

### Policy Appendix III: Financial Disclosure Policies for the DRCR Network

Version Date: December 22, 2009

1 (Adapted from the Conflict of Interest Policies of the Johns Hopkins University School of  
2 Medicine; initially approved by the DRCR.net Executive Committee on January 3, 2006)

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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 **PRIMARY COMMITMENT OF INVESTIGATORS SUPPORTED BY NIH FUNDS**

7 Despite the increasing frequency and complexity of the relationships of investigators with industry,  
8 government, and other entities, these relationships are governed by one basic principle:  
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10 *Investigators of the Diabetic Retinopathy Clinical Research Network (DRCR.net) recognize their*  
11 *primary responsibility, specifically, that they are conducting research sponsored by the National*  
12 *Institutes of Health (NIH) of the U.S. Department of Health and Human Services.*  
13

14 Acceptance of Network responsibilities and NIH funds entails a commitment to give one's best  
15 efforts to this end. At the same time, it is recognized that paid participation of investigators and  
16 staff in activities of their community-based practice or university based positions, government,  
17 professional associations, industry, and other private institutions may serve the best interest of the  
18 Network. The experience that such participation brings to the investigator is shared indirectly by  
19 the Network, and these outside activities often contribute to the richness and diversity of the  
20 Network. Moreover, as a result of such activities, society may benefit from the dissemination of  
21 knowledge and technology developed within the Network.  
22

23 A commitment to serve an institution, agency, or industrial organization other than the Network that  
24 competes with the Network should be made only after giving serious consideration to the amount of  
25 time and effort that can be given to another entity while satisfying the investigator's commitment to  
26 the Network. In addition, investigators and staff are expected to be discriminating in the selection of  
27 outside commitments in order to avoid impairment of the Network's reputation as a leading research  
28 entity within the ophthalmic community. Investigators should avoid commitments that could  
29 compromise the basic scholarly independence and freedom of action that are central to the Network.  
30 Where there is the possibility or appearance of a conflict of commitment or financial conflict of  
31 interest between an investigator's or staff's obligations to another organization and those to the  
32 Network, the investigator or staff member must discuss and then report in writing his or her plans  
33 with the Network Chair and Director of the Coordinating Center before making a commitment.  
34

35 Financial conflicts of interest usually can be managed through disclosure. **To maintain the**  
36 **academic integrity of the Network within the potential benefits of participation in interests**  
37 **outside of the Network, investigators and appropriate staff will provide financial disclosures**  
38 **(as defined in Question 14 below) at least on a biannual basis and within 30 days when there is**  
39 **a new financial disclosure due to a new Network protocol, change in a Network protocol, or a**  
40 **change in the Network investigator or staff's finances.** For non-research relationships (defined as  
41 consulting, scientific advisory boards, and the like), the disclosure should reflect whichever is higher  
42 within 4 categories (none, <\$10,000, between \$10,000 and <\$25,000, or >=\$25,000), including  
43 annual totals for the previous year and through the time of the annual report (usually completed by  
44 January and again by July), and written agreements which existed for the previous year, even if no  
45 payment has been received at the time of the disclosure. Research relationships (defined as  
46 participation in laboratory research or clinical trials) are not reported within categories. A substantial  
47 change is defined as any non-research relationships for consulting/honoraria/speakers bureau which

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48 go from below \$25,000 to \$25,000 or above, or when a new non-research relationship in the realm of  
49 employment, stock, stock options, or other occurs, or when a new research relationship develops.  
50 Investigators and appropriate staff should inform the Coordinating Center in writing within 30 days  
51 of a substantial change so that the Coordinating Center can amend the existing information and so  
52 that this new information can be reviewed and managed by the Network.

