POLICIES ON CONFLICTS OF INTEREST AND CONSULTING

A Conflict Of Interest may exist when a CCF Professional Staff member or Employee, or a member of his or her Immediate Family or an entity directed or controlled by any of them, has an interest in (including relationships with) a non-CCF party—whether investment, compensation, or otherwise—that could be reasonably perceived as influencing the Staff member’s or Employee’s actions or judgments in patient care, research, administrative decisions, or business transactions for CCF. For example:

- **Business** – A Conflict Of Interest may exist if a CCF Official receives financial benefits from an entity that does business with CCF.
- **Researcher** – A Staff member owning stock in a pharmaceutical company that sponsors his or her research would present a Significant Financial Interest in research.
- **Institutional (Research)** – A Staff member performing research sponsored by a company in which CCF itself owns stock may constitute an Institutional Financial Interest in research.

To assure professional and commercial integrity in all matters, CCF maintains a program that identifies and addresses Conflicts Of Interest, conflicts of commitment, and Consulting. These policies provide a comprehensive system of disclosure and oversight of all Conflicts Of Interest—for Professional Staff members, Employees, and the institution. The following six policies and three appendices address these issues:

<table>
<thead>
<tr>
<th>Policy</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy I</td>
<td>Conflicts of Commitment for the Professional Staff</td>
<td>2</td>
</tr>
<tr>
<td>Policy II</td>
<td>Conflicts of Interest in Business Affairs and in General</td>
<td>3</td>
</tr>
<tr>
<td>Policy III</td>
<td>Researcher Conflicts of Interest in Non-Human Subjects Research</td>
<td>5</td>
</tr>
<tr>
<td>Policy IV</td>
<td>Researcher Conflicts of Interest in Human Subjects Research</td>
<td>7</td>
</tr>
<tr>
<td>Policy V</td>
<td>Institutional Conflicts of Interest in Research</td>
<td>9</td>
</tr>
<tr>
<td>Policy VI</td>
<td>Consulting by the Professional Staff</td>
<td>11</td>
</tr>
<tr>
<td>Appendix A</td>
<td>Operating Guidelines of Conflict of Interest Committee</td>
<td>14</td>
</tr>
<tr>
<td>Appendix B</td>
<td>Legal Information</td>
<td>17</td>
</tr>
<tr>
<td>Appendix C</td>
<td>Glossary</td>
<td>18</td>
</tr>
</tbody>
</table>

These policies shall be administered in accordance with the obligations of tax-exempt organizations and consistent with applicable fraud and abuse laws. Violation of these policies may be grounds for loss of research privileges or disciplinary action up to and including termination from employment in accordance with the disciplinary policies of CCF. The reporting of interests that could result in Conflicts Of Interest or conflicts of commitment does not necessarily satisfy the reporting requirements of the Board of Trustees, the Institutional Review Board (“IRB”), or the Institutional Animal Care and Use Committee (“IACUC”).

These policies apply to The Cleveland Clinic Foundation (Ohio) and Cleveland Clinic Florida, including their regional medical practice centers, and any of their wholly-owned affiliates (collectively referred to as “CCF”), as well as all members of the Professional Staff (“Staff”) of CCF and any other CCF employee, agent, staff, student, fellow, trainee, or administrator (collectively “Employees”). All of the policies (Policies I through VI) apply to the Staff, but only Policies II through V apply to Employees. Capitalized terms are defined in the Glossary. CCF reserves the right to change these policies at any time. Changes to these policies must be approved by the Conflict of Interest Committee of the Board of Trustees. The IRB and the IACUC shall be apprised of changes to these policies that affect their operations.
POLICY I

CONFLICTS OF COMMITMENT FOR THE PROFESSIONAL STAFF

(Capitalized terms are defined in the Glossary.)

CCF recognizes that members of the Professional Staff (“Staff”) periodically serve in external consulting* roles and in other activities that may or may not require the use of their professional competence, e.g., as external consultants, members of Pharma Advisory Committees or boards of directors**, and medical reviewers for outside health care entities and licensing authorities. Service in external activities can be beneficial to Staff members professionally, CCF, its patients, and the public. These activities are generally permissible (subject to compliance with institutional policy**) provided that a Staff member’s commitment to professional responsibilities at CCF remains primary at all times. An overabundance of such external activities may conflict with a Staff member’s responsibilities at CCF.

Conflicts of commitment that are not appropriate could occur, for example, in the following areas:

- **Disproportionate Compensation** – If Honoraria or Consulting Compensation* to a Staff member from outside entities, in the aggregate, exceeds thresholds established from time to time by the Office of Professional Staff Affairs (“OPSA”), a potential for a conflict of commitment exists.

- **Conflict of Time** – When the time commitments for external activities—related to professional competence or not—encroach upon a Staff member’s ability to contribute at the level expected of other Staff members in the same specialty, a potential for a conflict of time commitment exists. Activities involving Honoraria and Consulting Compensation* may not exceed 20% of that portion of a Staff member’s time that is allocated to research or development as approved by the Staff member’s department chair, except that vacation time may be used to exceed the 20% limit.

