



Managing Conflicts of Interest

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1 SCOPE AND APPLICABILITY

- 1.1 The scope and purpose of this standard operating procedure (SOP) is to describe the policies and procedures of the VA Central IRB to identify, evaluate, and manage any perceived or actual conflicts of interest involving the research projects brought before it for review. These conflicts can be financial or another type of conflict, such as personal or business relationships. This includes the identification and management of any conflicts of the VA Central IRB members or any institutional conflict.
- 1.2 This SOP applies to all research projects involving human participants submitted to the VA Central IRB for review. The impact of conflicts may occur in any phase of the project, from the development of the project design to management and oversight of an approved project. Conflicts may also bias project reviews, analysis of data, and dissemination of the project results through publications and presentations.
- 1.3 All VA investigators, whether compensated or uncompensated, whether part-time or full-time, must comply with all VA and other requirements relating to conflict of interest. For each project submitted for review, the Principal Investigator/Study Chair (PI/SC), Co-PI/SC, investigators, and any other study personnel identified as serving in an "investigator" role are required to disclose any perceived or actual conflicts of interest.
- 1.4 Additionally, all VA Central IRB members, whether voting or nonvoting, are required to disclose any perceived or actual conflict of interest according to the requirements in this SOP.
- 1.5 This SOP also addresses perceived or actual institutional conflict of interest within the Veterans Health Administration Central Office and the Office of Research and Development (ORD) as the organizational entities in which the VA Central IRB operates and functions, and from which it receives its budgetary support.
- 1.6 It is the policy of the VA Central IRB that any conflicts of interest by investigators are appropriately disclosed and managed or resolved so they do not negatively impact human research participants.
- 1.7 It is the policy of the VA Central IRB that any VA Central IRB member having a conflict of interest with any projects being reviewed by the IRB recuse themselves so as to not negatively impact the impartiality of the VA Central IRB research project review processes. It is also the policy of the VA Central IRB, in accordance with federal personnel policy that no VA Central IRB member may accept a gift from a prohibited source or a gift that is given based on the members' position on the IRB.
- 1.8 It is the policy of the VHA Human Research Protection Program (HRPP) that the VA Central IRB operates independently and free from any organizational conflicts.
- 1.9 All VA personnel are expected and obligated to follow the Ethical Conduct for Employees of the Executive Branch guidelines.

2 DEFINITIONS

- 2.1 **Conflict of Interest.** Any situation in which financial or personal obligations or interests may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research. An appearance of COI is when the circumstances would cause a reasonable person with knowledge of the relevant facts to question an

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employee's impartiality in the review and conduct of human research protocols.

2.2 **Employee.** Refers to any employee of the Department of Veterans Affairs to include Without Compensation (WOC) employees or appointment through an Intergovernmental Personnel Act (IPA) appointment. Status as an employee is unaffected by pay or leave status.

2.3 **Financial Interest.** Financial interests are limited to those owned by the employee or by the employee's spouse or minor children. It includes any current or contingent ownership, equity, or security interest in real or personal property or a business and may include indebtedness or compensated employment relationship. It includes interests in the nature of stocks, bonds, partnership interests, fee and leasehold interests, mineral and other property rights, deeds of trust, and liens. It extends to any right to purchase or acquire any such interests, such as a stock option or commodity future. It does not include a future interest created by someone other than the employee, the employee's spouse, or dependent child or any right as a beneficiary of an estate that has not been settled. It does include service, with or without compensation, as an officer, director, trustee, general partner, or employee of any person, including a nonprofit entity, whose financial interests are imputed to the employee (5 CFR 2635.403(c)).

2.4 **Gift.** Any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. This includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. It does not include: (5 CFR 2635.203(b))

- Modest items of food and refreshments
- Greeting cards and other items of little intrinsic value
- Loans from banks or other financial institutions on terms generally available to the public
- Opportunities and benefits available to the public or to a class consisting of all government employees, whether or not restricted on the basis of geographic considerations
- Rewards and prizes given to competitors in contests or events open to the public unless the employee's entry into the contest or event is required as part of their official duties
- Pension or other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a former employer
- Anything which is paid for by the government or secured by the government under contract
- Anything for which market value is paid for by the employee

2.5 **Imputed Interest.** The financial interests of the following persons are considered to the same extent as if they were the employee's own interests: (5 CFR 2635.402(b) (2))

- Employee's spouse
- Employee's minor child
- Employee's general partner in a business
- An organization in which the employee serves as officer, director, trustee, general partner, or employee
- Any person with whom the employee is negotiating or has an arrangement concerning prospective employment

2.6. **Institutional Conflict of Interest.** An institutional COI may occur when the institution, or any of its senior management, has an external relationship or financial interest in a company or organization that

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itself has a financial interest in a VA investigator's research project.

