




STANDARD OPERATING PROCEDURE

TITLE:	Publications Standard Operating Procedures	SOP #:	OMN-109.00
DEPT:	Quality Assurance	REVISION #:	1.1
PREPARED BY:	James Lilliech	EFFECTIVE DATE:	09/1/2020
APPROVED BY:	Stephen M Casey, Partner		Page 1 of 16
SIGNATURE:		SIGNATURE DATE:	

1.0 Purpose

- 1.1 To describe the process for the development, review, and training for Omni Healthcare Communications Llc (OMNI-HC) Publications development and dissemination procedures (SOPs).

2.0 Scope

- 2.1 These procedures apply to all of OMNI-HC's service providers including; any employees, consultants, and contractors participating in services or other efforts managed by OMNI-HC for a client.

3.0 References

- 3.1 Including but not limited to:

- International Society of Medical Publication Planners (ISMPP) Good Publication Practice Guidelines GPP2 (https://www.ismpp.org/assets/docs/Inititives/GPP3/amwa%20gpp3%20presentation_tpena.pdf)
- International Committee of Medical Journal Editors' (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication http://www.icmje.org/recommendations/archives/2008_urm.pdf

4.0 Definitions

- 4.1 SOP – Standard Operating Policy and/or Procedure.
- 4.2 Authorized Designee – may include employees of OMNI-HC, consultants, subcontractors, and/or a Contract Research Organization.
- 4.3 CRO: Contract Research Organization

5.0 Responsibility

- 5.1 All OMNI-HC personnel and subcontractors will follow industry standards in the publication of research, including, but not limited to, the Good Publication Practice Guidelines (<http://www.gppguidelines.org/>) and the International Committee of Medical Journal Editors' (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org>). SAH is committed to conceptualizing, drafting, and publishing publications consistent with these guidelines and will accomplish this by ensuring that:
- All authors meet ICMJE requirements for authorship, and that acknowledgements are stated to recognize financial support, technical assistance, and/or contributions of those who do not qualify as authors
 - All authors are identified and have agreed to participate in accordance with the requirements for authorship prior to the initiation of a publication



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- Pertinent study results supporting a publication are provided to authors at the external authors' request; the manner in which access to data will be provided may differ depending on the circumstance and the specific request.
- Authors shall adhere to individual journal requirements for statements of disclosure and authorship contributions.
- Authors shall write according to industry guidelines and standards, including the following:
 - PhRMA (Pharmaceutical Research and Manufacturers of America) principles for communicating clinical trial results
 - Good Publication Practice for Pharmaceutical Companies
 - American Medical Writers Association Position Statement on the Contribution of Medical Writers to Scientific Publications
 - European Medical Writers Association guidelines on the role of medical writers in developing peer-reviewed publications
 - Consolidated Standards of Reporting Trials (CONSORT) statement for reporting the results of randomized controlled trials
 - MOOSE (Meta-analysis Of Observational Studies in Epidemiology) Group guidelines
 - Plagiarism is prohibited
- All publications covered by this Policy must go through the appropriate approval processes before submission
- Final drafts of all publications are approved by all authors before Submission

6.0 Procedure

6.1 The normal OMNI-HC publication development cycle includes:

- a kick-off discussion
- development of an outline where the lead author should be invited to participate in the outline development process
- review of at least 1 outline
- 2 working drafts
- 1 final draft

6.2 The Kick-off discussion should include all members of the Omni-HC publication team as well as the client.

6.3 The recommended timelines for author review of each publication type vary. OMNI-HC will provide sufficient review of publications in accordance with the requirements of the Vancouver guidelines.

Publication	Outline	First Draft	Subsequent Draft	Final
Abstracts	Not Applicable	Up to 5 business days	Up to 3 business days	Up to 3 business days
Posters/Presentations	Not Applicable	Up to 5 business days	Up to 5 business days	Up to 3 business days
Manuscripts/Reviews	Up to 5 business days	Up to 10 business days	Up to 10 business days	Up to 5 business days



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7.0 Standards of Conduct

7.1 OMNI-HC Teams working on publications will follow the OMNI-HC guidelines below pertaining to their conduct and relationships. OMNI-HC employees and subcontractors will be aware of their responsibilities to the company and to fellow employees.