- **Conflict of Business or Mission** – Staff members may not engage in consulting or other external activities that compete or conflict with CCF’s business activities or mission, and they must not divulge proprietary CCF business information.*

- **Conflict of Resources/ Intellectual Property** – Staff members may not utilize CCF resources or share intellectual property developed or acquired during their Staff appointment for the betterment of an external entity unless permitted by the Major Policies for the Professional Staff.*

The COI Committee shall provide disclosed financial interest information to Department and Division Heads, as appropriate, who shall monitor conflicts of commitment. The COI Committee, at its discretion, shall notify the Chief of Staff of circumstances that may be perceived as a conflict of commitment.

* Staff members are subject to the policies contained in the Major Policies for the Professional Staff. Particularly relevant to this policy are Policy VI, “Consulting by the Professional Staff,” and the “Intellectual Property and Commercialization Policy.”

** Fiduciary service as a member of an external board of directors requires the pre-approval of the Board of Governors and the Board of Trustees in accordance with the policy entitled, “Membership on Boards of Directors in Outside, For-Profit Businesses and Corporations.” Service on a Pharma Advisory Committee is not fiduciary service requiring these approvals, but such service, if compensated, does require pre-approval and compliance with Policy VI, “Consulting by the Professional Staff.”
Members of CCF’s workforce have broad access to confidential information regarding CCF’s clinical, business, research, and other activities, including CCF’s proprietary information, intellectual property, and strategic plans. No CCF Professional Staff member ("Staff") or Official, employee, agent, student, fellow, trainee, or administrator (collectively called “Employees”) shall use a position with CCF (including its wholly-owned affiliates), or confidential information acquired as a result of his or her position with CCF, to permit a Conflict of Interest to arise between CCF’s interests and his or her personal interests.

A Conflict Of Interest may exist when a CCF Staff member or Employee, or a member of his or her Immediate Family or an entity directed or controlled by any of them, has an interest in (including relationships with) a non-CCF party—whether investment, compensation*, or otherwise—that could be reasonably perceived as influencing his or her activities in patient care, research, administrative decisions, or business transactions for CCF. To help advance CCF’s mission, Staff members and Employees must respect the confidentiality of CCF’s information, act in the best interests of CCF, and disclose all of their existing and potential personal interests that may result in a Conflict Of Interest.

- **Members of the CCF Professional Staff** must report all existing and potential personal interests (including Significant Financial Interests in research**) that may result in a Conflict of Interest through the online Conflict of Interest Disclosure system both (1) prior to the interest occurring and (2) during their Annual Professional Reviews.

- **CCF Officials**, whether Members of the Professional Staff or not, must report as described above for the Professional Staff and also must report online any Institutional Financial Interests in research.*** (In addition to these requirements, CCF Officials who are elected Officers must separately comply with the conflict of interest requirements of the Board of Trustees.)

- **Employees** must report all existing and potential personal interests that may result in a Conflict of Interest prior to the interests occurring. Such reporting must be made to the Conflict of Interest ("COI") Committee.

Interests reported in prior years must be redisclosed annually if still applicable. The COI Committee will review all reported interests – whether they involve clinical care, research, or other activities - and notify the affected Staff member or Employee if the circumstances warrant further review, recusal, oversight, a management plan, or other action.

* Consistent with CCF’s Corporate Compliance Program, Staff members and Employees must not directly or indirectly accept any compensation or benefit—in cash or in kind, regardless of amount or value—which in any way might tend to influence their judgments or actions for CCF in a way that is detrimental to the best interests of CCF. The receipt of any such compensation or benefit should not be considered permissible merely because it appears to be a customary or common business practice in certain industries. Relationships with and/or benefits from medical vendors are discussed in other CCF policies and/or CCF guidance.

** Pursuant to Policies III and IV involving conflicts of interest in non-human and human subjects research for investigators.

*** Pursuant to Policy V involving institutional conflicts of interest in research.
CCF maintains the highest degree of integrity and fiscal responsibility and compliance with the obligations of tax-exempt organizations, physician self-referral laws, and applicable fraud and abuse laws. This policy is enacted, in part, to comply with these laws. Questions about the nature of circumstances to be disclosed may be addressed to the Chair of the COI Committee. Personal or institutional interests that may involve potential legal or compliance issues should be referred to the Office of General Counsel.
POLICY III

RESEARCHER CONFLICTS OF INTEREST
IN NON-HUMAN SUBJECTS RESEARCH

[This policy is superseded and replaced by IM&COI Policy III, Conflicts of Interest in Research adopted by the Board of Governors August 23, 2012, effective August 24, 2012. See accompanying document.]
[This policy is superseded and replaced by IM&COI Policy III, Conflicts of Interest in Research adopted by the Board of Governors August 23, 2012, effective August 24, 2012. See accompanying document.]
POLICY IV

RESEARCHER CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

(Capitalized terms are defined in the Glossary.)

[This policy is superseded and replaced by IM&COI Policy III, Conflicts of Interest in Research adopted by the Board of Governors August 23, 2012, effective August 24, 2012. See accompanying document.]
[This policy is superseded and replaced by IM&COI Policy III, Conflicts of Interest in Research adopted by the Board of Governors August 23, 2012, effective August 24, 2012. See accompanying document.]
POLICY V

INSTITUTIONAL CONFLICTS OF INTEREST IN RESEARCH

(Capitalized terms are defined in the Glossary.)