- 2.7. **Investigator.** An investigator is any individual who conducts research involving human subjects, including, but not limited to: the Principal Investigator (PI), Co-PI, co-investigator, and Local Site Investigator (LSI). The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures. (VHA Handbook 1200.05)

3 RESPONSIBILITY

3.1 All study team members serving in an investigator role on a particular research project are responsible for the disclosure of any perceived or actual financial conflicts of interest that they or their immediate family members may have related to the proposed project. Disclosure includes any compensation that may be affected by the outcome of the project. In addition, investigators must comply with COI management plans as directed by their local VA facilities and the VA Central IRB. Investigators are also responsible for identifying any perceived COI that may develop during the course of the project.

3.2 Local VA facilities are responsible for reviewing the financial disclosure forms submitted by their investigators who are planning to participate in a project that is being submitted to the VA Central IRB for review. The local VA facilities are responsible for carrying out the following functions in accordance with their local SOPs:

- Determining whether there are actual or perceived FCOIs that could affect an investigator's proposed, current, or future research activities;
- Determining whether conditions or restrictions, if any, need to be imposed to manage, reduce, or eliminate the conflicts;
- Reviewing any updates to the financial disclosure forms submitted by investigators and making a determination regarding the need to modify requirements for management of the FCOI;
- Reviewing individual projects or summaries of projects and the investigator's plan to manage any FCOI if applicable;
- Reporting findings and identifying steps to manage the FCOI to the VA Central IRB and the investigator;
- Establishing a process, in conjunction with the VA Central IRB, that uses specified evaluation criteria to allow the investigator to appeal a decision restricting the conduct of a project and requiring specific steps to manage, reduce or eliminate the FCOI;
- Determining, in conjunction with the VA Central IRB, whether compelling circumstances exist that would permit an investigator having a FCOI that cannot be adequately managed, reduced, or eliminated, to conduct the project; and
- Maintaining records of all financial disclosure forms, and all actions taken by the local VA facility with respect to identified conflict of interest for the time period that the project records are to be maintained per VA requirements.

3.3 The VA Central IRB is responsible for reviewing and requiring, if necessary, appropriate changes in research involving human participants, if it determines that the research may be affected by actual or

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perceived financial or other types of conflicts of interest. The VA Central IRB may also make a determination that a certain research project should not be conducted at a specified local VA institution. In making these determinations, the VA Central IRB considers the actions and recommendations of the local VA facilities if applicable. If a local facility does not have a mechanism in place for review of COI forms, the forms will be submitted for review to the VA Central IRB. If any COI is identified the form will be forwarded to the applicable regional Office of Government Ethics Office for review per this SOP.

3.4 VA Central IRB members are responsible for recusing themselves from review of all projects for which they have a conflict of interest. Members will leave the room, or if participating by video or teleconference, they will disconnect from the meeting.

