Office of Research Oversight Site Review Feedback Surveys

1. Introduction

The Office of Research Oversight (ORO) is dedicated to promoting the responsible conduct of Department of Veterans Affairs (VA) research for the protection of Veterans and others who volunteer in VA research, and for the benefit of all Veterans whose health and well-being are improved by the discoveries made through a sound and ethically grounded VA research program. ORO monitors, reviews, and investigates matters of research compliance that involve VA research. Specifically, ORO provides oversight of compliance with VA and other Federal requirements for the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information security, and research misconduct. ORO also provides training to facility Research Compliance Officers (RCO) and oversight of RCO auditing programs.

Per the statute (38 United States Code §7307) creating ORO within the Veterans Health Administration (VHA), ORO is required to "conduct periodic inspections and reviews, as the Director determines appropriate, of medical research programs of the Department." In fulfillment of this statutory requirement, ORO conducts four types of site reviews: Combined Program Reviews; Focused Reviews; For-Cause Reviews; and Technical Assistance Reviews. ORO Combined Program Reviews provide broad, proactive, integrated reviews of facility research oversight programs to assist VA facilities in fulfilling their responsibilities pertaining to: human research protections; research information security; laboratory animal welfare; research safety and laboratory security; and general research administration. ORO Focused Reviews are narrower in scope than Combined Program Reviews and target individual facility research program oversight areas and/or specific issues for review. ORO For-Cause Reviews are initiated in response to specific allegations of, or information about, the occurrence of potentially serious noncompliance with the laws, regulations, and policies governing VA research. ORO Technical Assistance Reviews provide VA research facilities with operational level evaluations and recommendations for fulfilling their responsibilities to conduct research in compliance with VA requirements.

Three of the aforementioned reviews, Combined Program Reviews, Focused Reviews, and Technical Assistance Reviews are routinely conducted by ORO in any given year. To continuously improve ORO's approach to conducting these site reviews, feedback on VA facility personnel's experiences, perceptions, and concerns regarding these reviews is solicited following the completion of the on-site portion (or equivalent for reviews conducted remotely[1]) of its compliance and technical assistance activities. To continuously improve ORO's approach to communicating noncompliance findings and apprising facility personnel of programmatic areas that should be evaluated for strengthening, ORO also solicits feedback from VA facility personnel on the timeliness, professionalism, readability, and accuracy of the reports that ORO issues for its Combined Program Reviews and Focused Reviews.

[1] In exceptional circumstances or where a VA facility has minimal active research, ORO may conduct a Combined Program Review or Focused Review remotely (i.e., without an on-site review portion).

This document presents the survey instruments used by ORO to obtain feedback from VA facility personnel, and sets forth procedures for: disseminating survey invitations following ORO site reviews and report issuances; administration of the surveys; and post-survey data sharing, data analysis, and action planning.

2. Survey Instruments

In consultation with the VHA National Center for Organization Development (NCOD), ORO developed five survey instruments for soliciting feedback. Three of the instruments solicit feedback on VA facility personnel's experiences, perceptions, and concerns with ORO's review activities for Combined Program Reviews (*see* **Appendix A**), Focused Reviews (*see* **Appendix B**), and Technical Assistance reviews (*see* **Appendix C**). The other two instruments solicit feedback on ORO's reports issued for Combined Program Reviews (*see* **Appendix D**) and Focused Reviews (*see* **Appendix E**). For all surveys, respondents are asked to rate their level of agreement or disagreement with provided statements about a review or report. A Likert scale is used for the surveys (1 – Strongly Disagree; 2 – Disagree; 3 – Neutral; 4 – Agree; and 5 – Strongly Agree). Free text response options are also provided to respondents at the end of the survey.

3. Survey Invitations

An invitation to take the appropriate online survey will be emailed to facility personnel following: (1) the on-site portion (or equivalent if conducted remotely) of a Combined Program Review; (2) the on-site portion (or equivalent if conducted remotely) of a Focused Review; (3) a Technical Assistance review; (4) issuance of a Combined Program Review report; and (5) issuance of a Focused Review report.