Presumption Against Conducting Research When CCF Holds Institutional Financial Interests

A Human or Non-Human Subjects Research project in which CCF or a CCF Official has an Institutional Financial Interest in the commercial sponsor of the research (or any other Financially Interested Company) is subject to the approval of the COI Committee. Approval may be granted if Compelling Circumstances exist that justify conducting the research. Compelling Circumstances are those facts that convince the COI Committee that the research may be conducted at or by CCF despite the Institutional Financial Interest. If the COI Committee determines that Compelling Circumstances exist, the research could be conducted only pursuant to a management plan approved by the COI Committee and ratified by the Institutional Review Board (“IRB”) and/or the Institutional Animal Care and Use Committee (“IACUC”), as applicable.

Institutional Financial Interests

An Institutional Financial Interest (“IFI”) occurs when one or more of the following circumstances exists (as more fully defined in the Glossary):

- CCF receives royalties from the sale of a product that is or was under investigation at CCF
- CCF holds any equity in a non-publicly traded sponsor of current CCF research
- CCF Holds equity exceeding $100,000 in a publicly traded sponsor of current CCF research, or
- An Official of CCF (or Immediate Family member or controlled entity), whether or not Participating in CCF research, has one or more of the following Significant Financial Interests in a Human Subjects Research sponsor at CCF or a product currently being investigated for clinical use at CCF:
  - Honoraria and Consulting Compensation Over $10,000 Per Year* from the sponsor
  - Any Equity or Royalties from a non-publicly traded sponsor
  - Equity or royalties exceeding $10,000 from a single publicly traded sponsor
  - Payments involving the research project not specified in the contracting document
  - Fiduciary Service** as an officer, partner, or governing board member

Other Reportable Relationships

The following (referred to as “other reportable relationships”) are not necessarily IFIs but are nonetheless reportable to the COI Committee by any CCF Staff member or administrator who, on CCF’s behalf:

- Participates Significantly in Major or Non-routine Purchases from a Research Sponsor
- Receives a Substantial Gift or Grant from a Research Sponsor – including equity or partnership interests

* Honoraria and Consulting Compensation of any amount paid to Staff is subject to the approval requirements of Policy VI.
** Fiduciary service as an officer or member of an external board of directors requires pre-approval in accordance with the policy entitled, “Membership on Boards of Directors in Outside, For-Profit Businesses and Corporations.”
Reporting to COI Committee

- **Departmental Reporting** – The CCF Treasurer, the Office of Sponsored Research, the Office of CCF Innovations, the Purchasing Department, the Center of Continuing Education (including UNITECH Communications), and the Office of Institutional Relations and Development must report to the Conflict of Interest (“COI”) Committee the terms of any arrangements or transactions that may create an Institutional Financial Interest or “other reportable relationship” for CCF (or a CCF subsidiary).

- **Disclosures by Officials and Committee Members** – CCF Officials and members of the IRB, IACUC, and COI Committee must annually report to the COI Committee (with prompt interim updating) all Significant Financial Interests (“SFIs”) or “other reportable relationships” that they (or their Immediate Family members) have in sponsors (or the sponsors’ direct and primary competitors) of current or anticipated CCF Human Subjects Research or Non-Human Subjects Research, whether or not they are involved in the research.

- **Other Reportable Relationships** – Any CCF Staff member or administrator who has an “other reportable relationship” should report that relationship to the COI Committee.

List of Financially Interested Companies

The COI Committee shall periodically evaluate the reports it receives and develop a listing of (institutionally) Financially Interested Companies and provide that listing to the IRB, IACUC, the Office of General Counsel, and the other CCF departments shown above.

Disclosures to Research Subjects and the Scientific Community

To the extent required by the COI Committee, the existence of an Institutional Financial Interest in Human or Non-Human Subjects Research that has been approved by the COI Committee must be disclosed as follows and as applicable:

- In IRB-approved consent forms, with an explanation that additional information will be provided to the research subjects upon request
- In or with a manuscript submitted for publication concerning the research
- In any substantive public communication of the research results
- To the principal investigator, co-investigators, collaborators, other research personnel working on the research project
- To the sponsor of multi-center trials
- To the IRBs and IACUCs of the other participating institutions.
POLICY VI
CONSULTING BY THE PROFESSIONAL STAFF

(Capitalized terms are defined in the Glossary.)

Engaging in External Activities

A Professional Staff member may use his or her professional competence to deliver outside lectures or engage in consulting or other external activities for which he or she receives compensation (“Honoraria and/or Consulting Compensation”) from a source other than CCF, as long as the Staff member complies with this policy. This policy also applies when the compensation—which may be direct or indirect, financial or otherwise—is received by an Immediate Family member (or an entity controlled or directed by the Staff member or family member). Examples of compensation include honoraria, consulting fees, lecture fees, stock or stock options, royalties, and “in kind” compensation.