4 PROCEDURE

4.1 Investigator Financial Conflict of Interest: Investigator FCOI will be identified and managed as follows:

- 4.1.1 All investigators or other personnel associated with a project to be reviewed by the VA Central IRB must complete a financial disclosure form and have it reviewed by their local VA facility in accordance with the local VA facility policies and procedures. In the event that the local facility cannot do this review, such as if the FCOI reviews are done by the local affiliate IRB, the investigator completes OGE Form 450 Alternative-VA, Research Financial Conflict of Interest Statement, and turns it into the Principal Investigator or Local Site Investigator as applicable for turn-in with the completed PI/SC or LSI Application, or request for amendment.
- 4.1.2 The findings of the local VA facility are submitted to the VA Central IRB as part of the Local Site Investigator Application package, or the Principal Investigator/Study Chair New Project Application as applicable. The findings can also be submitted directly to the VA Central IRB by the local VA facility.
- 4.1.3 Upon receipt of the Local Site Investigator Application package and/or the Principal Investigator/Study Chair New Project Application, VA Central IRB administrative staff members review the package to determine if the findings of the local VA facility or the OGE Forms 450 for each study team member serving in an investigator role are attached or if they are still pending receipt. If they are not attached, a staff member contacts the local VA facility to obtain them.
 - 4.1.3.1 Upon receipt of the local VA facility FCOI findings or OGE Forms 450, the VA Central IRB administrative staff reviews them to see if any FCOI was identified. If no FCOI was identified, the findings are filed in the project folder and a copy included with the study application. If a potential FCOI was identified and ruled out or the FCOI was resolved, such as sale of a stock, applicable documentation from the VA facility's Regional Ethics Office indicating the resolution must also be provided and kept on file.
 - 4.1.3.2 If an OGE Form 450 submitted to the VA Central IRB identifies a conflict, the form is sent to the applicable Regional Ethics Office by the VA Central IRB Manager for the study, along with a copy of the protocol, via encrypted e-mail based upon the state in which the VA medical facility where the investigator works is located. A copy of the e-

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mail addresses and state regional assignments can be found at Attachment 2. The Ethics Official will be asked to communicate directly with the investigator if there are any questions and then send the final determination to both the investigator and VA Central IRB Manager.

4.1.3.2 If any FCOI is identified and a management plan has been agreed upon, this information is included as part of the project package that is reviewed by the convened VA Central IRB. Projects in which a FCOI is identified and in which the FCOI has not been ruled out or resolved but for which a management plan has been submitted, are not reviewed under the expedited review procedure, even if the project is otherwise qualified for such review.

4.1.4 If a FCOI was identified and a management plan submitted, the convened VA Central IRB reviews the project, to include all materials given to potential participants, the Local Site Investigator Application and/or the Principal Investigator/Study Chair New Project Application as applicable, and the findings of the local and Ethics Official COI review, to determine the following:

- The nature of the project to include its scientific and scholarly integrity,
- The magnitude of the financial conflict of interest,
- The degree to which the financial conflict of interest is related to the project,
- The extent to which the project could be directly and substantially affected by the financial conflict of interest,
- The potential harm to research participants or the potential for coercion or undue influence during the selection or consenting process,
- Whether methods used for management of financial interest of parties involved in the project adequately protect the rights and welfare of participants, and
- Whether other actions are necessary to minimize risks to participants.

4.1.5 Based on its review, the VA Central IRB may agree with the actions of the local VA facility, investigator, and Ethics Official, or it may decide to place additional conditions or restrictions on the investigator or the project to further manage the FCOI. Examples of conditions or restrictions the VA Central IRB might impose on the investigator or project include, but are not limited to, the following:

- Public disclosure in publications and/or disclosure in consent forms to include the kind, amount, and level of detail of the information to be disclosed regarding the source of funding, funding arrangements, financial interests of parties involved in the project, and any financial interest management techniques applied
- Monitoring of the project by independent reviewers
- Modification of the project plan or of the roles of particular research staff
- Disqualification from participation in all or a portion of the project that would be affected by the FCOI
- Divestiture of conflicted financial interests in a reasonable period not to exceed 90 days from the date the divestiture is directed, except in cases of unusual hardship
- Severance of relationships that create actual or perceived conflicts