7.2 OMNI-HC will take a constructive approach to ensure that actions that would interfere operations or an employee's job are not continued.

7.3 Employees or subcontractors not conforming to OMNI-HC standards will result in one of the following forms of disciplinary action:

- verbal warning
- written warning
- termination

7.4 To arrive at the proper course of disciplinary action, OMNI-HC will consider the seriousness of the infraction, past record of the employee, and circumstances surrounding the matter will be considered.

7.5 Although it is impossible to identify every possible violation of standards of conduct, the following is a partial list of infractions that will result in disciplinary action:

- Falsifying company records including application for employment
- Revealing confidential information of any kind to anyone outside the company
- Theft, fraud, embezzlement, or industrial espionage
- Using company equipment, material, copy machines, office supplies, computers, computer files, electronic mail, mail systems, time or information for unauthorized purposes
- Abusing, destroying, or wasting company property or equipment
- Excessive absenteeism or tardiness
- Performance that does not meet the requirement of the position or that does not comply with company standards
- Working under the influence of drugs or excessive alcohol or bringing illegal drugs or drugs obtained without a valid prescription written for you by a licensed physician to any meeting or conference.
- Immoral or indecent conduct
- Engaging in any illegal activity while on the job or on company property
- Insubordination or the undermining of SAH, it's subsidiaries, or any of its employees or clients
- Use of language intended to provoke or threaten anyone while on the job or on company property, or use of obscene or profane language that is excessive or that can be heard by clients
- Interfering with an employee and the performance of his or her company duties
- Violation of any other policy of SAH as set forth in this Handbook
- Verbal, visual, or physical conduct constituting sexual harassment

8.0 Project Work Allotments

8.1 OMNI-HC personnel working on publications

- Manuscript (from Source Material) to Submission
- Review Article to Submission
- Abstract
- Poster



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- Slide Kit from Source Material (20 slides with notes)
- Case Study to Submission
- Editorial or Letter to the Editor to Submission

will use the following time allotments as general guidelines for time and effort in developing new client material:
 All time estimates are general guidelines for new clients only and dependent on final client specifications for any deliverable.

8.2 Manuscript from Source Material

8.2.1 Manuscript (from Source Material*) to Submission Time Allotment

Project Stage	Person
First Draft (if no outline is required, then writing time will include research & will be subsumed into the 1st draft stage)	Writer
	Program Director
	Program Manager
	Editor
Second Draft	Writer
	Program Director
	Editorial
Final Version (for submission)	Writer
	Program Director
	Program Manager
	Editor
	EA
	Graphics† (optional)
Overall	Writer
	Program Director
	Program Manager
	Editorial
	EA
	Graphics† (optional)
TOTAL	

*Source material should include a briefing document (concise outline or email) from client highlighting the author(s), key messages, key findings/interpretation, key references, CSR (if available), protocol, and summary data tables †Graphics time/cost is optional and not included in the total price.

8.2.2 Manuscript (from source material*) to Submission Stages

Project	Required Steps	No. of hours
Primary Manuscript (Writing from CTR – 4,000 words, up to 6 figures/tables and up to 6 authors)	<ol style="list-style-type: none"> 1. Complete 'Statement of Work' and validate with client 2. Develop project schedule and update as required 3. Manage budget and keep client updated as appropriate 	Writer Program Director Project Manager Editorial EA



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	<ol style="list-style-type: none"> 4. Research suitable target journals and agree with client 5. Develop outline (if needed) and submit to client for comments 6. Incorporate client comments into outline 7. Submit revised outline to authors for comments 8. Incorporate author comments into outline 9. Develop first draft manuscript in accordance with journal requirements and submit to client for comments 10. Incorporate client comments into first draft manuscript 11. Submit second draft manuscript to authors for comments 12. Incorporate author comments into manuscript 13. Submit third draft manuscript to client and authors for approval 14. Incorporate client and author approval comments 15. Redraw figures and carry out final editorial checks 16. Submit finalized manuscript to client for information 17. Obtain declarations from named authors 18. Prepare submission pack for lead author and facilitate submission to target journal 	
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*The absence of an appropriate brief from client highlighting the author(s), key messages/positioning, and key references may increase the time & cost. A change in scope of the manuscript will also increase time & cost.