For all Combined Program Reviews and Focused Reviews, an invitation to complete the appropriate post-review survey will be sent by ORO's Review Management and Integrity (RMI) Workgroup to the following facility personnel (or their designee who interacted with ORO in lieu of the listed individual):

- Medical Center Director (MCD);
- Associate Chief of Staff for Research and Development (ACOS/R&D);
- Administrative Officer for Research and Development (AO/R&D);
- Research Compliance Officer(s) (RCOs), Auditor(s) or Assistant(s) (RCAs); and
- Relevant Committee Chair(s), Research Service or Committee Coordinator(s), and/or any other individual(s) who typically have programmatic oversight responsibilities and with whom substantial time was spent interacting with ORO personnel as part of the review.

For all Technical Assistance reviews, an invitation to complete the post-Technical Assistance survey will be sent to the following individuals:

- MCD
- Any other individual(s) who typically have programmatic oversight responsibilities and with whom substantial time was spent interacting with ORO personnel as part of the review.

For all Combined Program Review and Focused Review report issuances, an invitation to complete the appropriate report survey will be sent to the following individuals (or their designee who is to receive the report in lieu of the listed individual):

- MCD
- ACOS/R&D
- AO/R&D
- RCO(s)

4. Survey Administration

Because survey respondents are affiliated with the research programs that ORO provides oversight of, there is the potential concern that respondents may not feel comfortable providing forthright responses to survey items if their identities or the identities of the facilities that they are affiliated with were known to ORO. To mitigate this concern, ORO has partnered with a third party, NCOD, to administer the survey on behalf of ORO, including hosting the electronic survey instruments, collecting responses *anonymously*, and providing ORO with *aggregated* data. ORO's involvement in administration of the surveys is limited to sending out the initial invitations to participate in the survey and follow-up reminders (*see* Section 3 above). On an annual basis, ORO will request that NCOD provide ORO with *aggregated anonymous* response data for each survey.

5. Survey Data Sharing, Analysis, and Action Planning

Following receipt of the aggregated survey responses from NCOD, ORO senior leadership will share the quantitative results with all ORO staff and ORO's Field Advisory Committee (FAC)[2]. ORO senior leadership will solicit feedback from staff and the FAC regarding areas of opportunity for ORO to practicably modify its processes to: address any broad concerns, if apparent from the survey responses, without negatively impacting ORO's statutory mandate to effectively assess for research noncompliance; and/or enhance ORO's ability to meet the needs of stakeholders. Based on feedback from ORO staff and ORO's FAC, ORO's Executive Committee (EC)[3] will evaluate what, if any, actions are warranted. Potential determinations resulting from ORO EC's deliberations include: ORO

[2] The ORO FAC serves as a consultative body that provides recommendations to ORO to enhance the efficiency and effectiveness of ORO's research compliance oversight activities. A broad array of individuals with varying responsibilities and stakes in VA's research enterprise serve on ORO's FAC. The FAC reviews ORO's activities and recommends strategies for enhancing ORO's efficiency and effectiveness. The FAC also serves as a liaison between the field and ORO, and brings forth recommendations and concerns from the field.

[3] The ORO EC is comprised of the ORO Executive Director, Deputy Executive Director, Medical Officer, and the Directors of ORO's Workgroups.

processes should be modified to address identified broad-based concerns; there are no broad-based concerns identified in the survey responses that warrant process changes; the survey results are inconclusive as to whether broad-based concerns exist and additional data must be obtained (e.g., results from additional surveys must be collected and aggregated to provide more robust data; additional mechanisms, such as focus groups, should be utilized to further explore whether actual underlying concerns exist; etc.); and/or that the survey instruments should be modified to more effectively discern whether there are broad-based concerns with ORO's review activities and reports.

