

American Academy of Anesthesiologist Assistants | American Society of Anesthesiologists In collaboration with Commission on Accreditation of Allied Health Education Programs

# **Policies and Procedures Manual**

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## **TABLE OF CONTENTS**

Ι.	AUTHORIZATION	3	
II.	FUNCTIONS	3	
III.	ACCREDITATION REVIEW	4	
IV.	REQUEST FOR RECONSIDERATION OF AN ADVERSE ARC-AA RECOMMENDATION	8	
v.	SITE VISITORS	9	
VI.	OUTCOMES BASED EVALUATION	. 16	
VII.	COMPLAINTS REGARDING ARC-AA AND ACCREDITED PROGRAMS	. 17	
VIII.	PROGRAMS	. 19	
IX.	DATA USE	. 23	
Appendix A: ARC-AA Data Request Form2		. 25	
Appendix B: Research Proposal Form		. 26	
Appendix C: Data Distribution Agreement – Statement of Intended Use of ARC-AA Data		. 27	
Appendix D1: Conflicts of Interest Policy – Acknowledgment Form		. 28	
Appendix D2: Conflicts of Interest Policy – Research Request Disclosure Form			
Appen	Appendix D3: Disclosure of Financial Interests		

These are the governing Policies Procedures of the Accreditation Review Committee for the Anesthesiologist Assistant (ARC-AA), Inc. Policies are presented in standard outline format. Operational Procedures that relate to a specific policy are presented in *italics* as indented paragraphs following the Policy.

#### I. AUTHORIZATION

- A. <u>Identity</u>. The Accreditation Review Committee for the Anesthesiologist Assistant (ARC-AA), Inc. ("ARC-AA") derives its identity from the policies of the Commission on Accreditation of Allied Health Education Programs ("CAAHEP") and its collaborating sponsors, the American Academy of Anesthesiologist Assistants ("AAAA") and the American Society of Anesthesiologists ("ASA"), which together provide accreditation services for education programs producing anesthesiologist assistants for entry into the profession.
- B. <u>Structure, Organization, and Policy and Procedure Development</u>. ARC-AA functions as a Committee on Accreditation within the CAAHEP system and adheres to the CAAHEP policies and procedures. ARC-AA will assure its policies and procedures are consistent with CAAHEP policies and procedures.
- C. <u>Policies and Procedures</u>. Members of the ARC-AA are responsible for adopting policies and procedures.

The ARC-AA uses a collaborative process, which may include input from communities of interest and CAAHEP, to develop policies and procedures which are then approved by the ARC-AA.

If a policy is not addressed here in the ARC-AA Policy Manual, then the CAAHEP Policy Manual will be the default. In cases when CAAHEP policies and ARC-AA policies differ, the more stringent of these apply.

#### **II. FUNCTIONS**

- A. <u>Program Review</u>. The primary function of ARC-AA is to assess the merits of applicant educational programs for accreditation by CAAHEP in accordance with the *Standards and Guidelines for the Accreditation of Educational Programs for the Anesthesiologist Assistant*.
- B. <u>Educational Outcomes Assessment</u>. ARC-AA is also responsible for evaluating and recommending means by which its collaborating sponsors may favorably influence the quality and availability of education for Anesthesiologist Assistants as a service to the public and professions.
- C. <u>Review CAAHEP Standards & Guidelines of Accreditation</u>. ARC-AA conducts periodic reviews of the CAAHEP Standards and Guidelines and revises them as necessary.
- D. <u>Accreditation Process Evaluation</u>. ARC-AA develops policies and processes that comply with the standards established for accrediting organizations and performs other functions pertinent to educational program accreditation.

#### **III. ACCREDITATION REVIEW**

ARC-AA will review educational program applications for accreditation to determine if the programs are in compliance with the established CAAHEP Standards and Guidelines for the Accreditation of Educational Programs for the Anesthesiologist Assistant.

All documents and communications involved in the accreditation and continuing accreditation processes conducted by ARC-AA will be in the English language.

A. <u>Program Documentation</u>. ARC-AA requires that programs seeking accreditation provide evidence, in the form of a written report, that a self-study has been conducted. Accredited programs will submit an annual report electronically and participate in a comprehensive review.

If requested information, including but not limited to the self-study report, annual report, request for clarification, etc., is not received within seven (7) days of the given due date, a program will be placed on administrative probation. If a specific due date is not given programs will respond within 30 days.

If requested information is not received in a timely manner or in the required format, when a program is undergoing comprehensive review, the program's self-study report may be returned without further review. Once returned, the program will begin the initial or continuing accreditation process again, including resubmitting all appropriate fees.

- B. <u>Anonymous Student Surveys</u>. ARC-AA will administer a survey to students during the program's comprehensive review process to collect information to assist the site visitors with validating information and formulating its questions. These surveys are different from the Student Surveys administered annually as part of the Resource Assessment.
  - 1. Administer Survey. ARC-AA will administer the survey upon receipt of the Initial or Continuing accreditation Self-Study Report (ISSR).
  - 2. Collect Data
    - a. ARC-AA will monitor survey response rate and update the Program Director as needed.
    - b. If less than 80% of each survey has been completed, then the Program Director will be notified and urged to encourage students to complete the survey.
  - 3. Distribute Data
    - a. ARC-AA will collect, collate, and send the survey results to the site visit team at least one month prior to the site visit.
    - b. The survey results for students will be collated in three (3) groups: 1st year students, 2nd year students, and all students. If there is a group of 3rd year students, then an additional group will be segregated.
    - c. Providing there is a response rate greater than 80%, the survey results will be distributed to the program after the site visit report and the Findings Letter have been completed and distributed to the program officials.

- 1) If a subgroup [1st year, 2nd year, or 3rd year] of students does not meet the threshold of 80%, then that subgroup will not be sent to the program.
- 2) If survey results are below the threshold of 80% for the entire group or any subgroup, then dialogue will be opened to identify the reason(s).
- 4. Confidentiality of Surveys
  - a. All survey data will remain confidential at all times, as with all other data disclosed by the program during the site visit and accreditation process.
  - b. All survey participants will remain anonymous at all times during the survey process. No personal identifying information will be requested of the students at any time.
- B. Core Elements of the Accreditation Process
  - 1. Program Initiates Accreditation Process through ARC-AA.

Upon receipt of the Request for Accreditation Service (located on the CAAHEP website), via e-mail, ARC-AA provides instructions for the program's next steps.

Note: If Continuing Accreditation, ARC-AA will notify the program in writing providing the self-study report submission date.

2. Submission of Self-Study Report.

A self-study report will not be considered complete nor accepted for review if any one of the following items are not met: Standard I Sponsorship, Standard III. Key Personnel (program director, medical director).