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### **WHEN IS A WRITTEN REPORT OF FINANCIAL DISCLOSURES NECESSARY AND WHO MUST COMPLETE A WRITTEN REPORT?**

57 Each January and July, all Network investigators and certified staff as determined by the Executive  
58 Committee will complete the on-line DRCR.net Financial Disclosure form. (Note: Throughout the  
59 remainder of this document, wherever the term “investigator” is used, it also should be considered  
60 as indicative of committee members and certified key personnel in the Network required to report  
61 this information as determined by the Executive Committee.) However, disclosure is a continuing  
62 obligation, and it also must be made if a new relationship becomes evident when an investigator’s  
63 ongoing relationship with an outside party changes, and promptly at any other time of the year  
64 when the situation within the annual report has changed.

65  
66 These reports will be reviewed by the Network Chair and Director of the Network’s Coordinating  
67 Center. Determination of whether a financial conflict of interest exists in a particular instance will  
68 always be a matter of judgment involving all the facts of the situation. While informal discussion  
69 with the Network Chair, Coordinating Center Director, or others, is always encouraged, such  
70 discussions do not replace the investigator’s requirement to provide a full written report as the best  
71 preventive measure to avoid any real or apparent conflict between the obligations of investigators  
72 to the Network and to their personal interests and other competing commitments.

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### **WHY IS A WRITTEN REPORT NECESSARY?**

76 Trust, good faith, and open discussion of controversial issues among colleagues are central to the  
77 life of the Network. The activities of investigators must be governed by thoughtful and shared  
78 consideration of individual circumstances, rather than rigid rules. The requirement for reporting in  
79 the situations outlined below is meant to ensure that conflicts of interest will be considered openly  
80 and fairly and that appropriate action will be taken to resolve those conflicts. Reporting thus serves  
81 to protect individuals in the Network, the Network as an entity, the NIH, and academic freedom in  
82 general.

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### **WHAT IF THE NETWORK IS CONSIDERING WORK WITH AN OUTSIDE ENTITY WITH WHICH THE INVESTIGATOR HAS A RELATIONSHIP?**

87 Whenever an investigator’s relationship to an outside party might appear to influence either the  
88 conduct of the Network’s business with the outside party or the conduct of research within the  
89 Network, a report must be made of that relationship. Any person serving as Network Chair or other  
90 members of the Executive Committee (or other committees as applicable) who have financial  
91 disclosures relevant to a company involved in discussions to collaborate with the Network will  
92 forego voting privileges regarding decisions on the collaboration. This policy will prevent putting  
93 any DRCR.net investigator in an inappropriate position and will ensure that financial biases are  
94 reduced or eliminated when voting takes place.

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## FREQUENTLY ASKED QUESTIONS

100 **1. Who is covered by the policy and required to complete a written conflict of interest report**  
101 **at least every 6 months?**

102 All investigators, committee members, and certified key personnel (as judged by the Executive  
103 Committee) in the Network are covered by this policy and must submit a report at least every six  
104 months.

105  
106 **2. Do I need to include relatives or a spouse in my report?**

107 You must indicate on the appropriate forms whether you or any of your dependents or spouse has a  
108 financial interest that could be affected by the Network's research or could appear to be affected by  
109 the Network's research.

110  
111 **3. Do government entities require this reporting, or is this just a policy of the Network?**

112 Under U.S. Public Health Service regulations, investigators receiving NIH funds must identify and  
113 manage, reduce, or eliminate financial interests related to research supported by this federal agency.  
114 By accurately reporting your relevant financial interests to the Network, you enable the Network to  
115 comply with these regulations. If you are an investigator in a clinical study whose results are being  
116 submitted to FDA for marketing approval, the sponsor would need you to complete a disclosure  
117 form so it can comply with FDA regulations.

118  
119 **4. Are there penalties for failing to report these conflicts with respect to government entities?**

120 In some cases, failure to disclose, eliminate, or manage conflicts of interest with research has led to  
121 investigative and legal action by plaintiffs, the Securities and Exchange Commission, and the  
122 Office for Human Research Protections (OHRP).