APPENDIX A: ORO Combined Program Review (CPR) Survey Items

Please indicate your title or role (Select one only)

- Medical Center Director or Chief of Staff or equivalent
- Associate Chief of Staff for Research and Development (ACOS/R) or equivalent
- Administrative Officer for Research and Development (AO/R) or equivalent
- Information Security Officer (ISO)
- Privacy Officer (PO)
- Research Compliance Officer (RCO) or Research Compliance Auditor/Assistant (RCA)
- Chair or Member of Research Committee(s) (e.g., IACUC, IBC, IRB, R&DC, SRS, etc.)
- Support Personnel for Research Committee(s) or Research Service
- Safety Officer (e.g., Facility Safety Officer, Industrial Hygienist, Chemical Hygiene Officer, etc.)
- Veterinary Medical Officer / Veterinary Medical Consultant
- Veterinary Medical Unit (VMU) Supervisor
- Other

For each of the statements, please indicate your level of agreement based on your direct knowledge and/or interactions with ORO personnel. If you do not have direct knowledge or did not have a direct interaction with ORO personnel to be able to provide a response for a given statement, please select "Don't Know or Not Applicable."

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO's written notification sent prior to the site review adequately explained the purpose of the review.						
ORO's written notification sent prior to the site review provided sufficient information to prepare for the review.						
ORO provided adequate advance notice (time) to allow facility personnel to prepare for the site review.						
The ORO remote interviews/meetings conducted via tele-/video-conferencing were effective for exchanging information.						
The ORO on-site interviews/meetings conducted in-person were effective for exchanging information.						

APPENDIX A: ORO Combined Program Review (CPR) Survey Items

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO personnel were professional and courteous.						
ORO personnel demonstrated appropriate subject matter expertise.						
Based on my interaction with ORO staff during the site review, I would feel comfortable contacting ORO in the future about research compliance-related matters.						
My facility will benefit from ORO's site review.						
ORO's Combined Program Review (CPR) integrated the reviews of multiple research oversight program areas in an effective manner.						
Compared to a format in which ORO conducts multiple site visits/reviews at my facility at different times but assesses fewer program areas per visit/review, I prefer ORO's Combined Program Review (CPR) format whereby several program areas are reviewed together in a single ORO site visit/review at one time.						

Please indicate up to three (3) aspects of ORO's site review that you thought were effective or valuable. (Please do not include names of any facility or ORO staff.)

Please indicate up to three (3) aspects of ORO's site review that you think could have been improved or didn't have value. (Please do not include names of any facility or ORO staff.)

Please use the space below to provide any additional feedback that you would like to offer ORO. (Please do not include names of any facility or ORO staff.)

APPENDIX B: ORO Focused Review (FR) Survey Items

Please indicate your title or role (Select one only)

- Medical Center Director or Chief of Staff or equivalent
- Associate Chief of Staff for Research and Development (ACOS/R) or equivalent
- Administrative Officer for Research and Development (AO/R) or equivalent
- Information Security Officer (ISO)
- Privacy Officer (PO)
- Research Compliance Officer (RCO) or Research Compliance Auditor/Assistant (RCA)
- Chair or Member of Research Committee(s) (e.g., IACUC, IBC, IRB, R&DC, SRS, etc.)
- Support Personnel for Research Committee(s) or Research Service
- Safety Officer (e.g., Facility Safety Officer, Industrial Hygienist, Chemical Hygiene Officer, etc.)
- Veterinary Medical Officer / Veterinary Medical Consultant
- Veterinary Medical Unit (VMU) Supervisor
- Other

Which research oversight areas did ORO review at your facility? (Select all that apply)

- General Research Administration (GRA)
- Animal Care and Use Program (ACUP)
- Human Research Protection Program (HRPP)
- Research and Development Committee (R&DC)
- Research Information Security Program (RISP)
- Research Safety and Security Program (RSSP)

For each of the statements, please indicate your level of agreement based on your direct knowledge and/or interactions with ORO personnel. If you do not have direct knowledge or did not have a direct interaction with ORO personnel to be able to provide a response for a given statement, please select "Don't Know or Not Applicable."