3. Review of Self-Study Report by ARC-AA and Executive Analysis Written.

Executive Analysis is provided to the program director.

4. Site Visit.

A site visit is required to be part of the evaluation process to determine compliance with the CAAHEP *Standards*. Site visitors represent both ARC-AA and CAAHEP.

- a. A narrative report of findings from the site visit will be provided to each program following a site visit. The Site Visit Report, in addition to stating the areas not meeting the CAAHEP *Standards*, will include a listing of the program strengths and may include recommendations. Programs will be given an opportunity to respond to the report of findings.
- b. The program's response to the report of findings will be taken into consideration when determining an accreditation action recommendation.

- 5. ARC-AA Reviews Program's Compliance with CAAHEP Standards.
  - a. Review the program's response to site visit findings letter including additional materials, if submitted.
  - b. Request additional materials as appropriate.
  - c. For programs seeking 1<sup>st</sup> Continuing Accreditation, the program may host a second site visit for one day and repeat steps 4 and 5.
- 6. Accreditation recommendation determined by ARC-AA.

After careful review of all documents, ARC-AA Board of Directors collectively determines a recommendation for each program. The recommendation options are located in CAAHEP policy. The ARC-AA recommendation for each program will be forwarded to CAAHEP where the final accreditation decision is made.

7. Notification of accreditation decision.

The program will be notified by CAAHEP of the accreditation decision.

8. Continuous Quality Review (Interim and Annual Reports).

ARC-AA monitors programs for effective compliance with published criteria through the use of interim and annual reports.

- a. Interim Reports are submitted by programs holding Initial Accreditation.
- b. Interim Reports are based on the site visit findings and at a minimum will include:
  - 1) Annual Report
  - 2) Student and faculty survey results (administered by the program or ARC-AA, depending on year)
  - 3) Advisory Committee Meeting roster, minutes
  - 4) Clinical Rotations verifiable second year student, one month, rotations with primary subspecialties, while not limiting verifiable first year clinical sites in the process
- c. Annual Reports are submitted by programs holding Continuing Accreditation.
- C. Accreditation Categories.

ARC-AA will utilize only those accreditation categories currently approved by CAAHEP as delineated in the CAAHEP Policy and Procedures Manual.

D. Length of Accreditation.

After a comprehensive review, accreditation is granted by CAAHEP, upon the recommendation of ARC-AA, to programs in compliance with the CAAHEP Standards and Guidelines.

1. If the program is requesting initial accreditation, ARC-AA may recommend to CAAHEP for the next comprehensive review, including a self-study report and site visit, occur no more than five (5) years from the date of CAAHEP action.

- If the program is requesting continuing accreditation for the first time, the ARC-AA may recommend to CAAHEP the next comprehensive review, including a self-study report and site visit, occur no more than five (5) years from the date of CAAHEP action.
- 3. If the program has participated in two (2) or more comprehensive reviews, including a self-study report and site visit, and all have resulted in a positive recommendation to CAAHEP, then ARC-AA may recommend accreditation to CAAHEP for the next comprehensive review, including self-study report and site visit, occur no more than ten (10) years from the date of CAAHEP action.
- E. First Continuing Accreditation Cycle.

Programs awarded Initial Accreditation participate in additional monitoring, which includes:

- 1. Submitting to the ARC-AA the collated results from the annual surveys with students and program personnel, and
- 2. The program submitting on an annual basis the verifiable second year student rotations in the primary subspecialties, while not limiting verifiable first year clinical sites.

ARC-AA will conduct the site visit one year after the first cohort graduates. If there are concerns that cannot be addressed through a progress report, a subsequent site visit may be required prior to being recommended for continuing accreditation.

#### IV. REQUEST FOR RECONSIDERATION OF AN ADVERSE ARC-AA RECOMMENDATION

- A. When ARC-AA first formulates a recommendation of Withhold of Accreditation, Probationary Accreditation, or Withdrawal of Accreditation, the Chief Executive Officer of the sponsor will be notified in writing of that ARC-AA action. The sponsor will have fourteen (14) calendar days after receipt of that written notice (sent certified mail, return receipt requested) to request reconsideration of that recommendation or to request voluntary withdrawal of its accreditation or application.
- B. The notification will include the specific areas where the program was found deficient (Standards cited), the rationale for those citations, and the suggested documentation by which the Program may demonstrate its compliance with the Standards.
- C. If the Program does not request reconsideration by the deadline, the original ARC-AA recommendation is forwarded to CAAHEP with the correspondence documenting that the Program was notified of it rights and that due process was followed.
- D. If the Program requests reconsideration, it is notified of a deadline to submit additional (new) material for consideration by ARC-AA.
- E. ARC-AA will place reconsideration of the original recommendation on its next agenda following the Program's deadline for submission of materials.
- F. The ARC-AA Board will review the reconsideration action based on all the materials at the time of the original recommendation as well as all new materials submitted by the Program.
- G. ARC-AA formulates a recommendation to CAAHEP for:
  - 1. Initial Accreditation or Withhold Accreditation for new programs, or
  - 2. Continuing Accreditation, Probationary Accreditation, or Withdrawal of Accreditation for currently accredited programs, including the Standards cited, the rationale for each citation, and the suggested documentation to correct each citation.
- H. If ARC-AA formulates a recommendation that could change the CAAHEP accreditation status of the program, the recommendation is forwarded to CAAHEP along with the correspondence documenting that the Program was notified of its rights and that due process was followed.
- I. If ARC-AA formulates a recommendation that would not change the CAAHEP accreditation status, but includes citations, the recommendation is not forwarded to CAAHEP and a Progress Report is requested of the Program.

#### V. SITE VISITORS

- A. <u>Composition of Site Visit Team</u>. A site visit team consists of either:
  - 1. two (2) anesthesiologist assistants or -
  - 2. one (1) anesthesiologist assistant and one (1) physician anesthesiologist.

The third member of the site visit team may be an anesthesiologist assistant, a physician anesthesiologist, a university dean, or an ARC-AA staff person.

At least one member of the team will be an educator.

A site visit team conducting a site visit to a program seeking Initial Accreditation should include a physician anesthesiologist, when available.

No site visitor will have any real or potential conflict of interest that may affect the evaluation. If the site visitor, program, or ARC-AA has reason to believe that a conflict of interest exists, the visitor will be excused, and another member selected. All site visitors are required to sign a confidentiality statement.

Observers may accompany the site visit team.

ARC-AA assigns a minimum of two (2) site visitors, and preferably three (3) site visitors, for each site visit. A single site visitor is acceptable only in unusual and extenuating circumstances and only with the approval of the ARC-AA Chair, the sponsor institution and the program administration.

