



Jaeb Center for Health Research

Financial Conflicts of Interest

July 1, 2012 rev. 9-8-14

1 **A. INTRODUCTION**

2
3 **1. Purpose of the Regulation**

4 The 2011 revised Financial Conflicts of Interest (FCOI) regulation 42 CFR Part 50
5 Subpart F promotes objectivity in research by establishing standards that provide a
6 reasonable expectation that the design, conduct, and reporting of research funded
7 under Public Health Service (PHS) grants or cooperative agreements will be free from
8 bias resulting from investigator financial conflicts of interest.

9
10 The Jaeb Center for Health Research (JCHR)'s FCOI policy is fully compliant with this
11 regulation and is broader than the regulation defined in 42 CFR Part 50 Subpart F in
12 two respects: (1) the threshold for reporting is >0 for for-profit entities (rather than
13 >\$5,000 as stipulated in the federal regulation) and (2) for JCHR employees, the policy
14 applies to all staff and not just investigators as stipulated in the federal regulation.

15
16 **2. Applicability**

17 For purposes of financial disclosure, the JCHR policy covers all staff, staff spouses, and
18 dependent children.

19
20 The policy also is applicable to investigators at other institutions with which JCHR has
21 contracted to participate in a JCHR-directed study if the other institution does not have a
22 FCOI policy compliant with regulation 42 CFR Part 50 Subpart F, as well as consultants
23 and collaborators who are not affiliated with an institution.

24
25
26 **B. DEFINITIONS**

27 **1. Investigator**

28 For purposes of this document, an *investigator* is defined as the project director or
29 principal Investigator and any other person, regardless of title or position, who is
30 responsible for the design, conduct, or reporting of research, which may include, for
31 example, collaborators or consultants. *Responsible for the conduct of research* is not
32 the same as performing a study procedure. For instance, a study staff member who
33 conducts visual acuity testing on a study participant is not considered an investigator.

34
35 **2. Employee Institutional Responsibilities**

36 *Employee Institutional Responsibilities* are defined as professional responsibilities
37 performed on behalf of JCHR, including all professional activities irrespective of whether
38 they are performed at JCHR or for JCHR, which may include for example: activities
39 such as research, research consultation, teaching, professional practice, institutional
40 committee memberships, and service on panels such as Institutional Review Boards or
41 Data and Safety Monitoring Boards.

42
43 **3. Financial Interest**

44 A *financial interest (FI)* is considered to be a financial interest consisting of one or more
45 of the following interests of the employee (or those of the employee's spouse and
46 dependent children) that reasonably appears to be related to the employee's
47 institutional responsibilities or is not related but occurs outside of the employee's
48 institutional responsibilities (e.g., consulting for a company while the employee is taking

49 annual leave time off). Financial interests related to the research means a financial
50 interest in the sponsor/funding agency, the product, or the service being tested.

51

52 An FI is defined as follows:

- 53 • With regard to any **publicly** traded entity, a *financial interest* exists if the
54 value of any remuneration received from the entity in the 12 months
55 preceding the disclosure and the value of any equity interest in the entity as of
56 the date of disclosure exceeds \$0.00. The JCHR policy does not set a “de
57 minimis” threshold and requires employees to report all FIs. For purposes of
58 this definition, remuneration includes salary and any payment for services **not**
59 **otherwise identified** as salary (e.g., consulting fees, honoraria, paid
60 authorship); equity interest includes any stock, stock option, or other
61 ownership interest, as determined through reference to public prices or other
62 reasonable measures of fair market value.
- 63 • With regard to any **non-publicly** traded for-profit entity, a FI exists if the value
64 of any remuneration received from the entity in the 12 months preceding the
65 disclosure exceeds \$0.00. The JCHR policy does not set a “de minimis”
66 threshold and requires employees to report all FIs. A FI also exists when the
67 Employee (or the Employee’s spouse or dependent children) holds any equity
68 interest (e.g., stock, stock option, or other ownership interest)
- 69 • With regard to any not-for-profit entity, a FI exists if the value of any
70 remuneration received from the entity in the 12 months preceding the
71 disclosure is \$5,000 or more.
- 72 • Intellectual property rights and interests (e.g., patents, copyrights), upon
73 receipt of income related to such rights and interests.