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO's written notification sent prior to the site review adequately explained the purpose of the review.						
ORO's written notification sent prior to the site review provided sufficient information to prepare for the review.						
ORO provided adequate advance notice (time) to allow facility personnel to prepare for the site review.						

APPENDIX B: ORO Focused Review (FR) Survey Items

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
The ORO remote interviews/meetings conducted via tele-/video-conferencing were effective for exchanging information.						
The ORO on-site interviews/meetings conducted in-person were effective for exchanging information.						
ORO personnel were professional and courteous.						
ORO personnel demonstrated appropriate subject matter expertise.						
Based on my interaction with ORO staff during the site review, I would feel comfortable contacting ORO in the future about research compliance-related matters.						
My facility will benefit from ORO's site review.						

Please indicate up to three (3) aspects of ORO's site review that you thought were effective or valuable. (Please do not include names of any facility or ORO staff.)

Please indicate up to three (3) aspects of ORO's site review that you think could have been improved or didn't have value. (Please do not include names of any facility or ORO staff.)

Please use the space below to provide any additional feedback that you would like to offer ORO. (Please do not include names of any facility or ORO staff.)

APPENDIX C: ORO On-Site Technical Assistance Survey Items

Please indicate your title or role (Select one only)

- Medical Center Director or Chief of Staff or equivalent
- Associate Chief of Staff for Research and Development (ACOS/R) or equivalent
- Administrative Officer for Research and Development (AO/R) or equivalent
- Information Security Officer (ISO)
- Privacy Officer (PO)
- Research Compliance Officer (RCO) or Research Compliance Auditor/Assistant (RCA)
- Chair or Member of Research Committee(s) (e.g., IACUC, IBC, IRB, R&DC, SRS, etc.)
- Support Personnel for Research Committee(s) or Research Service
- Safety Officer (e.g., Facility Safety Officer, Industrial Hygienist, Chemical Hygiene Officer, etc.)
- Veterinary Medical Officer / Veterinary Medical Consultant
- Veterinary Medical Unit (VMU) Supervisor
- Other

For which of the following did ORO provide technical assistance at your facility? (Select all that apply)

- General Research Administration (GRA)
- Animal Care and Use Program (ACUP)
- Human Research Protection Program (HRPP)
- Research Compliance Officer (RCO)
- Research and Development Committee (R&DC)
- Research Information Security Program (RISP)
- Research Misconduct Allegations (i.e., pertaining to inquiries/investigations into formal allegations of fabrication, falsification or plagiarism in research)
- Research Safety and Security Program (RSSP)

For each of the statements, please indicate your level of agreement based on your direct knowledge and/or interactions with ORO personnel. If you do not have direct knowledge or did not have a direct interaction with ORO personnel to be able to provide a response for a given statement, please select "Don't Know or Not Applicable."

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO's communication(s) prior to the site review adequately explained the purpose of the review.						
ORO's communication(s) prior to the site review provided sufficient information to prepare for the review.						
ORO provided adequate advance notice (time) to allow facility personnel to prepare for the site review.						

APPENDIX C: ORO On-Site Technical Assistance Survey Items

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
The ORO remote interviews/meetings conducted via tele-/video-conferencing were effective for exchanging information.						
The ORO on-site interviews/meetings conducted in-person were effective for exchanging information.						
ORO personnel were professional and courteous.						
ORO personnel demonstrated appropriate subject matter expertise.						
Technical assistance provided by ORO during the site review will be helpful for our facility.						
Based on my interaction with ORO staff during the site review, I would feel comfortable contacting ORO in the future about research compliance-related matters.						
My facility will benefit from ORO's site review.						

Please indicate up to three (3) aspects of ORO's site review that you thought were effective or valuable. (Please do not include names of any facility or ORO staff.)

Please indicate up to three (3) aspects of ORO's site review that you think could have been improved or didn't have value. (Please do not include names of any facility or ORO staff.)