- B. <u>Site Visitor Selection and Appointment</u>. Site visitor applicants will be qualified by education and experience.
  - 1. All Site Visitors
    - a. Successful completion of the CAAHEP Site Visitor Quiz.
    - a. If with a CAAHEP-accredited Anesthesiologist Assistant program, the program must be in good standing.
  - 2. Anesthesiologist Assistant
    - a. At least two (2) years of full-time experience or five (5) years of part-time experience as an Anesthesiologist Assistant educator with a CAAHEP accredited Anesthesiologist Assistant program; and,
    - b. Knowledgeable about education issues, especially curriculum, exam development, program evaluation, or student evaluation; and,
    - c. Qualify as a Program Director under current CAAHEP Standards; and,
    - d. If retired and not currently working with a CAAHEP accredited Anesthesiologist Assistant program, has worked in AA education within the past five (5) years; or
    - e. A current or past Director of the ARC-AA Board.
  - 3. Physician Anesthesiologist
    - a. Actively involved in Anesthesiologist Assistant education.
    - b. Knowledgeable about education issues; and,
    - c. Qualify as a medical director under current CAAHEP Standards; and,

- d. If retired and not currently working with a CAAHEP accredited Anesthesiologist Assistant program, has worked in AA education within the past five (5) years; or
- e. A current or past Director of the ARC-AA Board.
- 4. University Dean or Associate Dean

The dean position will function as a generalist for the site visit, reviewing and validating data that is not content specific to anesthesiologist assistant, unless the individual has previous experience as an anesthesiologist assistant or an anesthesiologist.

- a. Actively involved as a dean, or associate dean, of allied health.
- b. Have experience in working with programmatic or institutional accreditation.
- c. If retired and not currently working, has worked as an university dean or associate dean within the past five (5) years.
- 5. ARC-AA Staff Member

The staff member will function as a generalist for the site visit, reviewing and validating data that is not content specific to anesthesiologist assistant, unless the individual has previous experience as an anesthesiologist assistant or an anesthesiologist.

- a. Actively involved in programmatic or institutional accreditation activities.
- b. Knowledgeable about education issues.

Qualified persons wishing to be selected as site visitors should forward a current curriculum vitae and request for appointment as a site visitor to ARC-AA. The applications will be reviewed by ARC-AA and the decisions will be made.

Upon acceptance by ARC-AA, site visitors will be granted observer status. Following completion of the training requirements observers will be appointed as active site visitors.

C. <u>Site Visitor Expectations</u>. Active site visitor status is subject to review by ARC-AA and is based upon annual appointment recommendations by ARC-AA. Re-appointment recommendations for site visitors will be based upon: (a) the number of site visits during the prior year(s); and (b) assessment of the quality of their performance on observed site visit.

The general competencies expected of site visitors include:

- 6. An in-depth knowledge of:
  - a. The full scope of the program's resources, operations and components as described in the Self-Study Report prepared by the institution under evaluation.
  - b. The most current CAAHEP Standards and Guidelines.
  - c. The existing procedures for accreditation, including the mechanism for reconsideration.
  - d. The role of resource assessment and outcome evaluation in AA programs.
- 7. A general knowledge of:
  - a. The principles of institutional organization/administrations including:
    - 1) Institutional accreditation processes

- 2) Fiscal policy and planning
- 3) Various organizational/authority structures
- b. Curriculum design and instructional methods, including non-traditional approaches.
- c. Psychometric theory and application including:
  - 1) Cognitive testing and evaluation
  - 2) Performance evaluation
- d. Contemporary standard of anesthesia care, including current procedures and equipment, and the expected role of practitioners.
- e. Current learning resources related to anesthesiology, patient care, and medicine.
- f. Sensitivity to the potential for personal or professional bias.
- D. <u>Withdrawal of Site Visitor Appointment</u>. Individuals may be deleted from the roster of active site visitors if they: voluntary resign, are inactive for a period of three or more years, or fail to correct any deficiencies revealed on the evaluative process. In this context, 'inactive' is defined as one performing an average of less than one site visit every three years or failure to complete site visitor training within the three year period.
- E. <u>Responsibilities of the Site Visit Team</u>. The primary responsibilities of the site visit team include:
  - 1. Before the Site Visit
    - a. Confirm Participation

Selected team members should promptly notify ARC-AA of their willingness to participate in a scheduled site visit. Any real or potential conflict of interest should be considered and ruled out. Site visitors will decline any assignment in which a real conflict of interest may be perceived.

b. Review Self-Study Report

Team members will review the contents of the Self-Study Report in relation to the CAAHEP *Standards*. When necessary, the team captain should communicate with the program for any clarification of submitted materials.

c. Communicate with Team

Following review of the written report and the supplementary documentation, team members will communicate with each other to develop strategies for data collection and evaluation, outline specific areas of scrutiny, and identify concerns.

d. Finalize Site Visit Agenda

A mutually satisfactory agenda will be arranged in consultation with the Program Director of the program being visited. ARC-AA and team captain will be contacted if a change in the length of the visit is deemed appropriate. The program personnel may be asked to assist in arranging for appropriate accommodations and ground transportation. When possible, travel arrangements of the team members will be coordinated. Late arrival to or early departure from the sponsor institution reduces the efficiency of the site visit and can adversely affect the site visit team's ability to evaluate the educational program completely and objectively.

- 2. During the Site Visit
  - a. Preliminary Team Meeting

Arrangements should be made for the site visitors to meet prior to the formal agenda. At this meeting the team should compare notes and decide how they will conduct the various interviews and discuss any other concerns.

b. Orientation

All program personnel and representatives of the administration will be clearly informed about the purposes, function, and mechanics of the site visit and its relationship to the accreditation processes of ARC-AA and CAAHEP.

c. Collect & Interpret Data

The team members will collect, verify, and interpret all information likely to demonstrate how the program meets the *Standards* by:

- 4) Interviewing all key program personnel, support staff, students, graduates, and representation of advisory committees.
- 5) Reviewing and analyzing relevant documentation and reports, particularly resource assessment materials.
- 6) Inspecting pertinent facilities and resources.
- d. Documentation

Team members will carefully document all findings on the in the site visit report form. Evidence will be provided to substantiate all Standards 'not met' and/or 'partially met'. For all Standards cited as 'not met' or 'partially met' reference will be made to the number/letter designation of the applicable Standards(s).

e. Site Visit Report

A site visit report should be developed in a collaborative manner prior to the exit summation conference. It will be reviewed for accuracy prior to its submission. Errors identified will be corrected. Consistency between the observation and impressions of the site team and their documentation is essential. The site visit report will complement and validate, not duplicate, the Self-Study Report submitted by the program.

The team's report will address specifically any concerns. The report will be concise but will provide evidence, from objective sources, of the program's quality relative to the *Standards*.