†Graphics time/cost is optional and not included in the total price.

8.3 Review Article

8.3.1 Review Article Submission Time Allotments

Project Stage*	Person
Outline	Writer
	Program Manager
	Editor
First Draft	Writer
	Program Director
	Program Manager
	Editor
Second Draft	Writer
	Program Director
	Editor
Final Version (for submission)	Writer
	Program Director
	Program Manager

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	Editor
	EA
	Graphics† (optional)
Overall	Writer
	Program Director
	Program Manager
	Editor
	EA
	Graphics† (optional)
TOTAL	

8.3.2 Review Article to Submission Stages

Project	Required Steps	No. of hours
Review Article (Writing – 4,000 words, up to 6 figures/tables, 1 lead and 2 coauthors)	<ol style="list-style-type: none"> 1. Complete ‘Statement of Work’ and validate with client 2. Develop project schedule and update as required 3. Manage budget and keep client updated as appropriate 4. Research suitable target journals and agree with client 5. Develop outline and submit to client for comments 6. Incorporate client comments into outline 7. Submit revised outline to authors for comments 8. Incorporate author comments into outline 9. Develop first draft manuscript in accordance with journal requirements and submit to client for comments 10. Incorporate client comments into first draft manuscript 11. Submit second draft manuscript to authors for comments 12. Incorporate author comments into manuscript 13. Submit third draft manuscript to client and authors for approval 14. Incorporate client and author approval comments 15. Redraw figures and carry out final editorial checks 16. Submit finalized manuscript to client for information 	Writer Program Director Program Manager Editor EA



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	17. Obtain declarations from named authors 18. • Prepare submission pack for lead author and facilitate submission to target journal	
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8.4 Abstract

8.4.1 Abstract* Time Allotments

Project Stage	Person
First Draft	Writer
	Program Director
Final Version (for submission)	Writer
	Program Director
	Editor
	Editorial Assistant
OVERALL	Writer
	Program Director
	Editor
	Editorial Assistant
TOTAL	

*Excludes costs regarding tables/figures (if applicable)

8.4.2 Abstract Stages

Project	Required Steps	No. of hours
Abstract (Writing – 250 –400 words)	1. Complete 'Statement of Work' and validate with client 2. Develop project schedule and update as required 3. Agree author(s) with client 4. Develop first draft of abstract and send to client for comments 5. Incorporate client comments into first draft abstract 6. Submit second draft abstract to authors for comments 7. Incorporate author comments into abstract 8. Submit third draft abstract to client and authors for approval 9. Incorporate client and author approval comments 10. Carry out final editorial checks 11. Submit finalized abstract to client and authors for information 12. • Submit abstract or provide all materials for author to submit to congress	Writer Program Director Editor EA

8.5 Poster

8.5.1 Poster* Time Allotments

Project Stage	Person

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First Draft	Writer
	Program Director
	Editor
Final Copy (for Layout)	Writer
	Program Director
	Editor
Layout (Design)	Graphics
	Program Director
	Editor
Overall	Writer
	Program Director
	Editor
	Graphics
TOTAL	

*Excludes printing and shipping costs

8.5.2 Poster* Stages

Project	Required Steps	No. of hours
Posters (Writing – up to 1,000 words and 4 figures/tables)	<ol style="list-style-type: none"> 1. Complete 'Statement of Work' and validate with client 2. Obtain poster details/requirements from presenter/congress 3. Develop project schedule and update as required 4. Develop poster based on approved abstract and data provided by client 5. Submit first draft manuscript to client for comments 6. Incorporate client comments into manuscript 7. Submit second draft manuscript to presenter for comments 8. Incorporate presenter comments into manuscript 9. Submit third draft manuscript to client and presenter for approval 10. Incorporate client and presenter approval comments 11. Lay-out poster to approved design 12. Redraw figures 13. Submit laid-out poster to client and presenter for comments/approval 14. Incorporate client and presenter comments into laid-out poster 15. Submit finalized poster to client and presenter for information 16. • Print poster and send to presenter 	Writer Editor Program Director Layout