Pre-Approval of Honoraria and Consulting Compensation

Before engaging in any external activities that require one’s professional competence to earn the types of compensation described in (3)-(6) below, a Staff member must report the activity through the online Conflict of Interest Disclosure system and receive notice of approval from the COI Office Department chairs (or other immediate superiors) must acknowledge all external activities; the Staff member’s division chair (or next higher authority) will resolve any disputes that may occur.*

- **NO APPROVAL REQUIRED for These Types of Compensation**
  1. Book royalties
  2. Compensation for lectures, journal articles, educational tapes, visiting professorships, and services to professional societies or NIH study sections, unless they are described below in (4), (5), or (6)

- **PRE-APPROVAL REQUIRED for These Types of Compensation (see EXAMPLES below)**
  3. Any value of Honoraria or Consulting Compensation not described in (1) or (2) above
  4. Any direct or indirect compensation from the pharmaceutical or biotechnology health industry

- **PRE-APPROVAL OF WRITTEN AGREEMENT by Office of General Counsel (OGC) required**
  5. Any direct or indirect compensation for advising Financial Investment Firms or firms that broker for Financial Investment Firms (also requires approval of Conflict of Interest Committee)
  6. Any compensation over $10,000 from (2), (3), (4), or (5) above during any 12-month period from any single source

- **EXAMPLES of External Activities Requiring Pre-Approval**
  - Advising a pharmaceutical company or Financial Investment Firm about emerging technology
  - Serving on a scientific advisory board or other Pharma Advisory Committee
  - Speaking at a conference in return for payments from pharmaceutical companies (or their affiliates), including payments from medical education companies indirectly supported by industry
    - **Exception:** Pre-approval is not required for delivering an ACCME-accredited lecture (because industry sponsors may not select the speakers for ACCME-accredited lectures)
Retaining Compensation; Exceptions: Expert Witnesses Fees & Fund Ownership

Compensation for external activities may be retained by Staff members personally, except that (1) any compensation paid for any service—even “after hours” service—as an expert witness in a legal case must be remitted to CCF and credited to operating income and (2) Staff members may never accept ownership in an investment fund as compensation for consulting for a Financial Investment Firm.

Prohibited External Activities

Staff members must not:

- Receive compensation for clinical activities performed outside the scope of CCF employment
- Engage in activities in direct conflict with CCF’s mission or business position in a matter
- Engage in purely marketing activities for the pharmaceutical/biotechnology health industry, e.g., writing papers favoring a company’s products or disfavoring its competitors’ products
- Receive compensation from a non-CCF source for performing any of their CCF employment activities, e.g., surgery observation and shadowing
- Advise Financial Investment Firms or the investing public without pre-approval by both the Conflict of Interest (“COI”) Committee and OGC. This prohibition is necessary to avoid inadvertent violations of insider trading laws and the obligations of tax-exempt organizations. (Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered Financial Investment Firms. Consulting for them involves the institutional pre-approval process required when consulting for entities other than Financial Investment Firms.)
- Serve as an expert witness in a legal case without pre-approval by OGC
- Incur a Conflict Of Interest, including a Significant Financial Interest or Institutional Financial Interest in research, without disclosure to the COI Committee

Bona Fide Services; Fair Value; Keeping Records

Compensation from non-CCF sources must never be an inducement or reward for the referral or generation of health care business. External consulting activities must be bona fide services that are documented in writing by a letter or written agreement, and the compensation must be for a demonstrably fair market value. Detailed records of Honoraria and Consulting Compensation must be kept by Staff members for 5 years and given to CCF upon request. When entering into arrangements to engage in external activities, Staff members are encouraged to use personal legal counsel to ensure their own protection and compliance with applicable fraud and abuse laws.

No Liability Protection Afforded by CCF

CCF does not provide liability protection (insurance) for any external activities, except for OGC-approved pro bono and expert witness activities when the compensation, if any, is remitted to the CCF Treasurer.

Related CCF Policies and Non-Staff Employee Consulting

Staff members who engage in external activities are subject to all policies contained in the Major Policies for the Professional Staff, including the “Intellectual Property and Commercialization Policy.” Staff researchers and CCF Officials may be limited in their ability to engage in consulting for research sponsors by Policies III-V. Non-Staff Employees are not bound by this policy and its pre-approval requirements, but they are encouraged to adhere to its other requirements. Non-Staff Employees must disclose Conflicts Of Interest that may arise from consulting pursuant to Policy II, “Conflicts of Interest in Business Affairs.
and in General.” CCF reserves the right to prohibit any external activity if doing so is in the best interest of CCF, regardless of the nature of the activity or the Staff member’s compliance with this policy.

* Department chairs must acknowledge all external activities of Staff members. Division chairs must acknowledge all external activities of department heads and resolve any disputes between Staff members and their department heads. The Chief of Staff must acknowledge all external activities of division chairs and resolve any disputes between department chairs and division chairs. The Board of Trustees or its designated committees must approve external activities of Officers, e.g., President and Chief of Staff.
APPENDIX A
POLICIES ON CONFLICTS OF INTEREST AND CONSULTING

OPERATING GUIDELINES OF CONFLICT OF INTEREST COMMITTEE

(Capitalized terms are defined in the Glossary.)

Conflict of Interest ("COI") Committee Governance – The COI Committee’s members, including alternates and Chair, are nominated by the Chief of Staff’s office after consultation with the (Staff) COI Committee, and are appointed by the Board of Governors. The Chair of the COI Committee will report to the Chief of Staff regarding the Committee’s activities. The COI Committee shall provide reports of its activities to the Board of Governors annually or more frequently if requested.

