

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

2 Version Date: April 28, 2017

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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.net has  
8 developed a policy to promote objectivity in research by establishing a policy that provides a  
9 reasonable expectation that the design, conduct, and reporting of DRCR.net research is free from  
10 bias resulting from investigator financial conflicts of interest. For the purposes of this policy, the  
11 term “investigator” means any member of the DRCR.net who is expected to disclose financial  
12 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.

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18 **B. Definitions**

19 **1. Financial Interest**

20 A *financial interest (FI)* consists of one or more of the following interests of the investigator (or  
21 those of the investigator’s spouse and dependent children):

- 22 • With regard to any publicly traded entity, a *financial interest* exists if the value of any  
23 remuneration received from the entity in the 12 months preceding the disclosure and  
24 the value of any equity interest in the entity as of the date of disclosure exceeds \$0.00.  
25 The DRCR.net policy does not set a “de minimis” threshold and requires employees  
26 to report all FIs. For purposes of this definition, remuneration includes salary and any  
27 payment for services not otherwise identified as salary (*e.g.*, consulting fees,  
28 honoraria, paid authorship); equity interest includes any stock, stock option, or other  
29 ownership interest, as determined through reference to public prices or other  
30 reasonable measures of fair market value.
- 31 • With regard to any non-publicly traded for-profit entity, a FI exists if the value of any  
32 remuneration received from the entity in the 12 months preceding the disclosure  
33 exceeds \$0.00. The DRCR.net policy does not set a “de minimis” threshold and  
34 requires employees to report all FIs. A FI also exists when the investigator (or the  
35 investigator’s spouse or dependent children) holds any equity interest (*e.g.*, stock,  
36 stock option, or other ownership interest) in a non-publicly traded entity.
- 37 • Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of  
38 income related to such rights and interests.

39  
40 In addition, an FI exists whether remuneration is paid directly to the investigator OR to the  
41 investigator’s institution/legal entity on the investigator’s behalf.

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

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

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## 63 **2. Significant Financial Interest**

64 A *significant financial interest (SFI)* is defined as any of the following:

- 65 • An FI that is \$5,000 or more over the prior 12 months
- 66 • An FI value that cannot readily be determined or cannot be disclosed
- 67 • Any non-publicly traded equity (or non-publicly traded stock options)
- 68 • When the investigator (or the investigator's spouse or dependent children) holds any  
69 equity interest in a non-publicly traded company (e.g. stock, stock option, or other  
70 ownership interest)
- 71 • Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income  
72 related to such rights and interests

73

## 74 **3. Financial Conflict of Interest**

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

78

## 79 **4. Related Research**

80 *Related to DRCR.net research* means an entity whose financial interest could reasonably appear  
81 to be affected by the conduct or outcome of DRCR.net research, or in which the financial interest  
82 could be affected by the research. Examples include, but are not limited to, companies that hold  
83 patent rights for discoveries, drugs or devices being studied in DRCR.net 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.net if the DRCR.net investigator  
86 knows that the financial interests of such a company would reasonably appear to be affected by

87 DRCR.net research. This term also includes any entity acting as the agent of a financially  
88 interested company (e.g., a contract research organization). If there is any ambiguity as to  
89 whether the company is related to DRCR.net research, the company must be disclosed. In these  
90 cases, by examining the company's business and the scope of research conducted by the  
91 DRCR.net, the Network Chair and the Director of the Coordinating Center (or Executive  
92 Committee, where applicable) will judge whether the investigator's interest is with a "financially  
93 interested company".  
94

## 95 **C. Reporting Financial Disclosures**

### 96 **1. Personnel Required to Report**

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

107 In general, clinical site staff other than study investigators and study coordinators are not  
108 required to report financial interests according to this policy unless participating on a Network  
109 committee (e.g., Writing Committee, Executive Committee, etc.).  
110

### 111 **2. Financial Interests to Disclose**

112 All financial interests (FI) related to DRCR.net research must be disclosed. Disclosure is  
113 required whether remuneration is paid directly to the investigator OR to the investigator's  
114 institution/legal entity on the investigator's behalf. There is no minimum threshold for  
115 disclosure.  
116

### 117 **3. Frequency of Reporting**

118 Investigators are required to complete the online DRCR.net financial disclosure form (1)  
119 annually, each January, and (2) within 30 days of discovering or acquiring (e.g. through  
120 purchase, marriage, or inheritance) a new SFI or a substantial change to an FI. A substantial  
121 change is defined as when a previously reported FI increases to a higher category level defined  
122 as follows: \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by  
123 increments of \$20,000; amounts above \$100,000 by increments of \$50,000. In addition, for all  
124 investigators (excluding coordinators) at the time of initiating a new DRCR.net protocol, and for  
125 investigators selected for protocol development or manuscript development committees, the  
126 investigator will be required to review his/her current disclosure online to indicate whether there  
127 have been any changes.  
128

### 129 **4. Disclosure Process Details**

130 Financial disclosures are completed on the DRCR.net study website Financial Disclosure Form.

131 Financial disclosures are made separately for the following categories:

- 132 • Research Grant – a grant from the entity paid to an organization for research including  
133 clinical or lab research (e.g. clinical trial) or other research such as research conducted for  
134 scientific or public health purposes and not directly conducted primarily for the benefit of  
135 the company (e.g. data analyses projected intended for scientific publication)
- 136 • Professional Fees – monies paid to an individual or to an organization for services  
137 rendered, including honoraria, royalties, or fees for consulting, lectures, speakers bureaus,  
138 expert testimony, employment, stock/stock options or other affiliations.
- 139 • Board Membership or Office Positions
- 140 • Non-Financial Support – Examples include equipment, travel paid by the entity, writing  
141 assistance, administrative support, etc.
- 142 • Patents (planned, pending, or issued)
- 143 • Stock/stock options
- 144 • Other – Anything not covered in the above categories.