8.6 Slide Kit from Source Material (20 slides plus notes)

8.6.1 Slide Kit from Source Material (20 slides plus notes) Time Allotments

Project Stage	Person
Outline	Writer

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	Program Director
First Draft	Writer
	Program Director
	Editor
	Editorial Assistant
Second Draft	Writer
Final Version (for production)	Writer
	Program Director
	Editor
	Graphics
OVERALL	Writer
	Program Director
	Editor
	Editorial Assistant
	Graphics
TOTAL	

8.6.2 Slide Kit from Source Material (20 slides plus notes) Stages

Project	Required Steps for 20 slides (with notes)	No. of hours
Slides for Oral Presentation (Writing, including speaker notes)	<ol style="list-style-type: none"> 1. Complete 'Statement of Work' and validate with client 2. Develop project schedule and update as required 3. Develop up to 20 slides on agreed slide template, and presenter notes 4. Submit to client for comments 5. Incorporate client comments 6. Submit to presenter for comments 7. Incorporate presenter comments 8. Submit to client and presenter for sign-off 9. Incorporate client and presenter sign-off comments 10. Submit final slides and presenter notes to presenter 	Writer Program Director Editor EA Graphics

8.7 Case Study* (to journal submission)

8.7.1 Case Study* (to journal submission) Time Allotments

Project Stage	Person
First Draft	Writer
	Program Director
Second Draft	Writer
	Editor
	Program Director
Final Version	Writer
	Program Director
	Editor
	EA



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OVERALL	Writer
	Program Director
	Editor
	EA
TOTAL	

*Case series will need more time and should be charged at a higher rate

8.7.2 Case Study* (to journal submission) Stages

Project	Required Steps	No. of hours
Case Study (Writing – 2,000 words, 1 figure/table, 1 author)	<ol style="list-style-type: none"> 1. Complete 'Statement of Work' and validate with client 2. Develop project schedule and update as required 3. Manage budget and keep client updated as appropriate 4. Research suitable target journals and agree with client 5. Develop outline and submit to client for comments 6. Incorporate client comments into outline 7. Submit revised outline to author for comments 8. Incorporate author comments into outline 9. Develop first draft manuscript in accordance with journal requirements and submit to client for comments 10. Incorporate client comments into first draft manuscript 11. Submit second draft manuscript to author for comments 12. Incorporate author comments into manuscript 13. Submit third draft manuscript to client and author for approval 14. Incorporate client and author approval comments 15. Redraw figures and carry out final editorial checks 16. Submit finalized manuscript to client for information 17. Obtain declarations from named author 18. Prepare submission pack for author and facilitate submission to target journal 	Writer Program Director Editor EA

8.8 Editorial or Letter to the Editor (to journal submission)

8.8.1 Editorial or Letter to the Editor (to journal submission) Time Allotments

Project Stage	Person
First Draft	Writer
	Program Director
	Editor
Final Version	Writer
	Program Director
	Editor
	EA
OVERALL	Writer
	Program Director
	Editor



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	EA
TOTAL	

8.8.2 Editorial or Letter to Editor (to journal submission) Stages

Project	Required Steps	No. of hours
Editorial or Letter to Editor (Writing – up to 1,500 words and 1 table, 1 author)	<ol style="list-style-type: none"> 1. Complete ‘Statement of Work’ and validate with client 2. Develop project schedule and update as required 3. Manage budget and keep client updated as appropriate 4. Research suitable target journals and agree with client 5. Develop outline and submit to client for comments 6. Incorporate client comments into outline 7. Submit revised outline to author for comments 8. Incorporate author comments into outline 9. Develop first draft manuscript in accordance with journal requirements and submit to client for comments 10. Incorporate client comments into first draft manuscript 11. Submit second draft manuscript to author for comments 12. Incorporate author comments into manuscript 13. Submit third draft manuscript to client and author for approval 14. Incorporate client and author approval comments 15. Redraw figures and carry out final editorial checks 16. Submit finalized manuscript to client for information 17. Obtain declarations from named author 18. Prepare submission pack for author and facilitate submission to target journal 	Writer Program Director Editor EA