In addition, the report will be free from personal philosophical iterations and from convoluted terminology. The report will be candid and analytical and give an accurate picture of the strengths and weaknesses of the program.

For problem areas, there will be description of the specific suggestions made in writing by the site visitors to help the program address the situation.

f. Consultation Conference with the Program Director

After completion of the Site Visit Report, team members will arrange to meet the Program Director to confirm the data and discuss the site visit team's conclusions and recommendations. It is important to determine whether any of the conclusions have been based on faulty interpretations or incomplete information. This is an ideal time for the team to function as consultants, providing ideas and suggestions to help the program personnel address identified shortcomings.

g. Exit Summation Conference

The site visit team members will provide program personnel and administration officials with an objective oral review of the findings of the team. Those present during the summation conference will be documented. Team members will try to evaluate the degree of concurrence expressed by those present regarding the team's observations and determine the likelihood of correcting those Standards cited as 'not met' or 'partially met'. The team should reiterate their function and review the sequence of events for the accreditation process including the program's right to verify the facts in the report, the ability of the program to inform ARC-AA of improvements made prior to the close of the agenda, and the reconsideration mechanism.

The team will not indicate ARC-AA's accreditation recommendation and will not leave a copy of the Site Visit Report with the program.

- 3. After the Site Visit
  - a. Submit Site Visit Report to ARC-AA

The Site Visit Report must be submitted to ARC-AA within one (1) week of the completion of the site visit.

b. Send Findings Letter

The program will receive a formal written report from ARC-AA within four (4) weeks of the site visit. At this time, the program will be given the opportunity to respond to any inaccuracies of fact and to comment on the site visit team's interpretation of information gathered on site.

- F. <u>Professionalism</u>. All individuals associated with ARC-AA education, including committee members, site visitors, consultants and other representatives, will maintain the highest standard of professionalism and integrity and will conduct themselves in a manner that fosters respect for the integrity, expertise and reliability of all.
- G. <u>Complaint Against a Site Visitor</u>. A complaint or grievance of an approved site visitor's conduct during a site visit may be submitted by any student, faculty and/or fellow site visitor.

All written grievances will be forwarded to the Executive Director and the Chair of ARC-AA for review within 10 working days of the completion of the site visit. The ARC-AA Board of Directors will not intervene on behalf of individuals, or act as a court of appeal for individuals. It will intervene only when it believes that the practices or

- 4. To receive formal consideration, all complaints must be submitted in writing and signed. Submission of signed peer site visit evaluations will also be accepted but must clearly request formal consideration by the board to evaluate potential site visitor misconduct related to the CAAHEP *Standards and Guidelines* or established ARC-AA Policies & Procedures.
- 5. If the Executive Director or ARC-AA Chair determines the complaint does not relate to the established policies and procedures, the person initiating the grievance will be notified accordingly.
- 6. If the complaint does relate to the established policies and procedures, the Executive Director will acknowledge receipt of the complaint and share with the filing party a description of the process and policies that pertain to handling such complaints. If ARC-AA does not hear from the complainant within 10 working days, they will continue with AA does not hear from the complainant within 10 working days, they will continue with this process:
  - c. The Executive Director will forward the complaint to the ARC-AA Executive Committee. Attached to the complaint will be the program's findings letter, response (if received) and any other pertinent notes from the site visit.
  - d. ARC-AA will notify the site visitor of the substance of the complaint and will conduct a preliminary investigation of the alleged misconduct. ARC-AA will file a report of the investigation findings within 30 days of the site visitor's receipt of the letter of notice.
    - 1) During the course of investigation, the site visitor will be suspended from any site visit activities. If the site visitor was scheduled for a site visit, arrangements will be made for a replacement.
    - 2) The Executive Committee may request further information or material relative to the complaint from the complaining party, the institution or other relevant sources.
  - e. The identity of the complaining party will be kept confidential, unless the complainant authorizes disclosure of their identity, or unless such disclosure is required by legal process in a subsequent proceeding.
- 7. On receipt of the responses, the Executive Committee will consider the complaint and all relevant information obtained in the course of investigation and formulate an appropriate action according to the following guidelines:
  - a. If the complaint is determined to be unsubstantiated or unrelated to the established accreditation policies, the complaining party and site visitor will be so notified of the completion of the investigation.
  - b. If the investigation reveals the site visitor is not in compliance with the established site visitor policies, the Executive Committee will forward its recommendation to the ARC-AA Board for inclusion on the next available ARC-AA Board Agenda. Possible recommendation may include, but is not limited to:
    - issue of a warning of misconduct to the site visitor and required re-training regardless of previous date of training (multiple receipts of warning will result in removal from the ARC-AA approved Site Visitor roster);

- 2) demotion to team member (for team chairs only) and required re-training regardless of previous date of training;
- 3) suspension of the site visitor from the ARC-AA approved site visitor list for a period as determined by the ARC-AA Board of Directors.
- 8. Upon approval of the recommendation by the full ARC-AA Board of Directors, the Executive Director will notify the complainant of the result of the investigation.
- Should ARC-AA determine that the misconduct of the site visitor jeopardizes the review of the program; a second, abbreviated site visit may be held, at no additional charge to the program, at the program's request.
- H. <u>Confidentiality</u>. ARC-AA requires that its procedures and the actions of its site visitors are consistent with the need to maintain confidentiality during the review process in accordance with ARC-AA and CAAHEP policies. All information made available to site visitors for and during their evaluation will be considered confidential. Disclosure of any information obtained during the accreditation process will be a breach of confidence. Team members are also privy to a number of opinions expressed by individuals during interviews; these too will be confidential. Site visitors will refrain from discussion of any aspect of a sponsor institution, even positively, with anyone other than representatives of the sponsor institution, or individuals involved in the accreditation process.
- I. <u>Site Visit Evaluation</u>. Peer evaluation of team members will be completed after each site visit. Additionally, the Program Director and the senior officer of the sponsor institution who participated in the site visit are each given the opportunity to evaluate the site visitors both as a team and as individuals.

Post site visit questionnaires will be reviewed on an annual basis. Staff will mail a report regarding performance, to all site visitors who participated in a site visit during the previous year. Any site visitors receiving an unfavorable evaluation will be reviewed by ARC-AA.

- J. <u>Reasonable Expenses</u>. Site visit team members shall be reimbursed for reasonable expenses incurred as a result of the site visit pursuant to Section XV.E. of these Policies and Procedures.
- K. <u>Focused Site Visits</u>. Programs will be given 90 days' notice prior to the site visit. The program will be given three (3) days to confirm the assigned site visit dates. If no confirmation is received from the program, it will be assumed that assigned dates are acceptable. Random site visits are determined based on ARC-AA's review of the annual outcome reports and a programs' ability to meet the established thresholds. Selection may also be based on the date of the program's last site visit or any significant changes taking place within the program.