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124 Relevant PHS regulations are available at:

125 [http://grants2.nih.gov/grants/compliance/42\\_CFR\\_50\\_Subpart\\_F.htm](http://grants2.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm)

126 Relevant FDA rules are available at:

127 <http://www.fda.gov/oc/guidance/financialdis.html>

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129 **5. If I receive cash compensation for consulting for an entity involved with or competing with**  
130 **an area of research within the Network, is there a limit for participating in human subjects**  
131 **research and concurrently receiving consulting income and other payments?**

132 Setting a threshold above which financial interests constitute an unacceptable conflict of interest with  
133 human subject research is extremely difficult. Judging the relative risks presented by various levels  
134 and types of financial interests is necessarily subjective. This is evidenced by the fact that there is a  
135 range of thresholds set by academic medical centers and under various government regulations. In  
136 addition, these thresholds mean different things; some trigger reporting, while others trigger  
137 prohibition. While some argue that a conflict exists at any level of financial interest, to disallow all  
138 such income while conducting related human subjects research risks limiting investigators' access to  
139 cutting-edge treatments and clinical trials. After weighing a variety of factors, in general, a limit of  
140 \$25,000 for non-research relationships appears acceptable to the Executive Committee at this time.  
141 Exceptions might include equity (including stock options) valued over \$25,000 with an entity whose

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142 product is not being tested by the Network but is in direct competition by a product being tested in the  
143 Network. In this case, participation in human subjects research within a Network protocol evaluating a  
144 product which competes with a product in which the investigator holds equity could be permitted if  
145 there were limits on the number and percent of total subjects enrolled (depending on the protocol), if  
146 performance were monitored with this disclosure in mind, if it was not privately held equity (including  
147 privately held stock options) whose value cannot be determined on the open market, or privately held  
148 stock options, and if the investigator did not hold a leadership position for the protocol or on a writing  
149 committee for the protocol involving its product. It should be noted that financial interests of \$25,000  
150 or below still must be reported and reviewed by the Network Chair and Director of the Coordinating  
151 Center, and public disclosure in all relevant DRCR.net publications is required of investigators with  
152 any financial interest related to their research. All research relationships are managed by disclosure  
153 without a specific limit, although in the interest of transparency, the value of these relationships might  
154 be requested in specific circumstances, for example, research relationships held by leadership positions  
155 within the Network.

### 156 157 **6. How do I determine whether my consulting income, including in-kind support, exceeds \$25,000?**

158 Calculate the combined value of your consulting fees or speaking honoraria for the company in  
159 question (or companies, if the interests of more than one company may appear to be affected by the  
160 research project) with the value of *non-business related travel arrangements* paid for by the  
161 company (or companies). Include payments or equipment or supplies provided to your office or  
162 University if you have ownership or a fiduciary responsibility to the institution receiving these  
163 payments or equipment. Small gifts from companies such as paperweights and T-shirts should not  
164 be included.

165  
166 Of course, financial interests of any value that could affect or appear to affect one's research  
167 activity - whether or not involving human subjects - must be reported.

### 168 169 **7. Are travel expenses for consulting meetings included in the \$25,000 threshold for 170 presumptive prohibition of conducting human subjects research?**

171 Payment for "travel expenses incurred in the course of performing consulting services" is excluded. If  
172 a financially interested company (i.e., a commercial entity whose financial interests would reasonably  
173 appear to be affected by the conduct or outcome of the Network's research) pays for you to travel to a  
174 consultants' meeting, or to present results of one of their research projects, the cost of your business-  
175 related travel should not be included in calculating the \$25,000. However, additional payments (or  
176 'in kind' compensation) not directly related to your performance of the consulting services should be  
177 included when calculating the value of your aggregate payments from the company. Examples of such  
178 payments include expenses for family members, additional days of accommodation at the consulting  
179 site, or travel paid for by the company when no consulting services or research presentations are  
180 provided by the individual (for example, travel provided just to attend a meeting). You should follow  
181 Internal Revenue Service (IRS) rules on deductible business expenses in determining what is a  
182 business-related expense and what is 'in kind' compensation.