8.9. White Paper (25-30 pages, excluding references)

8.9.1 White Paper (25-30 pages, excluding references) Time Allotments

Project Stage	Person
Outline	Writer
	Program Director
First Draft	Writer
	Editor
	Program Director
	Editorial Assistant
Second Draft	Writer
Final Copy	Writer
	Editor
OVERALL	Writer
	Program Director
	Editor
	Editorial Assistant
TOTAL	



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*The absence of (1) an appropriate client brief or (2) experience with therapeutic area will likely increase the time & cost.

†Excludes extraneous production costs (eg, graphics, layout, printing to quality paper, shipping)

9.0 Publications Procedures Checklists

9.1 Manuscript Procedures Checklist (per Draft)

Project name and number: _____ DRAFT: _____	
Total allocated hours for this draft/total for project:	
MW: ___/___ E: ___/___ PM: ___/___	
Due date for this draft _____	
Approved outline dated _____ used	
MW/E/PM Most recent project specifications reviewed?	
PM/MW/E Target journal's Author Guidelines for Submission reviewed?	
Date/ Initial	Task Assignment
	MW Provide list of reference materials needed to PM
	PM Approve the list
	PM Authorize designated AD/EA to order outstanding references
	AD/EA Order references per approved list from PM
	E/MW After references are ordered by EA/AD , provide list of permissions needed, including cost if known, to PM
	MW Provide highlighted references in project folder
	• Hard copy
	• Acrobat version (references have been sent to PM)
	MW Send PDFs to designated AD or Editorial Assistant (EA) for filing in Master PDF library (References A-Z) and for entry into Client EndNote library
	MW Maintain PDF references in project folder
	MW Write, create, and revise manuscript, figures, and tables, incorporating client and editorial comments as received
	AD/EA Assemble reference binder (in alphabetical order until reference list is finalized (at Draft 3) as references become available (ongoing task)
	AD/EA Notify PM and MW of any references that are difficult to obtain. Once all references are in house, notify PM , MW , and E so that validation and citation check can proceed
	MW/ED Upon validation, sign off on data validation on Routing Form
	E/EA Verify all citation information per original references
	MW/E/EA Validate all data cited in manuscript before submission to client at each stage (ie, Draft 1, 2, & Final)
	MW Prepare project-specific EndNote library for manuscript
	MW Save EndNote library in project-specific folder
	MW Provide information to PM if:

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	<ul style="list-style-type: none"> • Figures need to be outsourced for creation • Permissions are needed
	MW Provide list of requested permissions to ED/AD for ordering, including date needed by
	EA/AD Provide list of needed permissions to PM , including any fees <ul style="list-style-type: none"> • All permissions requested? _____ obtained? _____ • Fees for permission to use figures/tables? \$ _____
	AD/EA Request permissions per PM -approved list and notify PM of cost and when permission to use material is received
	MW Provide appropriate titles and legends for tables and figures, including “Adapted from” or “Used with permission from” statements, if needed
	MW/PM Incorporate author comments. Please list authors: _____
	MW/PM Incorporate client comments. Please list clients if more than 1: _____
	MW/PM Save new draft file in project folder with draft number and date in file name (eg, AQUAVAN PtSatisfactionAbstract Draft 2.06.07.06)
	AD/EA Merge project-specific EndNote library with client-specific EndNote library and search for and delete duplicate
	MW/PM Add the following statements, if needed: <ul style="list-style-type: none"> • Conflict of interest/disclosure statements • Grant support statement • Acknowledgments
	MW Format bibliography/in-text reference citations <ul style="list-style-type: none"> • Per AMA style at Draft 1 and Draft 2 • Per target journal style at Draft 3/Final
	Total actual hours spent on this draft: MW: _____ ED: _____ E: _____ AD/EA: _____ PM: _____
Comments: Please add below, with your initials and the date.	