#### VI. OUTCOMES BASED EVALUATION

- A. <u>Criteria</u>. ARC-AA will use a number of criteria for outcomes measures, which include, but are not limited to, employer surveys, graduate surveys, student surveys, and the number of graduates passing the certification examination.
- B. <u>Reporting</u>. Programs will provide information on an annual basis using the electronic format designated by ARC-AA. Failure to do so within seven (7) days of the determined deadline may result in a program being placed on administrative probation.
- C. <u>Established Thresholds</u>. The following outcomes thresholds that programs must meet/maintain for accreditation:
  - 1. Graduate Surveys are administered six (6) months to one (1) year post graduation and have a 100% sent rate.
  - 2. Employer Surveys are administered six (6) months to one (1) year post graduation and have a 100% sent rate.
  - 3. Retention of 90% or greater of total enrollment, including attrition due to academic dismissal, clinical dismissal, or student withdrawal.
  - 4. Positive Placement of 90% or greater. Positive Placement requires the graduate to be employed as an AA or continuing their education.
  - 5. (NCCAA) Certification Success of 90% or greater.
- D. <u>Failure to Meet Established Thresholds</u>. Failure to meet the established thresholds will result in recommendations from ARC-AA and require an action plan be developed by the program and submitted to ARC-AA. The action plan should provide documentation regarding how the deficiencies will be corrected. Non-compliance, inability to correct deficiencies in a timely manner, or serious deviation from the threshold in any particular measure may trigger an unscheduled comprehensive review, progress report, or a change in the program's accreditation status.
- E. <u>Transparency of Outcomes</u>. All programs must publish on their websites, the 3-year review-window average results of the outcomes for: national credentialing examination(s) performance, job (positive) placement, and programmatic retention/attrition. The Programs must publish the first-time pass rate and the cumulative pass rate for the national credentialing examination(s) performance. The Programs may publish additional outcomes, such as graduate satisfaction, employer satisfaction, and programmatic summative measures.

At all times, the published results must be consistent with and verifiable by the online Annual Report of the program.

Each year in the Comments tab of the Annual Report, the program must state the website link where its results are published.

F. <u>Graduate and Employer Surveys</u>. For each group of graduating students, programs are required to conduct surveys of those graduates and the employers of those graduates within 6-12 months after graduation using the ARC-AA required graduate survey and employer survey items. Programs may use the ARC-AA survey as

#### VII. COMPLAINTS REGARDING ARC-AA AND ACCREDITED PROGRAMS

ARC-AA follows due process procedures when written and signed complaints are received by CAAHEP or ARC-AA alleging: that they or an accredited program are not following established policies or CAAHEP *Standards*; they have concerns about the ARC-AA management services company, a Director, or a site visitor. CAAHEP and ARC-AA maintain indefinitely a record of all complaints received.

To receive formal consideration, all complaints will be submitted in writing and signed. The complaint will demonstrate that reasonable efforts have been made to resolve the complaint, or alternatively that such efforts would be unavailing.

#### A. <u>Related to Accreditation Standards</u>

- 1. When received by CAAHEP, complaints are transmitted within five (5) working days to the chairperson and staff of ARC-AA for consideration. When received by the chair or staff of ARC-AA, a copy is forwarded to the CAAHEP office within five (5) working days.
- 2. Following consultation among staff of ARC-AA and CAAHEP, the chairperson of ARC-AA determines whether the complaint relates to the manner in which the program complies with the *Standards* or follows established accreditation policies.
  - a. If the complaint does not relate to the *Standards* or to established policies, the person initiating the complaint will be notified accordingly within 20 working days following receipt of the complaint by ARC-AA. A copy of this correspondence will be shared with CAAHEP.
  - b. If the complaint does relate to the *Standards* or to established policies, the Chair or representative of ARC-AA will acknowledge receipt of the complaint within 20 working days and share with the filing party a description of the process and policies which pertain to handling such complaints.
    - 1) The Chair or representative of ARC-AA will notify the Program Director and the chief executive officer of the sponsoring institution of the substance of the complaint and will request a preliminary investigation and report on the findings within 30 days of the sponsoring institution's receipt of the letter of notice.
    - 2) The Chair or representative of ARC-AA may request further information or material relative to the complaint from the complaining party, the institution, or other relevant sources.
    - 3) The CAAHEP office should receive copies of this correspondence.
    - 4) The identity of the complaining party will be kept confidential, unless the complainant authorizes disclosure of their identity, or unless such disclosure is required by legal process in a subsequent proceeding.
- 3. On receipt of the responses referred to above, ARC-AA will consider the complaint and all relevant information obtained in the course of investigation and formulate an appropriate action according to the following guidelines:

- a. If the complaint is determined to be unsubstantiated or unrelated to the *Standards* or established accreditation policies, the complaining party, officials of the program in question, and the appropriate official of the sponsoring institution, will be so notified within ten days of the completion of the investigation.
- b. If the investigation reveals the program may not be or may not have been in compliance with the Standards or may not have been following the established accreditation policies, one of two approaches will be taken.
  - The program must submit a report and documentation within 30 days following the investigation demonstrating the manner in which the substantiated complaint has been corrected. Should ARC-AA be satisfied with the response, the program, its sponsoring institution, and the party filing the complaint will be notified of ARC-AA's satisfaction with the resolution of the matter and notice that the program's accreditation status remains unaffected by the complaint.
  - 2) Should ARC-AA judge the program or sponsoring institution's response to the complaint inadequate and lacking in evidence of the program's continuing compliance with the *Standards* or adherence to accreditation policies, ARC-AA may request and arrange for a return site visit of the program as soon as reasonably feasible, but not more than 30 days following the investigation. The purpose of the return site visit will be limited to an investigation of the complaint and the manner in which it affects compliance with the Standards or with accreditation policies. The cost of the return site visit will be borne by ARC-AA.
    - a) Should ARC-AA, on evidence received through the return site visit, consider the program to remain in compliance with the *Standards* and in adherence with accreditation policies, the program, its sponsoring institution, and the complaining party will be notified of this assessment and the fact that the program's current accreditation status remains unaffected by the complaint.
    - b) Should ARC-AA consider the evidence of the site visit to indicate the complaint is valid and the program is not in compliance with the *Standards* or with accreditation policies, ARC-AA will recommend a change in accreditation status to CAAHEP.
- 4. Should ARC-AA judge the program or sponsoring institution's response to the complaint inadequate and lacking in evidence of the program's continuing compliance with the *Standards* or adherence to accreditation policies, all information regarding the complaint, a full report of its investigation, and ARC-AA's recommendation will be transmitted to CAAHEP for consideration and action.
- 5. CAAHEP and ARC-AA emphasize that they will not intervene on behalf of individuals or act as a court of appeal for faculty members or students in matters of admission, appointment, promotion or dismissal. They will act only when it believes practices or conditions indicate the program may not be in compliance with the *Standards* or with established accreditation policies.
- B. <u>Related to Management Services Company</u>. Complaints about the ARC-AA management services company must be submitted in writing to the Chair and must be signed. Anonymous complaints will not be accepted. Complaints will be reviewed by the Chair and legal counsel for further investigation, including a response from the management services company, culminating in action or disposition. If it is determined that further investigation is required and depending on the nature of the complaint, results of the investigation and any recommendations for action shall be discussed with the Executive Committee.