### 183 184 **8. What if an investigator has multiple consulting agreements with a company and is 185 evaluating devices from this company in a Phase III clinical trial that has nothing to do with 186 diabetic macular edema. This company also has products that compete with products under 187 evaluation by the DRCR.net for which I am an investigator. Do I have a potential conflict of 188 interest?**

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189 The conflict is generated by receiving money from a company that has a product in the field of  
190 what is under investigation with the Network, even though the investigator's payment is not for  
191 work with the competing product of that company, regardless of whether that company is working  
192 with the Network. The subject matter of the investigator's consulting work does not alter the  
193 existence of the conflict. Additionally, if an investigator has multiple consulting agreements from a  
194 company, it is the aggregate magnitude of the conflict which will be assessed (and potentially  
195 limited).

196  
197 **9. What if an investigator is the inventor of a device under evaluation or competing with a**  
198 **similar device under evaluation by the Network but has no equity or consulting income from**  
199 **the company licensing the device? Since the investigator is entitled to licensing-related**  
200 **payments, including royalty payments once the device is sold, but has no equity or consulting**  
201 **income from the licensee, can the investigator participate in Network studies of the device?**

202 The investigator/inventor may submit a written request to the Network Chair and Director of the  
203 Coordinating Center for exemption from the prohibition on conducting human subjects research  
204 with the Network while having a royalty interest in the study device. This situation would be  
205 presented to the Executive Committee, and if the Executive Committee is convinced it is very  
206 important for the investigator/inventor to participate in the study, depending upon the structure of  
207 the license, the Committee may recommend that these arrangements be permitted. If it does, it also  
208 will recommend that specific conditions be placed on the investigator's participation. Final  
209 determination concerning the investigator's role in the study would rest with the IRB for that  
210 investigator. In some cases, post-marketing royalty interest is a potentially manageable conflict of  
211 interest since income is not received until the invention has undergone extensive laboratory and  
212 clinical evaluation and approval by outside agencies.

213  
214 **10. For human subjects research performed by the Network, why does it matter if an**  
215 **investigator has stock in a start-up company whose stock is worthless at the time of the study?**

216 If an investigator proposes to participate in Network research in the field or competing field of a  
217 start-up company in which the investigator has equity, but in which the value of the stock is  
218 worthless at the time of the study, the value of the stock may be heavily influenced by the outcome  
219 of the research. This is because start-up companies generally have only one or a few products in  
220 development and their ability to raise capital depends on the outcome of early stage research on  
221 their products. Their ability to proceed, for example, from Phase I to Phase II studies is likely to be  
222 completely dependent on whether the Phase I study results are positive. Furthermore, increases in  
223 the value of start-up companies' stock can make them takeover targets. Thus, the ownership of  
224 stock in a start-up company with a product in the field or competing field of a Network study, even  
225 when the market value is zero at the time of the Network study, is a significant source of conflict of  
226 interest in research.

227  
228 **11. If an investigator is participating in a large Phase III drug trial within the Network**  
229 **sponsored by a large pharmaceutical company, and the investigator wants to purchase stock**  
230 **in the company for the investigator's minor childrens' portfolios, is this considered a conflict**  
231 **of interest?**

232 It is unlikely that the investigator's participation in the Network's Phase III drug trial will influence  
233 the outcome of the study, let alone the value of the sponsor's stock as a large pharmaceutical  
234 company. Nevertheless, the investigator's ownership of stock in the sponsor *creates an appearance*  
235 *of a conflict of interest*. It is advisable to avoid this type of investment until well after there is a

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236 possible appearance of a conflict of interest. Under the Network's policy, the investigator must  
237 report his or her ownership or proposed purchase of the sponsor's stock. If the value of the  
238 investment is \$25,000 or below, the investigator could be asked to either sell the stock or place it in  
239 escrow and publicly disclose ownership to subjects and in publications. It is unlikely the  
240 investigator would be allowed to hold stock valued in excess of \$25,000 and participate in the  
241 study, although the investigator might be allowed to hold stock of a competing study with one or  
242 more protocols in which the investigator is participating if there were limits on the number and  
243 percent of subjects enrolled, depending on the protocol, if performance were monitored with this  
244 disclosure in mind, if it was not privately held stock or privately held stock options, and if the  
245 investigator did not hold a leadership position in the protocol or on a writing committee.