Please use the space below to provide any additional feedback that you would like to offer ORO. (Please do not include names of any facility or ORO staff.)

Appendix D: ORO Combined Program Review (CPR) Report Survey Items

Please indicate your title or role (Select one only)

- o Medical Center Director or Chief of Staff or equivalent
- o Associate Chief of Staff for Research and Development (ACOS/R) or equivalent
- o Administrative Officer for Research and Development (AO/R) or equivalent
- o Information Security Officer (ISO)
- o Privacy Officer (PO)
- o Research Compliance Officer (RCO) or Research Compliance Auditor/Assistant (RCA)
- o Chair or Member of Research Committee(s) (e.g., IACUC, IBC, IRB, R&DC, SRS, etc.)
- o Support Personnel for Research Committee(s) or Research Service
- o Safety Officer (e.g., Facility Safety Officer, Industrial Hygienist, Chemical Hygiene Officer, etc.)
- o Veterinary Medical Officer / Veterinary Medical Consultant
- o Veterinary Medical Unit (VMU) Supervisor
- o Other

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO's report was issued within a reasonable timeframe following completion of the site review.						
ORO's report was professional in appearance.						
ORO's report presented information in a logical and understandable manner.						
The Executive Summary in ORO's report provided a useful high-level overview.						
The findings in ORO's report were well-supported by examples and specific regulatory/policy references.						
Corrective actions required to remediate noncompliance were clearly identified in the report.						

Please indicate up to three (3) aspects of ORO's report that you thought were effective or valuable. (Please do not include names of any facility or ORO staff.)

Please indicate up to three (3) aspects of ORO's report that you think could have been improved or didn't have value. (Please do not include names of any facility or ORO staff.)

Please use the space below to provide any additional feedback that you would like to offer ORO. (Please do not include names of any facility or ORO staff.)

Appendix E: ORO Focused Review (FR) Report Survey Items

Please indicate your title or role (Select one only)

- ○ Medical Center Director or Chief of Staff or equivalent
- ○ Associate Chief of Staff for Research and Development (ACOS/R) or equivalent
- ○ Administrative Officer for Research and Development (AO/R) or equivalent
- ○ Information Security Officer (ISO)
- ○ Privacy Officer (PO)
- ○ Research Compliance Officer (RCO) or Research Compliance Auditor/Assistant (RCA)
- ○ Chair or Member of Research Committee(s) (e.g., IACUC, IBC, IRB, R&DC, SRS, etc.)
- ○ Support Personnel for Research Committee(s) or Research Service
- ○ Safety Officer (e.g., Facility Safety Officer, Industrial Hygienist, Chemical Hygiene Officer, etc.)
- ○ Veterinary Medical Officer / Veterinary Medical Consultant
- ○ Veterinary Medical Unit (VMU) Supervisor
- ○ Other

Which research oversight areas were addressed in ORO's report? (Select all that apply)

- ○ General Research Administration (GRA)
- ○ Animal Care and Use Program (ACUP)
- ○ Human Research Protection Program (HRPP)
- ○ Research and Development Committee (R&DC)
- ○ Research Information Security Program (RISP)
- ○ Research Safety and Security Program (RSSP)

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Don't Know or Not Applicable
ORO's report was issued within a reasonable timeframe following completion of the site review.						
ORO's report was professional in appearance.						
ORO's report presented information in a logical and understandable manner.						
The Executive Summary in ORO's report provided a useful high-level overview.						
The findings in ORO's report were well-supported by examples and specific regulatory/policy references.						
Corrective actions required to remediate noncompliance were clearly identified in the report.						

Appendix E: ORO Focused Review (FR) Report Survey Items

Please indicate up to three (3) aspects of ORO's report that you thought were effective or valuable. (Please do not include names of any facility or ORO staff.)

Please indicate up to three (3) aspects of ORO's report that you think could have been improved or didn't have value. (Please do not include names of any facility or ORO staff.)

Please use the space below to provide any additional feedback that you would like to offer ORO. (Please do not include names of any facility or ORO staff.)