- C. <u>Related to Director(s)</u>. Complaints about a Director(s) of ARC-AA must be submitted in writing to the Executive Director and must be signed. Anonymous complaints will not be accepted. Complaints will be reviewed by the Chair, or the Vice Chair if the Chair is the one it concerns, and legal counsel for further investigation, including a response from the Director(s), culminating in action or disposition. If it is determined that further investigation is required and depending on the nature of the complaint, results of the investigation and any recommendations for action shall be discussed with the Board of Directors.
- D. <u>Related to Site Visitor(s)</u>. Refer to policy X.G. <u>Complaint Against a Site Visitor</u>.

#### VIII. PROGRAMS

- A. <u>Satellite Programs</u>. Satellite programs are not defined nor endorsed as models for AA programs and AA education.
- B. <u>Substantive Change</u>. Programs must immediately notify ARC-AA of any changes in its relationship with the school of medicine and/or with the Department of Anesthesiology affiliations;, sponsorship, sponsor administration personnel, program key personnel, increase in class size, decrease in clinical affiliates, and addition of distance education or satellite location needs. Substantive changes in Program status, sponsorship, administrative personnel or addition of distance education or satellite location or satellite location may require immediate submission of a Progress Report and may require submission of a Self-Study Report and/or scheduling of a return site visit.

ARC-AA may assess a fee if the substantive change results in a site visit.

- C. <u>Transfer of Sponsorship</u>. The sponsor must inform ARC-AA and CAAHEP of a change in sponsorship in accordance with established policy. If the program is scheduled for an initial or continuing accreditation site visit, the transfer of sponsorship process must be completed prior to a scheduled visit. A change of ownership must be reported to ARC-AA for determination of whether it constitutes a change of sponsorship.
  - 1. The chief executive officer or an official designee of the institution relinquishing sponsorship must provide ARC-AA and CAAHEP with written notice of the intent to transfer sponsorship of the program.
  - 2. ARC-AA will send the program an application for Transfer of Sponsorship.
  - 3. The chief executive officer or an official designee of the new sponsor will submit within 30 days of receipt of the application:
    - a. Completed application to ARC-AA
    - b. Transfer of sponsorship application fee
  - 4. A completed Initial Accreditation Self-Study Report must be submitted to provide reasonable assurance that the current *Standards* will continue to be met as demonstrated in the self-study report and at the site visit if one is required.
  - 5. ARC-AA reviews the documentation and makes a recommendation at its next scheduled meeting.
  - 6. After review of these materials for compliance with the *Standards*;
    - a. If the Transfer of Sponsorship Self-Study Report does not demonstrate compliance with the *Standards*, ARC-AA will forward to CAAHEP a recommendation for withholding accreditation.

- b. If a Transfer of Sponsorship Self-Study Report demonstrates compliance with the *Standards*, a recommendation for initial accreditation, with or without progress reports, will be forwarded to CAAHEP.
- D. <u>Program Director Appointment, Changes, and Qualifications</u>. Each anesthesiologist assistant program will have only one individual appointed and designated as the Program Director. The Program Director must meet the qualifications and fulfill the responsibilities stated in the *Standards*.
  - 1. The sponsor (institution) notifies ARC-AA in writing or via email of a vacancy or change in Program Director within 14 calendar days of the vacancy or change.
  - 2. If a vacancy occurs, the sponsor (institution) appoints an acting, interim, or permanent Program Director and notifies ARC-AA by completing the appropriate sections of the Personnel Change form within 30 calendar days of the vacancy.
    - a. <u>Acting</u>: A program may have an acting Program Director for no more than a total of six (6) months from the date of the vacancy. "Acting" is when the individual's qualifications do not meet the *Standards*.
    - b. <u>Interim</u>: A program may have an initial approval of an interim Program Director for up to twelve (12) months from the date of the vacancy. "Interim" is when an individual's qualifications meet the Standards, but the individual has not been permanently appointed to the position.
    - c. If the interim Program Director continues due to a prolonged absence of the permanent person (i.e., illness, educational leave, other approved leave of absence), the program may request a subsequent approval for an additional twelve (12) months.

No interim Program Director approval can be extended beyond 24 months.

- 3. The sponsor (institution) notifies ARC-AA of a new Program Director (acting, interim, or permanent) by completing the appropriate sections of the Personnel Changes form, available on the website.
- 4. The sponsor (institution) provides documentation of the qualifications, the written position description for the Program Director, and documentation of sufficient non-teaching time to fulfill the responsibilities.
- 5. ARC-AA notifies the program in writing of the approval of the individual or a required Progress Report for submission of additional documentation as specified and that failure to meet the qualifications within the specified time will result in an adverse accreditation recommendation.
- 6. An individual, who has been approved under previous *Standards*, will continue to be approved for the duration of their appointment in that position with the same institution as at the time of approval. This approval ceases if the individual is appointed at another institution.
- E. <u>Medical Director Appointment, Changes, and Qualifications</u>. Each anesthesiologist assistant program will have only one individual appointed and designated as the medical director. The medical director must meet the qualifications and fulfill the responsibilities stated in the *Standards*.
  - 1. The sponsor (institution) notifies ARC-AA in writing or via email of a vacancy or change in Program Director within 14 calendar days of the vacancy or change.

- 2. If a vacancy occurs, the sponsor (institution) appoints an Acting, Interim, or permanent medical director and notifies ARC-AA by completing the appropriate sections of the Personnel Change form within 30 calendar days of the vacancy.
  - a. <u>Acting</u>: A program may have an acting medical director for no more than a total of six (6) months from the date of the vacancy. "Acting" is when the individual's qualifications do not meet the *Standards*.
  - b. <u>Interim</u>: A program may have an initial approval of an interim medical director for up to twelve (12) months from the date of the vacancy. "Interim" is when an individual's qualifications meet the *Standards*, but the individual has not been permanently appointed to the position.

If the interim medical director continues due to a prolonged absence of the permanent person (i.e., illness, educational leave, other approved leave of absence), the program may request a subsequent approval for an additional twelve (12) months.