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- 4.1.6 The results of the FCOI review determination by the VA Central IRB are communicated in writing to both the investigator and the local facility R&D Committee, with a copy of this communication filed in the project file kept on file in the VA Central IRB Administrative Office. This is usually made part of the letter to the investigator detailing any other required modifications regarding a submitted project or site application or it can be a separate communication as determined by the VA Central IRB upon completion of its review. The review and determination of the VA Central IRB is also recorded in the meeting minutes.
- 4.1.7 When submitting continuing review reports, investigators must update their COI status through their local facility or, if no mechanism exists at their local facility to do this, an updated OGE Form 450 must be completed and submitted to the VA Central IRB.
- 4.1.7.1 The VA Central IRB requires that if a new reportable FCOI occurs prior to the due date for the continuing review report, the investigator must report the new FCOI immediately to the local VA facility in accordance with the local VA facility SOPs. An investigator will be considered noncompliant if such a change is not reported in a timely manner.
- 4.1.7.2 The findings of the local VA facility are then forwarded to the VA Central IRB within 30 days of the findings being rendered. If the new FCOI occurs within 30 days of the continuing review report submission, the findings of the local VA facility may be included as an attachment to the continuing review report.
- 4.1.8 When a new FCOI is reported, whether during continuing review or prior to continuing review, the VA Central IRB must consider all the issues listed in paragraph 4.1.4.
- 4.1.8.1 The VA Central IRB can make any of the same decisions as detailed in paragraph 4.1.5. In addition, the VA Central IRB may make the following additional stipulations:
- Re-obtaining consent from participants and/or removing the investigator from a direct role in participant selection or obtaining consent,
 - Investigator resignation or removal with appropriate substitution,
 - Modifying the project and/or the consent process or form, and
 - Requiring that conflicts of interest be disclosed in all publications or presentations of the project.
- 4.1.8.2 The results of the VA Central IRB's review are documented and reported to both the investigator and the local R&D Committee as detailed in paragraph 4.1.6.
- 4.1.9 Whether during initial review, continuing review, or any other type review, if the VA Central IRB determines that a FCOI exists that compromises the rights and welfare of human participants or the outcome of the project, it may determine that the conflicts cannot be sufficiently managed, reduced, or eliminated. The VA Central IRB can, as applicable, disapprove the project, terminate the project approval, or require that those investigators with the conflicts be eliminated as part of the project team.



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4.1.10 Investigators who do not appropriately disclose all FCOI pertaining to their projects or who do not adhere to approved management plans may be barred from submitting any further research projects to the VA Central IRB for review. Such failure is treated as investigator non-compliance and the procedures as set forth in VA Central IRB SOP 118, Serious and Continuing Non-compliance, are then followed.

4.2 VA Central IRB Member Conflict of Interest: The same definitions pertaining to what constitutes a conflict of interest that apply to investigators also apply to VA Central IRB members. VA Central IRB member conflicts of interest are identified and managed as follows:

4.2.1 No VA Central IRB member will participate in the initial or continuing review of any project; the review of any project modifications; or the review of issues, complaints, or noncompliance with regulations or VA IRB policies and procedures, in which they, an immediate family member, or any individual whose financial interests can be imputed to the member, has a perceived or actual financial or personal COI, except to provide information requested by the VA Central IRB.

4.2.2 Upon being assigned a project for review, each member will determine whether they have a conflict and if so, immediately inform the VA Central IRB Administrator or one of the VA Central IRB Co-Chairs so another Reviewer can be assigned. Likewise, if a member is serving as a Reviewer for a project and a conflict subsequently develops, the VA Central IRB Administrator or Co-Chair must be immediately informed so all project actions requiring review can be immediately re-assigned.

4.2.3 Upon being informed that a meeting agenda is available for review, each member must review the agenda to determine if they have any conflicts with any of the business scheduled to be reviewed at that particular meeting. This includes new projects, continuing reviews, and any other actions such as reported issues, complaints, or reports of noncompliance.

4.2.4 Prior to commencing the project review portion of a VA Central IRB meeting, members are reminded by the VA Central IRB Presiding Co-Chair of the COI policies. Members then declare whether they have any COIs and these are noted as part of the minutes.

4.2.5 VA Central IRB members having a COI must recuse themselves from the meeting room prior to the review of a project for which they have a COI, except when requested by the VA Central IRB Presiding Chair to remain present to provide information. After the member provides any requested information, the member must leave the meeting room until after completion of the project review by the VA Central IRB and the vote is taken and recorded. If members are participating by video or teleconference, they must disconnect. The member will then be contacted via e-mail to reconnect after the VA Central IRB has made its determination and the vote recorded.

4.2.6 The recusal of a member due to a COI on a particular project is annotated in the minutes to include the member's name and that the member left prior to the discussion and returned after the discussion and vote. The member having a conflict of interest does not count towards quorum and the number of voting members available to achieve quorum is adjusted accordingly when recording the vote.



