar
150 document) of activities conducted in this category may be requested for
151 clarification of appropriate reporting.
- 152 • Professional Fees– monies paid to an individual or to an organization for services
153 rendered, including honoraria, royalties, or fees for consulting, lectures, speakers bureaus,
154 expert testimony, employment, board membership, office positions, or other affiliations.
- 155 • Patents (planned, pending, or issued)
- 156 • Stock/stock options
- 157 • Other including non-financial support –equipment, supplies, or anything else not covered
158 in the above categories.

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160 Any listing on Open Payments as a General Payment but not reported to DRCR.net as a
161 professional fee should be reconciled on request by revising the prior DRCR.net disclosure or by
162 submitting a written as to why the Open Payments reporting is incorrect.

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164 All classifications above are irrespective of whether receipt of the financial support is directly to
165 the investigator or to the investigator’s institution/legal entity. The investigator will indicate
166 whether he/she has equity in the institution/legal entity.

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168 Support paid to the investigator and support paid to the institution for research will be reported
169 within the following categories: \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$100,000 by
170 increments of \$20,000; amounts above \$100,000 by increments of \$50,000, a statement that a
171 value cannot readily be determined, or a statement that the value cannot be disclosed (e.g.
172 confidentiality agreement with entity). Only support that is an appropriate fee for service and not

173 another type of support or gift should be counted as support paid for research, otherwise the
174 value should be reported as not for research.

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176 **D. Managing Financial Disclosures**

177 Ultimately it is the responsibility of JCHR and the investigator’s institution, if the institution has
178 a FCOI policy conformant to 42 CFR 50 Subpart F, to manage financial interests; however
179 DRCR Network has developed a policy to avoid FCOI within the Network.

180 **1. Policy to Avoid Financial Conflict of Interest**

181 The DRCR Network policy on avoiding FCOI within the Network relates to non-research SFI
182 paid directly to the investigator or to the investigator’s institution/legal entity on the
183 investigator’s behalf in which the investigator has equity. The Executive Committee reserves the
184 right to assess all disclosures as to whether a potential FCOI exists. The Executive Committee
185 also reserves the right to confirm for each protocol if this policy is appropriate. The following
186 includes the DRCR Network policy on avoiding FCOI within the Network.

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- 188 • Investigators with a non-research SFI that exceeds \$20,000 with an entity related to
189 DRCR Network research are presumptively prohibited from enrolling more than 10% of
190 the study participants into an applicable DRCR Network study.
 - 191 • The principal investigator of the DRCR Network Coordinating Center and a Network
192 Chair are presumptively prohibited from having a non-research SFI with an entity related
193 to DRCR Network research.
 - 194 • Other members of the Operations Group are presumptively prohibited from having a non-
195 research SFI exceeding \$20,000 with an entity related to DRCR Network research.
 - 196 • No more than 50% of the members of the writing committee will have a non-research SFI
197 with an entity related to the work being conducted for the specific DRCR Network
198 research. No lead author on a DRCR Network manuscript will have a non-research SFI of
199 \$20,000 or more with an entity related to the work being conducted for the specific
200 DRCR Network research.
 - 201 • No more than 50% of the members of any protocol development committee should have
202 a non-research SFI with an entity related to the work being conducted for the specific
203 DRCR Network research. In addition, the Protocol Chair for a study is presumptively
204 prohibited from having a non-research SFI with an entity related to the work being
205 conducted.
 - 206 • Members of the Data and Safety Monitoring Committee are presumptively prohibited
207 from having a non-research SFI with an entity related to DRCR Network research for
208 which the DSMC is monitoring.

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210 The determination of whether a FCOI exists in certain instances can be a matter of judgment
211 involving all the facts of the situation. The Network Chair and Director of the Coordinating
212 Center will oversee review of potential FCOI. If the investigator disagrees with the management
213 plan proposed by the Network Chair and Coordinating Center Director, the investigator can
214 make an appeal to the Executive Committee, which will delegate review of the disclosure to a
215 sub-Committee of the Executive Committee. When necessary the sub-Committee will provide
216 final decisions on behalf of the Network.

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2. Investigator Options When a Presumptive Prohibition is Identified to Avoid a FCOI

If a presumptive prohibition is identified, to avoid a FCOI, the following are examples on how unique instances might be managed.

- Preclude participation in the design or reporting of the study
- Divestiture – allow arrangements to go forward contingent upon the sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a certain date
- Severance of relationships that heighten or create actual or potential conflicts – investigators may be required, as example, to relinquish a seat on a board of directors or terminate a consulting arrangement with an outside entity in order to reduce the financial or fiduciary conflict of interest

The Network Chair and Coordinating Center Director, or the Executive Committee members (when cases are overseen by the Executive Committee) may recommend other conditions or restrictions on the proposed arrangements if such conditions or restrictions will contribute to the elimination, reduction, or management of the conflict of interest.

If an IRB determines that an FCOI exists, a management plan may be required.

E. Public Disclosure of Reported Financial Interests

All reported financial disclosures are available on the DRCR Network public website. Only the relationship, not the amount of the relationship is publically disclosed.

F. Additional Requirements for Investigators Covered Under JCHR Financial Conflict of Interest Policy

Investigators covered under the JCHR financial conflict of interest policy must abide by this DRCR Network policy as well as the JCHR policy (see policy http://publicfiles.jaeb.org/DRCRnetPoliciesv10_11_14_17Final.pdf).

The following additional requirements are required for investigators covered under JCHR policy:

1. Travel Reporting

Investigators must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), not reimbursed directly by JCHR, whether related to their institutional responsibilities or not (e.g., travel related to consulting performed while the investigator has taken annual leave time must be reported); however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by:

- a Federal, state, or local government agency,
- an Institution of higher education as defined at 20 U.S.C. 1001(a),
- an academic teaching hospital,

- 262 • a medical center, or
- 263 • a research institute that is affiliated with an Institution of higher education.

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265 The JCHR FCOI policy requires that the investigator disclose the purpose of the trip, the identity
266 of the sponsor/organizer, the destination, and the duration. In accordance with the JCHR FCOI
267 policy, the institutional official will determine if further information is needed, including a
268 determination or disclosure of monetary value, in order to determine whether the travel
269 constitutes an FCOI with the investigator's research.

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271 The disclosure must be reported within 30 days of travel.