74

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

- 76 • Salary, royalties, or other remuneration paid by JCHR to the Employee if the
77 Employee is currently employed or otherwise appointed by JCHR, including
78 intellectual property rights assigned to JCHR and agreements to share in
79 royalties related to such rights;
- 80 • Income from investment vehicles, such as mutual funds and retirement
81 accounts, as long as the Employee does not directly control the investment
82 decisions made in these vehicles;
- 83 • Income from seminars, lectures, or teaching engagements sponsored by
 - 84 ○ a Federal, state, or local government agency,
 - 85 ○ an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - 86 ○ an academic teaching hospital,
 - 87 ○ a medical center, or
 - 88 ○ a research institute that is affiliated with an Institution of higher
89 education;
- 90 • Income from service on advisory committees or review panels for
 - 91 ○ a Federal, state, or local government agency,
 - 92 ○ an Institution of higher education as defined at 20 U.S.C. 1001(a),
 - 93 ○ an academic teaching hospital,
 - 94 ○ a medical center, or

- a research institute that is affiliated with an Institution of higher education.

4. Significant Financial Interest

A *significant financial interest (SFI)* is defined as a FI that is \$5,000 or more; or when the employee (or the employee's spouse or dependent children) holds any equity interest in a non-publicly traded company (e.g. stock, stock option, or other ownership interest); or intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests

5. Financial Conflict of Interest

A SFI is considered to be a *financial conflict of interest (FCOI)* if it could directly and significantly affect the design, conduct, or reporting of research. This judgment is made by the JCHR Office of Research Administration.

C. INSTITUTIONAL PROCEDURES

1. Administration

The JCHR FCOI policy is administered through the Office of Research Administration.

The Director of Research Administration is the JCHR designated official responsible for reviewing financial disclosures and determining if a SFI is related to the research being conducted and if yes, whether it constitutes a FCOI.

JCHR may involve the individual in the determination of whether a significant financial interest is related to the funded research.

2. Retrospective Review

Whenever an individual's FCOI, regardless of source of funding, is not identified or managed in a timely manner, JCHR will conduct and document a retrospective review that includes, but is not necessarily limited to, the following elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the individual with the FCOI;
- Name of the entity with which the individual has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, JCHR shall update the previously submitted FCOI report pertaining to PHS research, specifying the actions that will be taken to manage the financial conflict of interest going forward.

142 **D. INVESTIGATOR REQUIREMENTS AND RESPONSIBILITIES**

143

144 **1. General**

145 Each Investigator who is planning to participate in research must disclose to the JCHR
146 Director of Research Administration the Investigator's FIs (and those of the
147 Investigator's spouse and dependent children) no later than the time of application for
148 research funding.

149

150 Each Investigator who is participating in research must submit an updated disclosure of
151 FIs at least annually, within 30 days of the request. Such disclosure shall include any
152 information that was not disclosed initially to JCHR or in a subsequent disclosure of FIs,
153 and shall include updated information regarding any previously disclosed FI that has
154 changed (e.g., the updated value of a previously disclosed equity interest).

155

156 Each Investigator who is participating in research must submit an updated disclosure of
157 FIs within 30 days of discovering or acquiring (e.g., through purchase, marriage, or
158 inheritance) a new FI, or when a previously reported FI increases to a higher category
159 level defined as follows: \$1-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts
160 between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by
161 increments of \$50,000.

162

163 **2. Travel Reimbursements and Sponsorships**

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

171

- 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.

176

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

182

183 **3. Training**

184 JCHR will require each investigator to complete training regarding the JCHR FCOI
185 policy prior to engaging in research and at least every four years, and immediately when
186 any of the following circumstances apply:

187

- JCHR revises its FCOI policies or procedures in any manner that affects the
188 requirements of employees;

188

- 189 • An investigator is new to JCHR; or
190 • JCHR finds that an investigator is not in compliance with the JCHR FCOI policy
191 or management plan.
192