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

149  
150 Investigators will disclose the amount of each relationship, separately for support paid to the  
151 investigator and support paid to the institution for research within the following categories: \$0-  
152 \$4,999; \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$100,000 by increments of \$20,000; amounts  
153 above \$100,000 by increments of \$50,000, a statement that a value cannot readily be determined,  
154 or a statement that the value cannot be disclosed (e.g. confidentiality agreement with entity).  
155 Only support that is an appropriate fee for service and not another type of support or gift should  
156 be counted as support paid for research, otherwise the value should be reported as not for  
157 research.

## 158 **D. Managing Financial Disclosures**

160 Ultimately it is the responsibility of the investigator’s institution or JCHR if the institution does  
161 not have a FCOI policy conformant to 42 CFR 50 Subpart F, to manage financial interests;  
162 however DRCCR.net has developed a policy to avoid FCOI within the Network.

### 163 **1. Policy to Avoid Financial Conflict of Interest**

164 The DRCCR.net policy on avoiding FCOI within the Network relates to SFI paid directly to the  
165 investigator or to the investigator’s institution/legal entity on the investigator’s behalf in which  
166 the investigator has equity. The Executive Committee reserves the right to assess all disclosures  
167 as to whether a potential FCOI exists. The Executive Committee also reserves the right to  
168 confirm for each protocol if this policy is appropriate. The following includes the DRCCR.net  
169 policy on avoiding FCOI within the Network.

- 170  
171 • Investigators with a non-research SFI that exceeds \$20,000 with an entity related to  
172 DRCCR.net research are presumptively prohibited from enrolling more than 5% of the  
173 study participants into an applicable DRCCR.net study that involves more than minimal  
174 risk.

- 175 • Investigators with a non-research SFI that exceeds \$20,000 with an entity related to  
176 DRCR.net research are presumptively prohibited from enrolling more than 10% of the  
177 study participants into an applicable DRCR.net study that does not involve more than  
178 minimal risk.
- 179 • Investigators with a non-research SFI less than \$20,000 with an entity related to  
180 DRCR.net research are presumptively prohibited from enrolling more than 10% of the  
181 study participants in any applicable DRCR.net study.
- 182 • The principal investigator of the DRCR.net Coordinating Center and the Network Chair  
183 are presumptively prohibited from having a non-research SFI with an entity related to  
184 DRCR.net research.
- 185 • Members of the Operations Group are presumptively prohibited from having a non-  
186 research SFI with an entity related to DRCR.net research.
- 187 • No more than 50% of the members of the writing committee will have a non-research SFI  
188 between \$5,000 and \$20,000 with an entity related to the work being conducted for the  
189 specific DRCR.net research. No member of any writing committee should have a non-  
190 research SFI of \$20,000 or more with an entity related to the work being conducted for  
191 the specific DRCR.net research.
- 192 • No more than 50% of the members of any protocol development committee should have  
193 a non-research SFI with an entity related to the work being conducted for the specific  
194 DRCR.net research. In addition, the Protocol Chair for a study is presumptively  
195 prohibited from having a non-research SFI with an entity related to the work being  
196 conducted.
- 197 • Members of the Data and Safety Monitoring Committee are presumptively prohibited  
198 from having a non-research SFI with an entity related to DRCR.net research for which  
199 the DSMC is monitoring.

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201 The determination of whether a FCOI exists in certain instances can be a matter of judgment  
202 involving all the facts of the situation. The Network Chair and Director of the Coordinating  
203 Center will oversee review of potential FCOI. When necessary the Executive Committee will  
204 provide final decisions on behalf of the Network.

205  
206 **2. Investigator Options When a Presumptive Prohibition is Identified to Avoid a FCOI**

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

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

217  
218 The Network Chair and Coordinating Center Director, or the Executive Committee members  
219 (when cases are overseen by the Executive Committee) may recommend other conditions or

220 restrictions on the proposed arrangements if such conditions or restrictions will contribute to the  
221 elimination, reduction, or management of the conflict of interest.

222

## 223 **E. Public Disclosure of Reported Financial Interests**

224 For each DRCR.net presentation or publication, the DRCR.net provides the relevant ICMJE  
225 form on the DRCR.net public website.

226

## 227 **F. Additional Requirements for Investigators Covered Under JCHR Financial Conflict of** 228 **Interest Policy**

229 Investigators covered under the JCHR financial conflict of interest policy must abide by this  
230 DRCR.net policy as well as the JCHR policy (see policy  
231 <http://publicfiles.jaeb.org/jaeb/FCOIpolicydocumentfinal.pdf>).

232

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

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### 235 **1. Reporting FI Regardless of Relationship**

236 In addition to reporting FI as defined in section B.1, investigators must also report as an FI any  
237 not-for-profit entity related to DRCR.net research, if the value of any remuneration received  
238 from the entity in the 12 months preceding the disclosure is \$5,000 or more.

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### 240 **2. Travel Reporting**

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

247

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

258

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