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- 4.2.7 If a VA Central IRB member is unsure whether a conflict of interest exists, the member may consult a Deputy Ethics Officer within the VHA Office of General Counsel (OGC).
- 4.2.8 Non-voting members are subject to the same COI policies and procedures as voting members. This includes non-affiliated WOC employee members, other affiliated WOC members, and other VA employee members.
- 4.2.9 Ad hoc consultants must return a project without any recommendations to the VA Central IRB if they have a COI. The Consultant indicates the COI on the reviewer checklist and returns it, along with the project documentation.
- 4.2.10 The VA Central IRB Administrator ensures that VA Central IRB members receive continuing education in conflict of interest policy and as changes in VA policy occur.
- 4.2.11 All documentation regarding VA Central IRB member COI is kept on file in the member folders or in the VA Central IRB Meeting administrative files, as applicable, documented in the minutes as applicable, and is accessible if required for auditing and monitoring purposes.
- 4.2.12 If a VA Central IRB member fails to disclose a COI, the Intuitional Official (IO) Designee with appointment authority, or the IO if the member is a Co-Chair, may terminate the member's appointment on the Board. If the individual is a VA employee located at a local VA facility, the ACOS of the VA facility will be informed of the COI and the failure to disclose it appropriately. If requested by the IO Designee or IO, a review of all the research in which the affected member had a vote will be conducted to determine if any further action regarding those projects is required.
- 4.3 Institutional Conflicts of Interest: Within the VHA Central Office HRPP, Institutional COI is managed as follows:
- 4.3.1 There may be situations in which study teams and sponsors attempt to put pressure on the VA Central IRB or individual members to move studies through the review process more quickly or to overlook certain deficiencies or stipulations that they do not wish to comply with.
- 4.3.2 To guard against such potential COIs, the VA Central IRB deliberations and decisions are independent of the funding services within ORD. The VA Central IRB has the final authority to approve research. Such independence is established based on the nationally diverse membership of the VA Central IRB, as well as oversight by the Office of Research Oversight (ORO) and the Principal Deputy Under Secretary for Health (PDUSH), who serves as the IO for the VHA Central Office Human Research Protections Program (HRPP).
- 4.3.3 If a project involves a patent, the VA Central IRB is notified by the Technology Transfer Office of the approved patent. Any potential conflict of interest will be evaluated by the VA Central IRB in consultation with the Office of General Counsel prior to approval of the research.



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5 DOCUMENTATION REQUIREMENTS

5.1 Required information relating to financial conflict of interest is documented on the applicable VA Central IRB forms and in the minutes for members and maintained in accordance with VA Central IRB SOPs and VHA and federal requirements.

5.2 Required information for investigators is documented through receiving a memorandum from the local facility concerning its review or through receipt of the OGE Form 450 from investigators and any subsequent documentation generated as a result of an OGE review and submission of a management plan. All investigator documentation is maintained in the applicable project study file in accordance with VA Central IRB SOPs.

6 REFERENCE

- 6.1 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch
- 6.2 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects.
- 6.3 21 CFR 54, Food and Drug Administration, Financial Disclosure by Clinical Investigators
- 6.4 FDA Guidance, Financial Disclosures by Clinical Investigators, March 20, 2001
- 6.5 VHA Handbook 1200.01, Research and Development (R&D) Committee
- 6.6 VHA Handbook 1200.18, Intellectual Property
- 6.7 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- 6.8 ORD Special Advisor for Policy and Planning E-mail message, New Required FCO Disclosure Form, dated December 9, 2013.