193 **E. INSTITUTIONAL RESPONSIBILITIES FOR PHS-FUNDED RESEARCH**

194
195 **1. JCHR Procedures**

196 JCHR will:

- 197 • Maintain an up-to-date written, enforced policy on FCOI that complies with 42
198 CFR 50 Subpart F.
199 • Make the FCOI policy available on the JCHR website (www.jaeb.org).
200 • Inform each employee of the JCHR FCOI policy, the employee’s responsibilities
201 regarding disclosure of FIs, and of these regulations, and require each
202 investigator to complete training regarding JCHR’s FCOI policy prior to engaging
203 in research related to any PHS-funded grant and at least every four years, and
204 immediately when any of the following circumstances apply:
205 ○ JCHR revises its FCOI policies or procedures in any manner that
206 materially affects the requirements of employees;
207 ○ JCHR finds that an employee is not in compliance with the JCHR FCOI
208 policy or management plan.
209 • Provide guidelines consistent with 42 CFR Part 50 Subpart F for the designated
210 Institutional official to determine whether an individual’s SFI is related to PHS-
211 funded research and, if so related, whether the SFI is a financial conflict of
212 interest.
213 • Determine if the SFI is with an entity that could directly or indirectly be affected
214 by the PHS-funded research in which the individual is participating.
215 ○ If yes, determine whether the SFI could directly and significantly affect the
216 design, conduct, or reporting of the PHS-funded research.
217 ▪ In a multi-center study, as a general rule, a FCOI will not be
218 considered to be present if an investigator enrolls fewer than 10%
219 of the patients in the study, assuming the investigator is not the
220 protocol chair or has a comparable position that could substantially
221 affect a protocol’s design or results reporting. In general, an
222 individual with a SFI would be considered to have a FCOI if the
223 individual serves as a protocol chair, as a lead author of the primary
224 manuscript, or as the presenter at a national or international
225 meeting of the primary study results (management in such cases, in
226 general, will be to prohibit the investigator from serving in these
227 roles).
228 ○ If yes, take such actions as necessary to manage the FCOI.
229 ○ Management of an identified FCOI will include development and
230 implementation of a management plan and, if necessary, a retrospective
231 review and a mitigation report pursuant to 42 CFR 50.605(a).
232 • Provide initial and ongoing FCOI reports to the PHS as required pursuant to 42
233 CFR 50.605(b).
234 • Maintain records relating to all disclosures of FIs and JCHR’s review of, and
235 response to, such disclosures (whether or not a disclosure resulted in the

236 Institution's determination of a financial conflict of interest) and all actions under
237 the JCHR policy or retrospective review, if applicable, for at least three years
238 from the date the project's final expenditure report is submitted to the PHS or,
239 where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b)
240 for different situations.

- 241 • Enforce adequate employee sanctions or other administrative actions to ensure
242 compliance as appropriate. Employees who are shown to be non-compliant will
243 be referred to the Human Resources Manager and/or Executive Director and
244 disciplinary action may be taken up to and including suspension with or without
245 pay and termination of employment.
- 246 • Certify, in each application for funding to which 42 CFR Part 50 Subpart F
247 applies, that JCHR:
 - 248 ○ Has in effect an up-to-date, written, and enforced administrative process
249 to identify and manage financial conflicts of interest with respect to all
250 research projects for which funding is sought or received from the PHS;
 - 251 ○ Shall promote and enforce employee compliance with the requirements of
252 42 CFR Part 50 Subpart F including those pertaining to disclosure of
253 significant financial interests;
 - 254 ○ Shall manage FCOIs and provide initial and ongoing FCOI reports to the
255 PHS Awarding Component consistent with 42 CFR Part 50 Subpart F;
 - 256 ○ Agrees to make information available, promptly upon request, to the HHS
257 relating to any employee disclosure of FIs and JCHR's review of, and
258 response to, such disclosure, whether or not the disclosure resulted in the
259 JCHR's determination of a FCOI; and
 - 260 ○ Shall fully comply with the requirements of 42 CFR Part 50 Subpart F.

261
262 Strategies to manage financial conflicts of interest include:

- 263 • Retrospective review in accordance with the policy contained in Section C.2
- 264 • Mitigation reporting in accordance with the policy contained in Section E.5
- 265 • Project specific policies which preclude the Principal Investigator, Network Chair,
266 Coordinating Center Director, Operations/Executive Committee members,
267 members of the Data Safety Monitoring Board from having a non-research
268 Significant Financial Interest with an entity related to the project specific research
- 269 • Project specific policies which preclude more than 50% of the members of a
270 Protocol Development or Writing Committee from having a non-research
271 Significant Financial Interest with an entity related to the project specific research
272 Prohibitions on enrollment of patients vary by project depending upon the level of
273 risk and the nature of the study. Depending on the policies established by the
274 Project, investigators may be prohibited from enrolling patients, may be limited to
275 no more than 5% of the study participants, or may be limited to no more than
276 10% of the study participants. Investigators and researchers who are non-
277 compliant with the Project and JCHR policies or the established management
278 plan will be decertified and will no longer be permitted to participate in research
279 conducted by JCHR.