The ultimate authority regarding conflict of interest activities resides with the Board of Trustees COI Committee.

COI Committee Members – The COI Committee membership should include the following representation: a member of the CCF Professional Staff who does not conduct Human Subjects Research; the chair or vice chair of the Institutional Review Board (“IRB”); an attorney from the Office of General Counsel (“OGC”); a representative from the Office of Professional Staff Affairs (“OPSA”); a representative from the Office of Media Relations; and a representative from CCF Innovations (non-voting for institutional conflicts only). For consideration of Institutional Financial Interests ("IFIs") only, the COI Committee membership is expanded to include two members of the Board of Trustees, at least one of whom must vote as part of the majority for any approvals. One of the two Trustees is the Chairman of the Conflict of Interest Committee of the Board of Trustees and the other is selected by him or her. CCF Innovations representatives may deliberate but not vote on IFIs. Recusal is required whenever any member has a conflict of interest regarding any matter under review. An alternate should be available to replace the CCF Trustee when unavailable.

Review Process – The COI Committee reviews any disclosure or request to authorize an activity involving interests that may result in a Conflict Of Interest, including Significant Financial Interests (“SFIs”) and IFIs in research, clinical operations, and educational activities, and makes and documents the following determinations: (a) for SFIs and IFIs in research—whether or not Compelling Circumstances exist that justify conducting the research, or (b) for other personal interests—whether the proposed activity may proceed. The COI Committee may invite individuals to attend meetings to discuss their interests. The COI Committee should be mindful that the data integrity risks of Non-Human Subjects Research are the same as those in Human Subjects Research. For IFIs involving CCF Officials, the greater the rank or authority of the Official and the more closely that Official supervises research, the more closely the Official’s research-related financial interests and leadership roles will be scrutinized. The COI Committee shall collaborate with the COI Committee of the Board of Trustees to develop an appropriate conflict management plan for each interest disclosed by a Trustee that raises a potential conflict of interest in research, medical education, or the practice of medicine or surgery. The following lists of factors to consider and optional management strategies are provided as resources that may (or may not) be used by the COI Committee, at its discretion, in evaluating whether a research project may be conducted when SFIs and IFIs have been identified:

Factors to Consider in Evaluations

• A description of the research, including the risks to human subjects involved in the research
• Any unique expertise of the investigator, e.g., inventorship, that may make his or her involvement essential
• The nature and amount(s) of the financial interest that are related to the research
• The potential financial gains in the immediate and long-term future in the event the research is successful
• The extent to which the research results could be influenced by the financial interest
• The steps proposed by the investigator for effective oversight and management of the financial interest
• (For IFIs only) whether CCF is uniquely qualified (by special facilities or equipment, unique patient population, qualifications of its investigators, etc.) to conduct the research and safeguard the research subjects

Optional Management Strategies – For Researchers and CCF Institutional Officials

• Reduction of role on Pharma Advisory Committee, e.g., ex officio, non-voting (if for CCF Official with research oversight duties, restrict role for 3 years until after research completed)
• Restriction of Honoraria and Consulting Compensation, e.g., to less than $10,000 per year
• Reduction or divestiture of equity in company, including stock and options
• Reduction or elimination of royalty income
Restriction from fiduciary service, such as an officer or director
• Disclosure of SFIs to others working on the research; to the sponsor; in publications and presentations
• Disclosure of SFIs in research informed consent documents
• Annual report to COI Committee on compliance with a management plan
• Recusal in all matters related to the research study (if CCF Official and non-investigator)

Additional Optional Management Strategies – For the Institution
• Reduction or elimination of royalties from the sale of the investigational product
• Divestiture of equity if sponsor is non-publicly traded, including options or warrants
• Reduction of equity to less than $100,000 if sponsor is or becomes publicly-traded
• Limitation of research to a non-primary research site and/or not serving as the coordinating site
• Use of a data and safety monitoring board composed entirely or partially of non-CCF members
• External IRB approval in addition to the approval of CCF’s own IRB
• Presence at IRB meeting of “community CCF IRB member” or that IRB member’s approval

When the COI Committee determines that the research or other activity may proceed, the COI Committee provides management and oversight of the potential COIs related to the research or other activity, which may include periodic compliance audits and which must include periodic reviews at least annually. The COI Committee, with the advice of the OGC, approves (1) a conflict management plan (the “Plan”) that describes the financial interest, the conditions under which the activity may proceed, and the individuals subject to the Plan (the “Interested Parties”) as well as (2) a brief report (the “Summary Report”) that summarizes the Plan. Significant conflict management plans should contain an additional paragraph describing the depth and frequency of any compliance audits that are required by that Plan. The COI Committee will use its best efforts to develop a standard approach to managing those types of interests for which a standard approach is reasonable. Any changes in the Plan require COI Committee approval. The Board of Trustees provides joint oversight and management (with the COI Committee) of Plans involving Interested Parties who are CCF Officers. The COI Committee distributes copies of the Plan (including the Summary Report) to the Interested Parties, the OGC, OPSA, and the IRB (with the precise amounts and natures of the financial interests redacted from the IRB copy). The Committee sends the Summary Report only to the Interested Parties’ Department Chairs (or other administrative superiors in the event of conflicts of interest), departmental research coordinators, the Director of Sponsored Research, the Director of Media Relations, and (for Institutional Financial Interests only) to the Board of Governors for informational purposes. The Summary Report may be provided by the IRB to human research subjects who request more information than that contained in the informed consent form. IRB representatives who are members of the COI Committee may reveal the precise amount and nature of a financial interest to the IRB with the approval of the principal investigator. The COI Committee may perform audits to ensure management Plan compliance and full and accurate disclosure of SFIs, leadership roles, and/or IFIs by CCF Staff members and Employees.