Revision History

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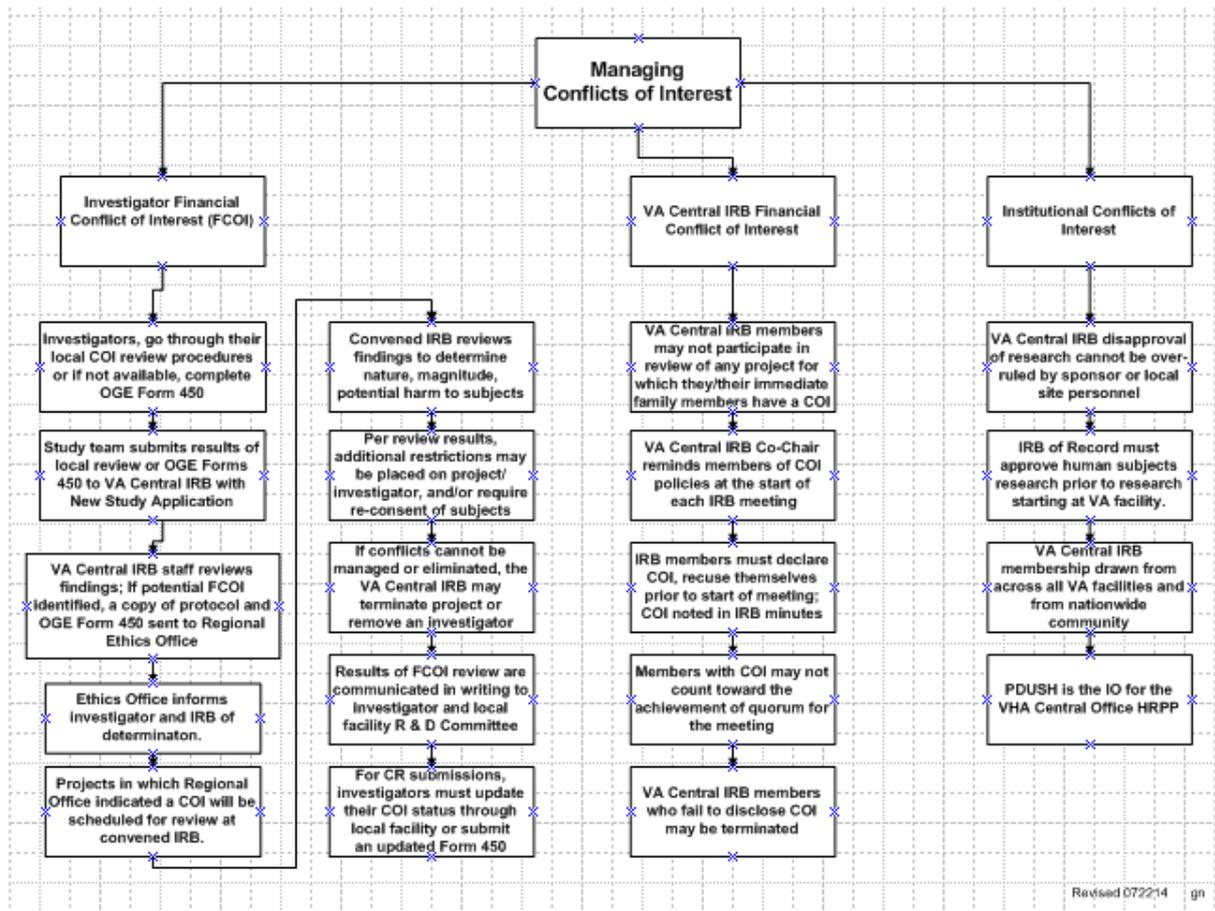
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Attachment 1: VA Central IRB SOP 103 Process Chart



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Attachment 2: Government Ethics Officials Contact Sheet

To Contact a Government Ethics Official at Department of Veterans Affairs:

VA Central Office (VACO):

VA's Designated Agency Ethics Official (DAEO):

Walter A. Hall, Assistant General Counsel

VA's Alternate Designated Agency Ethics Official:

Renée L. Szybala, Associate General Counsel

They and other Deputy Ethics Officials at VA Central Office may be contacted at

GovernmentEthics@va.gov or (202) 461-6000 or (202) 461-7694

Outside VACO:

OGCNorthEastEthics@va.gov for ME, NH, VT, MA, RI, CT, NY, NJ, DE, PA, OH, WV, MI, WI

OGCSouthEastEthics@va.gov for VA, NC, SC, GA, FL, MS, AL, LA, southern TX, Puerto Rico

OGCMidwestEthics@va.gov for DC, MD, IN, KY, TN, AR, MO, IL, IA, MN, ND, SD, NE, KS,

OGCWestEthics@va.gov for northern TX, OK, NM, AZ, CO, UT, WY, MT, ID, NV, CA, OR, WA, HI, AK, Guam, Philippines

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