280
281
282 **2. Subrecipients in PHS-funded Research**

283 If JCHR carries out a PHS-funded research project through a subrecipient (e.g.,
284 subcontractors or consultants), JCHR as the awardee institution must take reasonable
285 steps to ensure that any subrecipient Investigator complies with 42 CFR Part 50
286 Subpart F by:

- 287 • Incorporating as part of a written agreement with the subrecipient, terms
288 that establish whether the FCOI policy of JCHR or that of the subrecipient will
289 apply to the subrecipient's Investigators.
 - 290 ○ If the subrecipient's Investigators must comply with the subrecipient's
291 FCOI policy, the subrecipient shall certify as part of the agreement
292 referenced above that (1) its policy complies with 42 CFR Part 50 Subpart
293 F and (2) it will report any FCOIs within 30 days of determining that an
294 FCOI pertinent to the project exists.
 - 295
 - 296 ○ If the subrecipient cannot provide such certification, then the agreement
297 with the subrecipient must indicate that investigators are subject to
298 JCHR's FCOI policy for disclosing FIs that are directly related to the
299 subrecipient's involvement in the project.
- 300
- 301 • Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of
302 all subrecipient Investigators consistent with 42 CFR Part 50 Subpart F prior to
303 the expenditure of funds and within 60 days of any subsequently identified FCOI.
304

305 **3. Remedies for PHS-funded Research**

306 If the failure of an Investigator to comply with JCHR's FCOI policy or a financial conflict
307 of interest management plan appears to have biased the design, conduct, or reporting
308 of the PHS-funded research, JCHR shall promptly notify the PHS Awarding Component
309 of the corrective action taken or to be taken. JCHR will follow any and all directions and
310 instructions from the PHS Awarding Component on how to maintain appropriate
311 objectivity in the PHS-funded research project.

312

313 JCHR will submit, or permit onsite review of, all records pertinent to compliance with 42
314 CFR Part 50 Subpart F. If the PHS Awarding Component determines that a particular
315 FCOI will bias the objectivity of the PHS-funded research to such an extent that further
316 corrective action is needed, or that JCHR has not managed the FCOI in accordance
317 with 42 CFR Part 50 Subpart F, JCHR will abide by any special award conditions,
318 suspension of funding or other enforcement actions imposed by the PHS Awarding
319 Component until the matter is resolved.

320

321 In any case in which the HHS determines that a PHS-funded project of clinical research
322 whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or
323 treatment has been designed, conducted, or reported by an individual with a FCOI that
324 was not managed or reported by JCHR as required by 42 CFR Part 50 Subpart F,
325 JCHR will require the individual involved to disclose the FCOI in each public
326 presentation of the results of the research and to request an addendum to previously
327 published presentations.

328 **4. Reporting for PHS-funded Research**

329 Prior to JCHR's expenditure of any funds under a PHS-funded research project, JCHR
330

331 shall provide to the PHS Awarding Component a FCOI report regarding any SFIs found
332 by the Institution to be a FCOI and ensure that JCHR has implemented a management
333 plan in accordance with 42 CFR Part 50 Subpart F. In cases in which JCHR identifies a
334 FCOI and eliminates it prior to the expenditure of PHS-awarded funds, JCHR shall not
335 submit a FCOI report to the PHS Awarding Component.
336

337 For any SFI that JCHR identifies as being a FCOI subsequent to the Institution's initial
338 FCOI report during an ongoing PHS-funded research project (e.g., upon the
339 participation of an individual who is new to the research project), JCHR shall provide to
340 the PHS Awarding Component, within 60 days, a FCOI report regarding the financial
341 conflict of interest and ensure that the Institution has implemented a management plan
342 in accordance with this 42 CFR Part 50 Subpart F.
343

344 Pursuant to the sections on Retrospective Review and Mitigation Reporting in this policy
345 document, where such FCOI report involves a SFI that was not disclosed in a timely
346 manner by an individual or, for whatever reason, was not previously reviewed or
347 managed by JCHR (or was not reviewed or reported in a timely manner by a
348 subrecipient), JCHR will complete a retrospective review to determine whether any
349 PHS-funded research, or portion thereof, conducted prior to the identification and
350 management of the financial conflict of interest was biased in the design, conduct, or
351 reporting of such research. Additionally, if bias is found, JCHR will notify the PHS
352 Awarding Component promptly and submit a mitigation report to the PHS Awarding
353 Component.
354

355 Any FCOI report shall include sufficient information to enable the PHS Awarding
356 Component to understand the nature and extent of the financial conflict, and to assess
357 the appropriateness of JCHR's management plan. Elements of the FCOI report shall
358 include, but are not necessarily limited to the following:

- 359 • Project number;
- 360 • PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- 361 • Name of the individual with the financial conflict of interest;
- 362 • Name of the entity with which the individual has a financial conflict of
363 interest;
- 364 • Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement,
365 honorarium);
- 366 • Value of the SFI (dollar ranges are permissible: \$5,000–\$9,999; \$10,000–
367 \$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000;
368 amounts above \$100,000 by increments of \$50,000);
- 369 • or a statement that the interest is one whose value cannot be readily determined
370 through reference to public prices or other reasonable measures of fair market
371 value;
- 372 • A description of how the SFI relates to the PHS-funded research and the basis
373 for JCHR's determination that the financial interest conflicts with such research;
374 and
- 375 • A description of the key elements of JCHR's management plan, including:
 - 376 ○ Role and principal duties of the conflicted employee in the research
377 project;