246

247 **12. Can an investigator serve on the board of directors of a company with a product in the**  
248 **field or competing with the field of investigation by the DRCR.net and perform human**  
249 **subjects research within the Network on one of the products of that company? Is this**  
250 **allowed?**

251 An investigator's role as a member of the board of directors involves a legal obligation to act in the  
252 best interests of the company (a "fiduciary" obligation). This could place the investigator, as a  
253 board of directors member, in conflict with his or her obligations as an investigator conducting  
254 human subject research and in general, investigators with a board of directors position will be  
255 prohibited from research within the Network on one of the products of that company or in the field  
256 of that company. For example, the company's survival or ability to raise money may be dependent  
257 on recruiting patients and completing a phase I clinical trial that the investigator is directing while,  
258 as an investigator, one may have serious concerns about whether or how the study should proceed.

259  
260 Likewise, although the investigator personally may not be involved in the human subjects studies,  
261 if the investigator supervises individuals (for example, co-investigators, or staff) who are  
262 conducting such studies, the conflicted investigator's service on the board of directors could create  
263 a conflict with the investigator's primary duties to the research team.

264

265 Investigators in this situation or potentially in a position to be in this situation should consider  
266 participating on a scientific advisory board that does not have a fiduciary responsibility to the  
267 company (the compensation of which, as explained above, would have to be \$25,000 or less per  
268 year).

269

270 **13. What does an investigator do about existing licensing and consulting agreements, since**  
271 **these specific policies did not exist prior to January 1, 2006?**

272 The Network's Executive Committee recognizes that agreements signed before the January 1, 2006  
273 represents obligations on the part of the investigators. Nevertheless, the Network must implement  
274 these policies for human subjects research. Such arrangements of course need to be reported to the  
275 Network Chair and Director of the Coordinating Center and brought into compliance at the earliest  
276 opportunity, while the Network leadership recommends measures to minimize the conflicts with the  
277 Network's research. IRBs overseeing the investigator retain final authority in allowing concurrent  
278 financial interests and human subjects research.

279

280 **14. How does an investigator determine whether his or her financial interest "may reasonably**  
281 **appear to be materially affected by" Network research in which the investigator participates,**  
282 **and therefore should be reported?**

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283 If the publication or presentation of the results of the Network's research could be viewed by a  
284 scientific audience or non-scientific audience (such as stock analysts, news reporters, or lay  
285 consumers of health information) as having an impact on the value of the company stock or  
286 products sold by the company with which the investigator has a consulting contract or equity or  
287 royalty interest, the arrangements should be reported. The investigator should be conservative in  
288 evaluating the "relatedness" between the investigator's financial interests and the investigator's  
289 research activity (i.e., err on the side of reporting). The NIH likely is "risk-adverse" in these  
290 matters. This is particularly important, since even the appearance of a conflict of interest is  
291 significant. In some cases, Network Chair and Director of the Coordinating Center may determine  
292 that the relationship between an investigator's financial interest and his or her research project is so  
293 remote (or unreasonable to expect) that there is no need for action. However, that determination  
294 should be made by disinterested individuals and not by the potentially biased investigator.  
295 Therefore, investigators are required to report financial interests that may appear to a reasonable  
296 person to be potentially affected by their research results, interpretations, publications and  
297 presentations.

### 298 299 **15. Who oversees reporting of conflicts of interest of the Network Chair, the Principal** 300 **Investigator and Director of the Coordinating Center, and the Executive Director of the Jaeb** 301 **Health Center for Research?**

302 These reports will be reviewed by the Executive Committee regarding any management. The  
303 Network Chair will be recused from discussions applicable to the Network Chair; the Principal  
304 Investigator and Director of the Coordinating Center, and the Executive Director of the Jaeb Health  
305 Center for Research will be recused from discussions applicable to them.