Comparative Authority of COI Committee, IRB, and IACUC – Neither the IRB nor the Institutional Animal Care and Use Committee (“IACUC”) may approve research that has been disapproved by the COI Committee. Neither the IRB nor the IACUC may approve monitoring procedures or other conditions that are less protective of research subjects than those imposed by the COI Committee. Otherwise, no authorization granted by the COI Committee may supersede the authority of either the IRB or the IACUC. The IRB or IACUC may impose more stringent restrictions upon research than those imposed by the COI Committee. The IRB or IACUC may disapprove research despite a determination by the COI Committee that Compelling Circumstances exist.

Appeals – Determinations of the COI Committee may be appealed to the Board of Governors. Requests for appeal must be in writing and be submitted to the Chief of Staff, with a copy to the COI Committee Chair. Determinations of the COI Committee are in effect during the appeal. Decisions of the Board of Governors are final and are submitted in writing to the Staff member or Employee, the COI Committee, the IRB or IACUC, the Staff member’s or Employee’s department chair. If the Board of Governors modifies the COI Committee’s determination, the COI Committee modifies and reissues the Plan and Summary Report.

Reporting by IRB and IACUC – The IRB and IACUC alerts the COI Committee and the Chairman of the Division of Clinical Research (for Human Subjects Research) and the Chairman of the Lerner Research Institute (for Non-Human Subjects Research) whenever a Staff member or Employee known to have a Significant Financial Interest proposes to conduct SFI-related research. The IRB or IACUC withholds final approval of the research until informed of the COI Committee’s determinations.
Reporting by CCF Innovations – Prior to executing a technology licensing agreement, the Office of CCF Innovations determines whether the agreement would create either an Institutional Financial Interest or a Significant Financial Interest for any Staff member or Employee in ongoing or proposed research, and if so inform the COI Committee of the proposed terms of the agreement. The COI Committee then reviews the matter.

Protection from Discovery – The COI Committee, the Board of Governors, and the IRB, while administering their responsibilities as described herein, are review committees described in O.R.C. Sec. 2305.25, entitled to the protections from discovery in legal proceedings afforded by law. Summary Reports are prepared for public disclosure and are not intended to be protected from discovery.
APPENDIX B
POLICIES ON CONFLICTS OF INTEREST AND CONSULTING

LEGAL INFORMATION

(Capitalized terms are defined in the Glossary.)

Intellectual Property and Publication Rights – CCF Staff members and Employees are accountable for the integrity of publications that bear their names. A principal investigator may receive, analyze, and interpret all data generated in the research and publish the results, regardless of the outcome of the research. Neither CCF, its Staff members, nor its Employees should enter research agreements that permit a research sponsor or other Financially Interested Company to require more than a reasonable time for pre-publication review, or that interfere with a Staff member’s or Employee’s access to the data developed at CCF or ability to analyze that data independently. Members of the Professional Staff are also subject to the policies entitled “Guidelines for Manuscripts and Books,” “Commercial Publication of Medical Professional Works,” and “Intellectual Property and Commercialization Policy” contained in the Major Policies for the Professional Staff.

Medicare Fraud/Referral Prohibitions – In general, federal law prohibits a person from knowingly and willfully offering or paying anything of value (direct or indirect) to any person to induce that person to refer or purchase, lease, order or arrange for services which are reimbursable by a federal health care program. The general purpose of the statute is to prohibit anyone from paying or accepting payment in exchange for the referral of Medicare or Medicaid patients. There are certain “safe harbors” identifying specific types of practices that would not violate federal law. For instance, certain consulting arrangements are permissible so long as the payment to the consultant is for legitimate services and in an amount that reflects the fair market value of the services. Also, commercial research sponsors or vendors may provide funding for research or other bona fide purposes to CCF, even though CCF may order supplies from that vendor. If the purpose of the funding is to induce referrals from CCF, however, the funding would be prohibited. Federal law also broadly prohibits physicians from making certain referrals to entities with which they have a financial relationship unless a statutory exception applies. There are a series of exceptions that apply to this prohibition as well, e.g., a bona fide consulting agreement where specific requirements are met.

Insider Trading – The securities laws broadly prohibit fraudulent activities of any kind in connection with the offer, purchase, or sale of securities. These provisions are the basis for many types of government enforcement activities, including actions against illegal insider trading. Insider trading is illegal when a person trades a security while in possession of material nonpublic information, including information from medical research trials, in violation of a duty to withhold the information or refrain from trading in that security. “Tipping” other traders of such information who then trade a security affected by the tip is also illegal, as is acting on an illegal tip.

