Totality Closeout Documentation Checklist

Pharmaceutical Group

Update October 2024

Totality

IMPORTANT NOTE

- Direction provided in the [HCC Policy manual](#) supercedes information provided in this document. Any examples provided are intended as best practice and not to be considered as direct interpretation of policy.

Totality

How to Use This Document / Contents

- Click on the transaction type at right to view the associated Totality Closeout documentation

  - *To return to this page, click on the HOME icon:* 🏠

- Upload all documentation within Totality prior to attestation and closeout

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* Updated section:
"Applicable to All Totality Transactions" *

Totality

Business Expense (Field/Home Office)

Applicable to all Totality Transactions

- System Required Documentation, including business rationale, objectives, deliverables, FMV, etc. *(located within the Totality transaction marked with a red asterisk)*
- Dated Screen Shots of OIG, EPLS, US State License Verification (if applicable) uploaded in Totality; date that FDA Debarment check was completed
- Advisor rationale for selection and Resume/CV or Credentials to support ability to perform the needed services
- Fully executed HCP Contracts; include Government employee release form *(if interacting/consulting with a government employee)*
- Proof of Payment(s) made, e.g., invoices, preferably in local currency
- IF APPLICABLE: Cross Border Documentation, Confirmation of active Third Party Intermediary (TPI) Due Diligence for vendor/TPI

Business Expense (Field/Home Office)

- Letter of Request (LOR)
- Completed Sponsorship Request Form (as required)
- Program Agenda, where applicable (or if available at the time of review), (including date, location, schedule, speaker information, time allotted per topic, other activities planned, e.g., dinner).
- Documentation of Manager approval
- Event prospectus (if applicable) outlining the different levels of sponsorship and benefits associated with each level; if benefits captured in the LOR, they should match what is captured in the prospectus.
- In case any benefits received in exchange for sponsorship funding involved the presentation of content to an external audience, confirmation that this content was reviewed and approved per the applicable process.
- For Commercial Sponsorships and Memberships, attestation from Project Owner that the services/activity occurred, and that Company used all benefits it paid for. If any benefits were not used, this should be captured in the attestation. This attestation can be in the form of an email or word document if to be uploaded by someone other than the Project Owner, or direct text entry into the platform by the Project Owner.
- Signed Sponsorship Agreement specifying the payment amount, what the Company will receive for its commercial Sponsorship, any materials for which the Company will provide input, and any rights or obligations of each party.
  - Completed/executed contract (dated and signed by authorized representatives of all parties before services begin).
  - Include "ICD number" if provided – the original contract maintained in the contract database

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General Consulting/Marketing and Advertising/Promotion

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General Consulting

System Required Documentation:
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Final Report
- Discussion Guide
- Meeting Minutes
- Itemized Invoice

Marketing and Advertising/Promotion

System Required Documentation:
- Project Deliverable/Proof of Service
- Promotional/Content Review

Examples of Proof of Service Documents:
- Approved Materials
- Itemized Invoice

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Advisory Board

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Advisory Board / Steering Committee

- **Agenda** including time and presenter/facilitator(s) allotted to each topic; **Format** (in-person, virtual, hybrid); if in-person, confirmation of appropriate **venue/location**
- **Final Approved Materials**, presentations, pre-reads, etc., as well as documentation of review and approval of all materials
- Final Approved Steering Committee Charter, if applicable
- Completed **Employee Attendee Justification** Form
- **Proof of Service Documentation** or additional documentation to provide proof of service.   This could be meeting minutes, a final summary report, etc.
- **Rationale for selection of each advisor** must be captured
- **Participants**: confirmation of active participation from each advisor could include listing each advisor full name in the meeting minutes, In-person (sign-in sheet), Virtual (downloaded participant list)
- Documentation of **CBI Tool requirements** met for country of each participant
- **FMV rate cards** for all advisors, each specialty, country
- **Execution Summary:** Documentation of how meeting deliverables/information was/will be used by the company. This may be a summary statement, excerpt from business plan, strategy or tactic.
- **Transfer Of Value (TOV) Details** (include invoices, all payments, travel/hospitality reimbursement, etc.) - upload/attach according to HCC Review System and timeline requirements

Promotional Speaker Programs/Speaker Training

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Promotional Speaker Programs

System Required Documentation:
- Approved Materials
- Promotional/Content Review
- Sign-In Sheet
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Sign-In Sheet

Speaker Training

System Required Documentation:
- Approved Materials
- Sign-In Sheet
- Promotional/Content Review
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Sign-In Sheet
- Educational/Training Materials

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Symposium/Educational Materials/Market Research (Un-blinded)

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Symposium

System Required Documentation:

- Agenda
- Approved Materials
- Publication or Record Location(if applicable)
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Sign-In Sheet
- Approved Presentation Deck

Education Materials

System Required Documentation:

- Promotional/Content Review
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Survey Results
- Final Report
- Publication/Materials Developed
- Story Boards/Video Location

Market Research (Un-blinded)

System Required Documentation:

- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Final Report
- Publication or Record Location
- Itemized Invoice

Please note that double blinded market research does not need to be captured in Totality. as a Full Transaction

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Investigator Meeting/Company Sponsored Research/Research Related Activities

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Investigator Meeting

System Required Documentation:
- Agenda
- Sign-in Sheet
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Sign-In Sheet
- Approved Presentation Deck

Company Sponsored Research

System Required Documentation:
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Itemized Invoice

Research Related Activities

System Required Documentation:
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:

- Final Report
- Approved Presentation Deck

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Preceptorships/Publications/Investigator Initiated Studies

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Preceptorships

System Required Documentation:
- Agenda
- Project Deliverable/Proof of Service

Examples of Proof of Service Documents:
- Itemized Invoice

Publications

System Required Documentation:
- Project Deliverable/Proof of Service
- Promotional Content Review (is applicable)
- Publication or Record Location

Examples of Proof of Service Documents:
- Final Publication/Manuscript
- Record Location
- Poster or other Materials

Investigator Initiated Studies (IIS)

System Required Documentation:
- Project Deliverable/Proof of Service
- Publication or Record Location
- Letter of Request
- Budget

Examples of Proof of Service Documents:
- Final Budget
- Manuscript
- Itemized Invoice

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Totality Resources