- 378 ○ Conditions of the management plan;
- 379 ○ How the management plan is designed to safeguard objectivity in the
- 380 research project;
- 381 ○ Written confirmation of the employee's agreement to the management
- 382 plan;
- 383 ○ How the management plan will be monitored to ensure compliance; and
- 384 ○ Other information as needed.
- 385

386 For any FCOI previously reported by JCHR with regard to an ongoing PHS-funded
387 research project, JCHR shall provide to the PHS Awarding Component an annual FCOI
388 report that addresses the status of the FCOI and any changes to the management plan
389 for the duration of the PHS-funded research project. The annual FCOI report shall
390 specify whether the financial conflict is still being managed or explain why the financial
391 conflict of interest no longer exists. JCHR shall provide annual FCOI reports to the PHS
392 Awarding Component for the duration of the project period (including extensions with or
393 without funds) in the time and manner specified by the PHS Awarding Component.

394 **5. Mitigation Reporting for PHS-Funded Research**

396 If bias is found following a retrospective review of a FCOI in PHS-funded research,
397 JCHR is required to notify the PHS Awarding Component promptly and submit a
398 mitigation report to the PHS Awarding Component. The mitigation report must include,
399 at a minimum:

- 400 ● the key elements documented in the retrospective review above;
- 401 ● a description of the impact of the bias on the research project;
- 402 ● JCHR's plan of action or actions taken to eliminate or mitigate the effect of the
- 403 bias;
- 404 ● extent of harm done, including any qualitative and quantitative data to support
- 405 any actual or future harm;
- 406 ● analysis of whether the research project is salvageable.
- 407

408 Thereafter, the JCHR will submit FCOI reports annually, as specified elsewhere in this
409 document. Depending on the nature of the financial conflict of interest, JCHR may
410 determine that additional interim measures are necessary with regard to the employee's
411 participation in the PHS-funded research project between the date that the FCOI or the
412 employee's noncompliance is determined and the completion of the Institution's
413 retrospective review.

414 **6. Public Accessibility with Respect to PHS-funded Research**

416 Prior to JCHR's expenditure of any funds under a PHS-funded research project, JCHR
417 shall ensure public accessibility, via a publicly-accessible website or written response to
418 any requestor within five business days of a request, of information concerning any
419 FCOI disclosed to JCHR that meets the following three criteria:

- 420 ● The SFI was disclosed and is still held by the senior/key personnel as defined by
- 421 42 CFR Part 50 Subpart F;
- 422 ● JCHR determines that the SFI is related to the PHS-funded research; and
- 423 ● JCHR determines that the SFI is a FCOI.
- 424

425 The information that JCHR makes available via a publicly-accessible website or written
426 response to any requestor within five business days of a request shall include, at a
427 minimum, the following:

- 428 • the individual's name;
- 429 • the individual's title and role with respect to the research project;
- 430 • the name of the entity in which the significant financial interest is held;
- 431 • the nature of the significant financial interest;
- 432 • and the approximate dollar value of the significant financial interest (dollar ranges
433 are permissible: \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–
434 \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of
435 \$50,000),
- 436 • or a statement that the interest is one whose value cannot be readily determined
437 through reference to public prices or other reasonable measures of fair market
438 value.

439
440 The information that JCHR posts on a publicly-accessible website shall be updated at
441 least annually. In addition, JCHR shall update the website within 60 days of JCHR's
442 receipt or identification of information concerning any additional FCOIs of the senior/key
443 personnel for the PHS-funded research project that was not previously disclosed, or
444 upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research
445 project, if the Institution determines that the significant financial interest is related to the
446 PHS-funded research and is a financial conflict of interest.

447
448 The website shall note that the information provided is current as of the date listed and
449 is subject to updates, on at least an annual basis and within 60 days of JCHR's
450 identification of a new FCOI.

451
452 If JCHR responds to written requests, JCHR will note in its written response that the
453 information provided is current as of the date of the correspondence and is subject to
454 update, on at least an annual basis and within 60 days of the Institution's identification
455 of a new FCOI, which should be requested subsequently by the requestor.

456
457 Information concerning the FCOIs of an individual subject to this policy shall remain
458 available, for responses to written requests or for posting via the Institution's publicly-
459 accessible website for at least three years from the date that the information was most
460 recently updated.