### 306 307 **16. Are royalties from the publication of academic textbooks or other publications that report** 308 **subject matter in the field or competing field of Network research a conflict to be reported?** 309 **What about Continuing Medical Education endeavors?**

310 Publication of professional textbooks is considered a desired endeavor that is traditionally  
311 considered not to generate significant financial conflicts of interest if the textbook is not sponsored  
312 by a company in the field or competing field of Network research. Thus, an investigator's interest in  
313 royalty from such works is not subject to review under the Network's conflict of interest policy.  
314 Similarly, CME activities that are performed under an entity accredited by the Accreditation  
315 Council for Continuing Medical Education (ACCME) are considered a desired endeavor that is  
316 traditionally considered not to generate significant financial conflicts of interest if the CME activity  
317 is not sponsored by a company in the field or competing field of Network research. Note that an  
318 educational grant by a company in the field of Network research to an ACCME entity not in the  
319 field generally is *not* considered a conflict as the educational grant is not under the control of the  
320 company providing the grant.

### 321 322 **17. The financial interests of an investigator's supervisor or institution (such as a University)** 323 **may appear to have a financial conflict with the Network's research. Is this a conflict of** 324 **interest for the investigator?**

325 The interests of an institution or supervisor to whom the investigator reports carry potential  
326 conflicts of interest or the appearance of a conflict of interest with research conducted by the  
327 Network, even though the investigator has no control over that supervisor's or institution's  
328 finances. These instances need to be managed individually at this time, trying to maintain  
329 consistency with the existing policy throughout this document.

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331 **18. An investigator or legal entity employed by that investigator receives funding from a**  
332 **company to participate in research in the field or competing field of Network research. How**  
333 **should that be reported?**

334 Any funding going directly to an investigator from an entity that participates in research in the field  
335 or competing field of Network research, even if that funding is not for such research, would need to  
336 report that payment as a potential financial conflict of interest.

337

338 It usually is impossible for an investigator to be aware of all funding that may come to a legal entity  
339 for whom the investigator works, e.g., an ophthalmologist at a university would not necessarily be  
340 aware of all funding from a company to that university. However, the investigator should report any  
341 funding that comes to that university that supports the investigator's research if that company is in a  
342 field or competing field of Network research. In general, this amount of funding that goes to a legal  
343 entity that employs the investigator, but not to the investigator, would not be counted towards the  
344 \$25,000 limits discussed above (assuming that the investigator does not have equity in the legal  
345 entity).

346

347 **19. How are stock options or warrants in publicly-traded companies valued for the purpose of**  
348 **this policy?**

349 For the purpose of determining the magnitude of an investigator's equity interest in a publicly-  
350 traded company, options and warrants are valued at the current market price of the company's  
351 stock. For example, if Dr. Jones holds an option to purchase 10,000 shares of Acme Biotech and  
352 Acme Biotech is trading at \$5 per share, Dr. Jones' interest in the company will be considered to be  
353 worth \$50,000. If Dr. Jones exercises all his options and immediately sells the resulting Acme  
354 stock, Dr. Jones receives \$50,000.

355

356 For tax purposes, options and warrants may need to be valued differently. In order to convert  
357 options to stock, the holder must pay a certain price per share ("strike price") and the difference  
358 between the strike price and the market price of the stock may be important for calculating one's tax  
359 liability.

360

361 However, to determine the value of the asset for reviewing a conflict of interest, the trading price of  
362 the stock would be used.

363

364 This is consistent with valuing stock (not stock options) at its trading price, regardless of what an  
365 individual paid to acquire the stock. For instance, Dr. Smith may own \$40,000 worth of ABC  
366 Pharma stock, which was purchased last year for \$20,000. While the profit is \$20,000, the current  
367 value of his ABC Pharma stock is \$40,000. Accordingly, the current market value of that  
368 company's stock is used to determine the value of stock as well as options, warrants, and similar  
369 equity interests.

370

371 **20. What if an investigator disagrees with the opinion of the Network Chair or Director of the**  
372 **Coordinating Center regarding the perception and management of conflicts of interest?**

373 The investigator in this situation should present an appeal to the Executive Committee whose  
374 members will make a final decision.