Promotional Prohibitions – Staff members and Employees who conduct FDA-regulated research are prohibited from representing in a promotional context that an investigational new drug, device, or other test article is safe or effective (or otherwise beneficial) before it has received regulatory approval. Press releases and other promotional disclosures prepared by commercial sponsors or manufacturers using the name of CCF, its Staff members, or its Employees should be submitted to the Chief Marketing Officer for prior approval. Staff members are also subject to the policy entitled “The Use of the Foundation’s Name or Logo” contained in the Major Policies for the Professional Staff.

Regulation of Profits on Test Articles – Neither CCF nor a research sponsor may charge for an investigational new drug, device, or other test article a price greater than necessary to recover certain costs.

Mandatory Contract Review – Written agreements, pre-approved by the Office of General Counsel (“OGC”), are required for all Staff Honoraria and Consulting of (a) more than $10,000 during a 12-month period from a single source or (b) any amount from Financial Investment Firms—for details see Policy VI, “Consulting by the Professional Staff.” All other proposed written agreements regarding research should be submitted to the Office of Sponsored Research, which may triage the contracts to OGC and/or CCF Innovations as appropriate. This includes all research grants and contracts, training/fellowship agreements, clinical trial contracts, GCRC contracts, data analysis contracts, data use agreements (DUAs), confidential disclosure agreements (CDAs), material transfer agreements (MTAs), cooperative agreements, letters of intent, and related subcontracts.
APPENDIX C
POLICIES ON CONFLICTS OF INTEREST AND CONSULTING

GLOSSARY

(Capitalized terms are defined in the Glossary.)

ACCME means Accreditation Council for Continuing Medical Education.

CCF means The Cleveland Clinic Foundation (Ohio) and its regional medical practice centers. “CCF” also includes Cleveland Clinic Florida and Clinic Care, Inc. and their wholly-owned affiliates. “CCF” does not include the Cleveland-area hospitals of the Cleveland Clinic Health System or their wholly-owned affiliates.

Compelling Circumstances means those facts that convince the COI Committee that proposed research may be conducted despite the existence of a Significant Financial Interest or an Institutional Financial Interest. Considerations that may be evaluated by the COI Committee in determining whether the proposed research may be conducted are listed in Appendix A, “Operating Guidelines of the COI Committee.”

A Conflict Of Interest may exist when a CCF Staff member or Employee, or a member of his or her Immediate Family or an entity directed or controlled by any of them, has an interest in (including relationships with) a non-CCF party—whether investment, compensation, or otherwise—that could be reasonably perceived as influencing his or her activities in patient care, research, administrative decisions, or business transactions for CCF.

Employee means an Official, employee, agent, student, fellow, trainee, or administrator. For purposes of these policies, Employee does not refer to members of the Professional Staff.

Financial Investment Firm means an entity that provides investment services to the public, including brokerage firms and hedge funds. Consulting for Financial Investment Firms or the investing public can involve inadvertent violation of insider trading laws or the obligations of tax-exempt organizations. Staff members are prohibited from serving as Consultants for financial investment firms or the investing public—regardless of the amount of compensation—without both pre-approval by the Conflict of Interest (“COI”) Committee and a contract review by OGC. (Private equity or venture capital firms that evaluate new technologies for their own benefit are not considered Financial Investment Firms. Consulting for them involves the institutional pre-approval process that is required when consulting for entities other than Financial Investment Firms.)

Financially Interested Company means an entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research. This term includes the manufacturer (including business partners) of the drug or the device or other sponsor of the research. This term includes any entity acting as the agent of a Financially Interested Company, e.g., a contract research organization. (This term also includes companies that provide direct and primary competition for the investigational product, if the Staff member or Employee actually knows that the financial interests of such a company would reasonably appear to be affected by the research.)

Honoraria and/or Consulting Compensation means direct or indirect compensation—e.g., honoraria, lecture fees, consulting fees, stock or stock options, royalties, or “in kind” compensation—received by a Staff member (or his or her Immediate Family member) or any foundation, trust, or other entity controlled or directed by the Staff member (or Immediate Family member) from a source other than CCF for an activity performed by the Staff member while using his or her professional competence.

Human Subjects Research means a systematic investigation performed with human subjects (including development, testing, and evaluation) designed to develop or contribute to generalizable knowledge, regardless of the source of funding or whether the research is subject to federal regulation. For purposes of this Policy, the term “Human Subjects Research” includes clinical investigations and experiments regulated by the U.S. Food and Drug Administration that involve any of the following for human use: a drug, biological product, medical device, human food or color additive, electronic product, and any other regulated test article.

Immediate Family means a CCF Staff member or Employee and his or her spouse, domestic partner, dependent children, and other dependents.
**Institutional Financial Interest** ("IFI") means one of the following circumstances:

- **Royalties** – When CCF or a subsidiary is entitled to receive royalties (payments linked to the sale of a product) that is or was under investigation at CCF,

- **Any Equity in Non-publicly Traded Sponsor** – When, through CCF’s technology licensing activities or investments related to such activities, CCF or a subsidiary has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a current non-publicly traded sponsor of research at CCF.