No interim medical director approval can be extended beyond 24 months.

- 3. The sponsor (institution) notifies ARC-AA of a new medical director (acting, interim, or permanent) by completing the appropriate sections of the Personnel Changes form, available on the website.
- 4. The sponsor (institution) provides documentation of the qualifications, the written position description for the Program Director, and documentation of sufficient non-teaching time to fulfill the responsibilities.
- 5. ARC-AA notifies the program in writing of the approval of the individual or a required Progress Report for submission of additional documentation as specified and that failure to meet the qualifications within the specified time will result in an adverse accreditation recommendation.
- 6. An individual, who has been approved under previous *Standards*, will continue to be approved for the duration of their appointment in that position with the same institution as at the time of approval. This approval ceases if the individual is appointed at another institution.
- F. <u>Sponsorship</u>. A sponsor (institution) change of ownership, chief executive officer, and dean (or equivalent position<sup>1</sup>) must be reported to ARC-AA within 14 calendar days of the effective date of the change.

Any decision adversely affecting the sponsor's institutional accreditation, and/or authorization under law or other authority to provide an anesthesiologist assistant program must be reported to CAAHEP and the within 14 calendar days of the receipt of such notice.

- 1. The sponsor (institution) notifies ARC-AA in writing or by email of the new chief executive officer or dean (or equivalent position).
- 2. Notice of Adverse Decision
  - a. Upon receipt of the notice of a decision adversely affecting the institutional accreditation status and/or the authorization for an anesthesiologist assistant program, the chief executive officer submits a copy of the notice to ARC-AA.

<sup>&</sup>lt;sup>1</sup> An equivalent position is that position to which the Program Director reports, if it is not the Dean.

b. ARC-AA at its next scheduled meeting reviews the decision and makes a determination if the institutional circumstances adversely affect the accreditation of the anesthesiologist assistant program.

ARC-AA notifies the chief executive officer of its decision and any request for additional information within 14 calendar days after the meeting.

- G. Program Retention of Student Records.
  - 1. <u>Outcome Data</u>. Programs are required to maintain a file of raw data for outcomes for the most current 5-year window (consistent with the most recent accreditation comprehensive review). This includes:
    - a. Graduate Surveys
    - b. Employer Surveys
    - c. Placement data
    - d. NCCAA exam statistics
  - 2. Programs are required to maintain the following documentation for all students:
    - a. Grading Policy
    - b. Grading Scale
    - c. Pass Score
    - d. Official roster of students most recently assessed cohort in each of the cognitive domain areas
    - e. Copy of blank exam(s) and/or other required assessments covering each objective in the cognitive domain areas.
    - f. Grade book or transcripts covering all students in the covered cohorts, documenting satisfactory completion of each objective.

Electronic record keeping is encouraged.

#### IX. DATA USE

The Board of Directors of ARC-AA recognizes the value of data collected via the annual report, self-study, site visit report, and other official data sources and realizes the importance of making such data available to researchers. ARC-AA encourages the use of official accreditation related records and data for legitimate research purposes under the following conditions:

- A. Access to ARC-AA data will be determined and approved by the Executive Director, Chair of the Board, and Chair of an appointed Ad-Hoc Data Subcommittee for one of the following purposes:
  - 1. **Research purposes for publication** to test a stated hypothesis or answer a specific research question. A request for authorization for use of ARC-AA data requires, at minimum, the submission of the following documents:
    - a. ARC-AA Data Request Form (See Appendix A)
    - b. Research Proposal Form (See Appendix B)
    - c. Data Distribution Agreement (See Appendix C)
    - d. Submission of ARC-AA Conflict of Interest Research Request Disclosure Form (See Appendix D2, and if applicable Appendix D3)
    - e. Submission of Institutional Review Board (IRB) approval
  - 2. **Research purposes not for publication** where data will be used for project investigation that is not intended to be published in a peer-reviewed journal or any other media. A request for authorization for use of ARC-AA data requires at minimum the submission of the following documents:
    - a. ARC-AA Data Request Form (See Appendix A)
    - b. Submission of ARC-AA Conflict of Interest Research Request Disclosure Form (See Appendix D2, and if applicable Appendix D3)
- B. ARC-AA is responsible for ruling on the merit of the request for data. Approval for use of data will be based upon, but not limited to, the following criteria:
  - 1. The value and importance of the research to Anesthesiologist Assistant education
  - 2. The integrity of the hypothesis and the appropriateness of the proposed research methodology
  - 3. Assurance that the data can support testing of the hypothesis
  - 4. Financial considerations or burden placed on ARC-AA
  - 5. Qualifications to do the research
  - 6. Record of published research in refereed journals and prior research projects
- C. Requests must include an official institutional human subject review approval prior to data release.
- D. All expenses incurred by ARC-AA as a result of the project (e.g. personnel costs, use of copiers, telephones, etc.) shall be reimbursed at cost. In addition, a data usage fee will be determined by the Executive Director in consultation with the Chair of the Board, Chair of the appointed Ad-Hoc Data Committee, and the Executive Committee. Additional fees may be assessed based on the complexity of data and as needed if future requests are made for additional information within the scope of the original project.
- E. All data, surveys and reports remain the property of ARC-AA.
- F. ARC-AA reserves the right to review and comment on the final manuscript/report prior to publication.

- G. If the data requested is to be used for publication of any additional manuscripts not proposed in the initial application, then the principal investigator must submit another application to ARC-AA requesting the use of that data for those additional manuscripts.
- H. The following statement must be published in the manuscript.

"The author wishes to thank ARC-AA for permission to use program records and for technical assistance. The analysis and opinions contained in the manuscript are those of the author(s). All compilations of data from the records made available were prepared by the author(s) who is/are solely responsible for the accuracy and completeness of the compilations. ARC-AA is not a party to nor does it sponsor or endorse the conclusions or discussions in the manuscript."

## Appendix A: ARC-AA Data Request Form

Type of Request (Please check one)			
Research Proposal Request 🗌 Non-Research Information Request			
Name of Requestor/Principal Investigator:			
Affiliation/Institution:			
Address:			
City, State, Zip Code: _			
Contact Telephone #:			
E-Mail Address:			
Date of Request:			
What research question is intended to be answered by the data?			
What specific data will be collected?			
Explain the intended use of the data.			
If a manuscript will be submitted for publication, indicate the intended journal.			
(For ARC-AA Use Only)			
Approved Denied Explanation:			
Executive Director:			
Date:			
Chairperson, Ad-Hoc Data Subcommittee:			
Date:			
Chairperson, ARC-AA Board:			
Date:			

### Appendix B: Research Proposal Form

The following form is to be completed for all research proposals.