9.2 Checklist for Syllabi

Front cover:	
	Title
	Date, time, location
	“Sponsored by” statement [and logo(s)]: This publication is [jointly sponsored] by [X] and [X] and made possible through an [unrestricted] educational grant from [X].

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	Commercial support acknowledgment and company logo(s)
	Release date and expiration date
Inside:	
	Statement of Need/Program Overview
	Target Audience
	Educational/Learning Objectives
	All applicable Accreditation Statements (ACCME, ANCC, ACPE, etc)
	Credit Designation statement
	Disclosure of Conflicts of Interest statements
	<ul style="list-style-type: none"> • CME Provider statement • Faculty statements • Sponsor-reported Financial Relationships statement
	Disclosure of Unlabeled Use statement
	Method of Participation/Estimated Time to Completion
	List of faculty with academic titles/affiliations
	Faculty Conflict of Interest Disclosure statements
	Provider Disclosure statements
	Commercial support acknowledgment and company logo(s)
	Statement of fees: There is no fee for this activity.
	If activity carried ACPE credit: Description of the requirements for successful completion and subsequent awarding of credit (eg, participation and completion of the evaluation and registration forms) and statement indicating when certificates of completion will be distributed to the participants
	Disclaimer statement (“The opinions expressed...”)
	Copyright statement
	Permission statement re use of copyrighted materials
	Faculty presentations
	<ul style="list-style-type: none"> • Biographies • Presentation Abstract • Presentation text and/or slides • References
	Post-test Evaluation and Request for Credit form
Back cover:	
	Commercial support/sponsorship acknowledgment and all relevant logos

9.3 Checklist for Slide Kits (a.k.a. Faculty Resource Binders)

Front cover:	
	Artwork
	Title of activity/faculty resource
	“Provided as an educational service of ...” statement and logo
	Release date



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Contents:	
	Program overview
	Learning objectives
	List of faculty advisors with academic titles/affiliations
	Faculty biographies
	Faculty disclosure statements
	Introductory letter (from either Advisory Board / Ascendant or Omni)
	Computer requirements
	Hard copy of slides, with commentary
	Tabs
	Glossary or resource section, if applicable
CD-ROM Imprint:	
	Artwork
	Title of activity/faculty resource
	Release date
Contents of CD-ROM:	
	Title
	“Provided as an educational service of ...” statement and logo
	Commercial support acknowledgment and company logo
	Slides with commentary (read-only)
Slide imprint options:	
	Title of activity
	Plain
	Numbered
Back cover:	
	Commercial support acknowledgment and company logo
Binder spine:	
	Title of activity

9.4 Checklist for Print based Enduring Materials (eg, monographs, Journal, Supplements, Newsletters, Reprint Carriers)

Cover:	
	Activity title



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	“Sponsored by” statement and logos: This publication is jointly sponsored by [X] and [X] and made possible through an [unrestricted] educational grant from [client]
	Revision date, if applicable
	Release date and expiration date
Inside:	
	List of faculty with academic titles/affiliations
	Table of Contents
	Inside front text, in the following order:
	<ul style="list-style-type: none"> • Continuing Education Accreditation Statements • Commercial Support statement • Program Administrator info
	Financial Disclosure and Conflicts of Interest (provider, then faculty)
	Commercial support acknowledgment and company logos
	<ul style="list-style-type: none"> • Disclosure of Off-label Uses • Disclaimer statement • Statement of Need • Target Audience • Educational/Learning Objectives
	Post-test/Evaluation form
	Activity text, in the following order:
	<ul style="list-style-type: none"> • Introduction • Faculty bios and presentations, respectively • References, respectively OR all together at end of presentation text • Post-test Evaluation and Request for Credit form (include expiration date)
	All applicable accreditation and designation statements (ACCME, ANCC, ACPE, etc)
	General disclosure and copyright statements