- **Equity Exceeding $100,000 in Publicly-Traded Sponsor** – When, through CCF’s technology licensing activities or investments related to such activities, CCF or a subsidiary has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a current publicly-traded sponsor of research at CCF. (Exception: Mutual Funds and Fiduciary-Managed Funds – Interests of any amount in publicly-traded, diversified mutual funds or in funds in which the investment decision making is made by fiduciary managers appointed by CCF but not otherwise affiliated with CCF are not Institutional Financial Interests.)

- **CCF Officials** – When a CCF Official (or Immediate Family member or controlled entity), whether Participating in research or not, holds a personal Significant Financial Interest ("SFI") in any commercial research sponsor that is sponsoring Human Subjects Research or a product being investigated for clinical use at or by CCF, except that having equity or royalties up to $10,000 from a publicly-traded sponsor is not an IFI if the Official is not participating in the research.

**Non-Human Subjects Research** means basic research, animal research, or other research that is not Human Subjects Research.

**Officer** means one of the following persons: President and Chairman of the Board of Governors, Vice Chairman of the Board of Governors/Chief of Staff, Chief Academic Officer, Chairman of the Lerner Research Institute, Chief Operating Officer, Chief Financial Officer, Secretary, Assistant Secretary, Treasurer, and Controller. Officers are elected by the Board of Trustees and are subject to the conflict of interest disclosure and management requirements of the Board of Trustees in addition to being subject to these policies.

**Official** means one of the following persons: an Officer of CCF, the Chairman of CCF Innovations, the Chairman of the Division of Clinical Research, other division chairs, and physician department chairs.

**Participate(ing) in research** means a CCF Staff member’s or Employee’s doing any of the following under the auspices of CCF or pursuant to the review and approval of the CCF Institutional Review Board ("IRB") or Institutional Animal Care and Use Committee ("IACUC"), whether the research is conducted at a CCF-owned facility, in a Cleveland Clinic Health System hospital, or anywhere else in the world:

- Designing or directing research
- Serving as the principal investigator, co-investigator, or sub-investigator
- Enrolling research subjects (including obtaining human subjects’ informed consent, if applicable)
- Making decisions related to eligibility to research subjects’ enrollment in research
- Analyzing or reporting research data
- Submitting manuscripts concerning the research for publication as a primary author or co-author

**Pharma Advisory Committee** means a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee of a pharmaceutical or biotechnology company. Service on a Pharma Advisory Committee is not “fiduciary service” as discussed in these policies; however, service on a Pharma Advisory Committee, if compensated, does require pre-approval and compliance with Policy VI, “Consulting by the Professional Staff.”

**Significant Financial Interest** means one or more of the following interests of a CCF Staff member or Employee (or Immediate Family member, or any foundation, trust, or other entity controlled or directed by any of them) in the research sponsor or any other Financially Interested Company. Salary from CCF and cost-related payments for services or reimbursement from CCF are not Significant Financial Interests.
• **Honoraria or Consulting Compensation Exceeding $10,000** – Consulting fees, honoraria, lecture fees, other emoluments, or “in kind” compensation directly or indirectly from a Financially Interested Company (or entitlement to the same), whether for consulting, lecturing, service on a Pharma Advisory Committee, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the prior calendar year exceeded $10,000, or are expected to exceed that amount in the next twelve months. (CCF Staff members and Employees are also subject to Policy II entitled, “Conflicts of Interest in Business Affairs and in General.” Members of the Professional Staff are also subject to the requirements of Policy I entitled, “Conflicts of Commitment” and Policy VI entitled, “Consulting by the Professional Staff.”)

• **Equity** – Equity interests held either directly or indirectly, including stock and stock options, of any amount in either a publicly-traded or non-publicly-traded Financially Interested Company (or entitlement to the same).

  *(Exception: Mutual Funds and Fiduciary-Managed Funds – Interests of any amount in publicly-traded, diversified mutual funds or in funds in which the investment decision making is made by fiduciary managers appointed by CCF but not otherwise affiliated with CCF are not Significant Financial Interests.)*

• **Royalties** – Royalty income (payments linked to product sales), or the written contractual right to receive future royalties, directly or indirectly under a patent, license or copyright, where research is directly related to the licensed technology or work.

• **Payments Not Described in the Research Contract** – Any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the agreement between the sponsor and CCF). This includes any bonus or milestone payments to a Staff member or Employee in excess of reasonable costs incurred in the research. (Milestone payments that are contingent upon the achievement of particular research results are absolutely prohibited.)

  • **Reasonable Research Costs** – Payments to CCF, or via CCF to the Staff member or Employee, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and CCF are not Significant Financial Interests.

• **Fiduciary Service** – An appointment to serve, in either a personal or representative capacity, as an officer, director, partner, or governing board member of a commercial sponsor of research conducted at or by CCF, whether or not compensation is received for such service. (Members of the Professional Staff are also subject to the policy entitled “Membership on Boards of Directors in Outside, For-Profit Businesses and Corporations” contained in the Major Policies for the Professional Staff.) Service on a Pharma Advisory Committee is not “fiduciary service”; however, service on a Pharma Advisory Committee, if compensated, does require pre-approval and compliance with Policy VI, “Consulting by the Professional Staff.”

**Staff** means a member of the CCF Professional Staff.