Please e-mail in a single, complete pdf file the ARC-AA Data Request Form, Research Proposal Form, and the Data Distribution Agreement to:

Jennifer Anderson Warwick, Executive Director ARC-AA jennifer@arc-aa.org

Research proposals must address all of the sections listed below. Place the pages in the following order and number the pages consecutively, beginning with the title page.

1. Title of Study:

2. Investigator Information:

3. Research Abstract

Objective: Methods: Discussion: References:

#### 4. Consent:

A brief description of each section of research proposal abstract is included below.

**<u>Title:</u>** The title should be brief, specific, and clear while stimulating interest. The title should not contain abbreviations.

**Investigator Information**: List the full names of all investigators, degrees, and institutional affiliations. If a large research or investigative group is submitting the proposal, the use of a collective study group name is encouraged.

**Abstract:** The abstract must consist of the following four sections:

- **Objective** Include a clear statement of the study purpose and/or the hypothesis. Any information, such as past work or controversy, that may add credibility to the need for the study should be included here.
- *Methods* Include the following elements if relevant: study design, population, observations or key outcome measures, analytical methods, and any other relevant methodology.
- **Discussion** Include a statement about how the study objective will enhance an understanding of the issue under investigation. Brief justification and interpretive statements should be included here.
- *Literature Review* List citations in consecutive numerical order.

## Appendix C: Data Distribution Agreement – Statement of Intended Use of ARC-AA Data

Principal Investigator:

Organization/Institution:

Address:

City, State, Zip Code:

Telephone #:

E-mail Address of Principal Investigator:

Study Title:

It is agreed as follows:

- The principal investigator must provide evidence that the research project has been approved by an official Institutional Review Board prior to the release of any data by ARC-AA.
- ARC-AA data requested for this study is to be used solely for the above stated research project.
- This agreement applies solely to the research project stated above and described in Appendix B. Additional research projects based on the release of these data must be resubmitted to ARC-AA for review and approval.
- This agreement for use of ARC-AA data is nontransferable. Substantive changes made to the research project described above and/or the appointment of a new principal investigator will require the completion of a new "Data Distribution Agreement" form.
- ARC-AA data will not be used, either alone or in conjunction with any other information in any manner whatsoever to identify individuals or educational programs from which the data was obtained.
- Prompt publication of the results of the research project described above is encouraged. The principal investigator
  agrees to provide to ARC-AA a copy of any abstract or manuscript once it has been accepted for publication or
  presentation. The copy must be submitted to ARC-AA a minimum of forty-five (45) days prior to publication or
  presentation in order to permit review and comment by ARC-AA. In addition, it is understood that ARC-AA retains
  the right of rebuttal to the journal of record.
- Each manuscript/abstract will be reviewed by ARC-AA for consistency of data interpretation with previous publications.
- The principal investigator agrees to provide a copy of any and all published work resulting from the use of ARC-AA data to ARC-AA.
- The principal investigator agrees to acknowledge the contributions of ARC-AA in any and all presentations, disclosures, and publications resulting from the study described above.
- All survey instruments, survey items, and survey data remain the sole property of ARC-AA.

Signature of Principal Investigator: Date:

## Appendix D1: Conflicts of Interest Policy – Acknowledgment Form

I, \_\_\_\_\_\_, am a (Director) (Officer) (committee member) STRIKE THOSE NOT APPLICABLE of Accreditation Review Committee for the Anesthesiologist Assistant (ARC-AA), Inc. ("ARC-AA") and do hereby acknowledge and affirm the following:

- (1) I have received a copy of the Conflicts of Interest Policy;
- (2) I have read and understand the Conflicts of Interest Policy;
- (3) I have agreed to comply with the Conflicts of Interest Policy; and
- (4) I understand ARC-AA is a non-profit organization and in order to maintain its federal tax exemption it must engage primarily in activities that accomplish one or more of its tax-exempt purposes.

Signature

Date

Printed or Typed Name

## Appendix D2: Conflicts of Interest Policy – Research Request Disclosure Form

Research reviewed by ARC-AA must be accompanied by disclosure (for all researchers, their spouses, and their dependent children) of any Financial Interest in the research under review. Financial Interest means (i) anything of monetary value that could reasonably appear to be affected by the research, or (ii) anything of monetary value in entities whose interests could reasonably be affected by the research. Financial Interest includes, but is not limited to, (i) salary and other payments for services (e.g., consulting fees or honoraria); (ii) equity interests (e.g., stocks, stock options or other ownership interests); and (iii) intellectual property rights (e.g., patents, copyrights and royalties from such rights). Disclosure is required at the time of application to ARC-AA.

- 1. Name:
- 2. Telephone Number & E-mail Address:
- 3. Role in Project:
- 4. Title of Project:
- 5. Principal Investigator:

#### 6. Sponsor or Other Entity Providing Support:

#### Declaration Regarding Financial Interest (Please check as appropriate)

I hereby declare that I, my spouse, and my dependent children have **NO FINANCIAL INTEREST** in the research described in this application.

I hereby declare that the ATTACHED DISCLOSURE OF FINANCIAL INTERESTS accurately represents any and all such interests currently held by myself, my spouse, and my dependent children in the research described in this application.

I will promptly update this Declaration should the relevant Financial Interests of myself, my spouse, or my dependent children change during the conduct of this research, or within one year following the completion of this research.

Signature: Date:

## Appendix D3: Disclosure of Financial Interests

Name:

I, my spouse, or dependent children:

- Own stock or have stock options or other equity interests in the sponsor or product (*Do not include stock held in a mutual fund*.)
- Serve in a managerial position with the sponsor
- Act as a paid consultant for the sponsor
  - Serve as member of an advisory or administrative board of the sponsor
  - Receive payment(s) of any type from the sponsor or any other party (e.g., grants, consulting fees, salary, payments for board membership, honoraria, retainers, etc.)
    - a. If you do expect to receive payment from the sponsor, please indicate below what this payment is for, i.e., grants, consulting fees, salary, payments for board membership, honoraria, retainers, etc.
    - b. If you do receive payment from the sponsor, how much did you receive in the last twelve months?
    - c. How much do you expect to receive in the next 12 months?
  - Have intellectual property rights, patents, trademarks, copyrights, royalties, or other financial or proprietary interests in the research

Have any of the relationships noted above with a competitor of the sponsor

Have equity interests, intellectual property rights, patents, copyrights, proprietary interests, financial interests, or commitments of any kind, in addition to what was disclosed above, which may be perceived as a conflict of interest, as affected by the result of this research.

Please describe any steps taken to minimize conflict or bias. Use additional sheets if needed. If no steps are being taken to manage the financial interests disclosed above, explain clearly why you think such steps are not needed. If a previously approved plan remains in effect, so indicate.

Signature:

Date: