

KUALI COEUS GRANTS QUICK START GUIDE

Submitting a Proposal Development document for a Commercial Clinical Trial

A Proposal Development document will route to the Office of Clinical Research if the Sponsor or Prime Sponsor is Commercial AND no federal money or money from another institution is involved. In order to ensure the document routes correctly, please ensure that:

- The accurate sponsor is entered
- The accurate Prime Sponsor is entered, when applicable
- The Clinical Trials? checkbox is selected

A Validation Warning message may generate before the Proposal Development document is submitted into routing if these criteria are not met. The message will state, "The Clinical Trials checkbox is selected but the Prime Sponsor has not been entered. Please enter a Prime Sponsor if applicable." If this message generates, please review the Proposal Development document and update as needed.

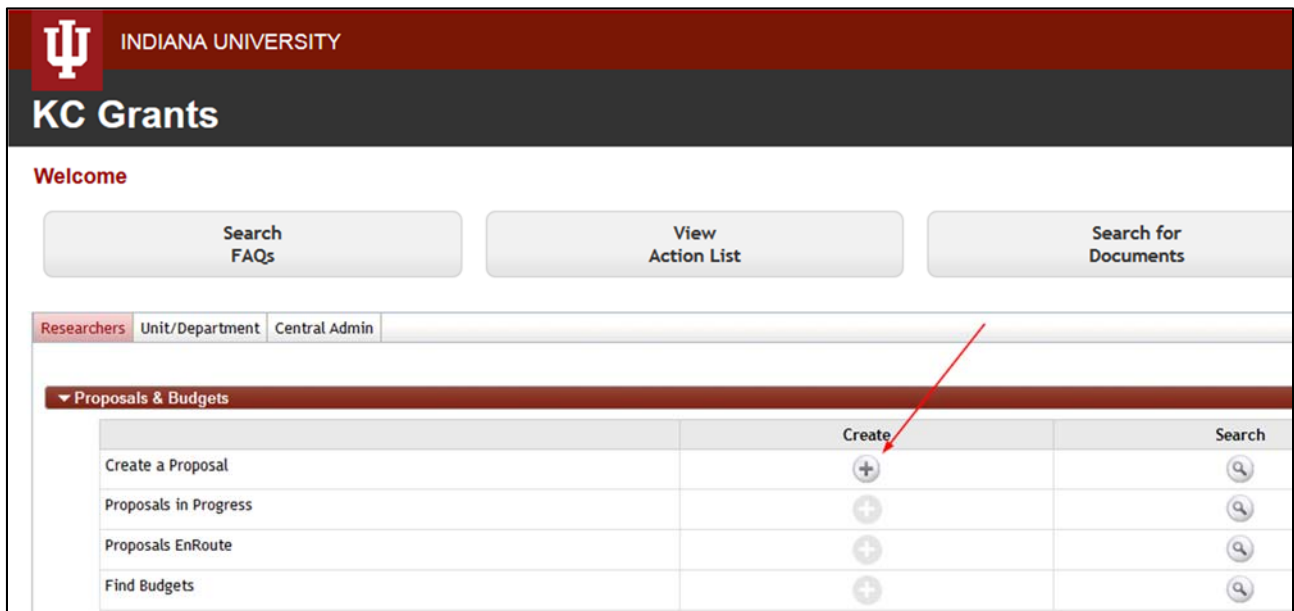
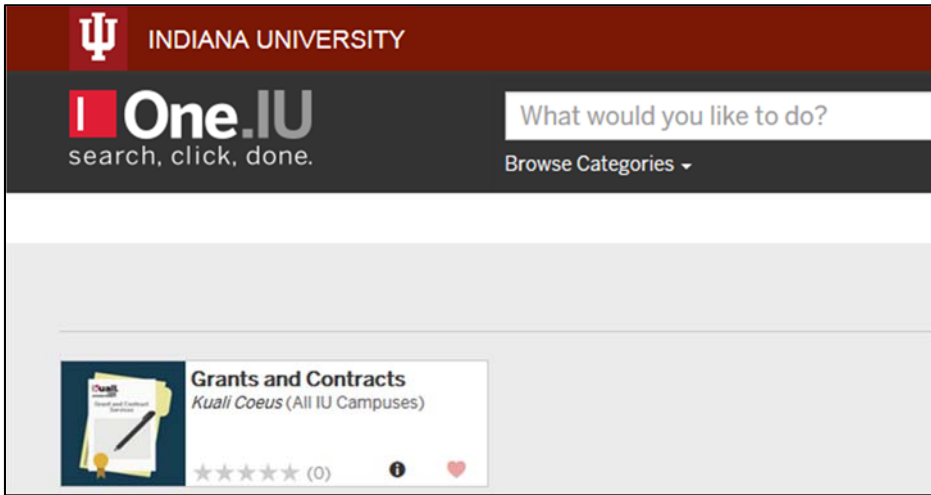
For specific questions regarding a Commercial Clinical Trial, please contact the Office of Clinical Research contracts team:

Phone: (317)278-2546

Email: ocr@iu.edu

STEP 1: Create a new Kuali Coeus (KC) Proposal Development document to route a Clinical Trial Agreement (CTA)

- Open Grants and Contracts Kuali Coeus from One.IU.edu
- Click plus sign icon to Create a Proposal



STEP 2: Complete Required Fields for Save

- Enter Description
 - Enter 'CTC' and a brief description of the proposal
 - Example: CTC, New XYZ Pharmaceutical Contract
 - **Select Proposal Type** - **Select New** for CTA/Subcontract
 - If routing an amendment for PI change then select the Proposal Type of Revision.
 - If routing an amendment for budget increase then select Supplement.
 - If both PI change *and* budget increase, select Supplement.
 - Enter Lead Unit
 - Format (all caps) = Campus-Unit
 - Example: IN-HEMO
 - NOTE: This field becomes uneditable after initial Save
 - Select Activity Type of Service/Other
 - This is the required Activity Type for all commercially funded CTA's
 - Enter Project Title
 - Lookup or Enter Sponsor Code
 - Enter Project Start Date
 - Enter Project End Date
 - If Proposal Type = Revision then **MUST** select a Revision Type
 - Select Supplement if the amendment includes additional funds
 - Select Other for all other amendments
 - Click Clinical Trial? Checkbox
 - Enter Sponsor Deadline Date
 - Select Sponsor Deadline Type
 - Enter Prime Sponsor ID if the funding source differs from main sponsor
 - Ensure Prime Sponsor (i.e. pass through source) is entered when applicable or the Proposal Development document may not route correctly to the Clinical Trials Contracting office
 - Click Save
- NOTE: The Proposal Development Document Number (Doc Nbr) at the top right of the screen is the main identification number used for the routing proposal

Proposal Development Document

Doc Nbr: 47553902 Status: In Progress
Initiator: loatar Created: 09:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L.

Proposal 525 Key Personnel Special Review Custom Data Abstracts and Attachments Questions Budget Versions Permissions Proposal Actions Medusa

Document was successfully saved.

Document Overview

Description: CTC, New GOG Corp/Immunogen Contract

Organization Document Number:

Explanation:

Required Fields for Saving Document

Proposal Number: 87201

Proposal Type: New

Lead Unit: IN-HEMO - HEMATOLOGY/ONCOLOGY

Activity Type: Service/Other

Project Title: Technical or Scientific Official Project Title

Sponsor Code: 054512
GOG CORPORATION

Project Start Date: 07/01/2016

Project End Date: 06/30/2019

Institutional Fields Conditionally Required

Award ID:

Original Institutional Proposal ID:

Revision Type: select

Clinical Trial?:

Sponsor & Program Information

Sponsor Deadline Date: 03/31/2016

Sponsor Deadline Type: Target

Sponsor Name: GOG CORPORATION

Prime Sponsor ID: 061706
IMMUNODER, INC.

NSF Science Code: select

Sponsor Proposal ID: GOG ID#

Notice of Opportunity: select

CFDA Number:

Opportunity ID:

Sponsor Proposal ID: GOG ID#

Does this proposal include subaward(s)?

STEP 3: Enter additional optional fields if applicable

- Enter Sponsor Proposal ID if there is a sponsor identification number tied to the contract
- Enter any applicable delivery/ mailing/ submission information in the Delivery Info panel
 - A Sponsor contact may be entered in the Mailing Name & Address by adding the contact to the rolodex OR the information may be manually entered in the Mail Description box
- Enter any other fields as needed

The screenshot displays the 'Proposal Development Document' interface. At the top right, document details are shown: Doc Nbr: 4798992, Status: In Progress, Initiator: loader, Created: 08:21 AM 03/21/2016, Sponsor/S2S: GOG CORPORATION/None, and PI: Carter, Tracey L. A navigation bar includes tabs for Proposal, S2S, Key Personnel, Special Review, Custom Data, Abstracts and Attachments, Questions, Budget Versions, Permissions, Proposal Actions, and Medusa. A message states 'Document was successfully saved.' The form is divided into several sections: 'Document Overview', 'Required Fields for Saving Document', 'Sponsor & Program Information', 'Organization/Location', and 'Delivery Info'. The 'Sponsor & Program Information' section contains fields for Sponsor Deadline Date (03/31/2016), Sponsor Deadline Type (Target), Sponsor Name (GOG CORPORATION), Prime Sponsor ID (061706), NSF Science Code, Sponsor Div Code, Anticipated Award Type, Agency Routing Identifier, Opportunity Title, Program Guidelines URL, Sponsor Deadline Time, Notice of Opportunity, CFDA Number, Opportunity ID, Sponsor Proposal ID (GOG ID#), Does this proposal include subaward(s)?, Sponsor Program Code, and Prev Grants.Gov Tracking ID. The 'Delivery Info' section includes Mail By, Mail Account ID, Mailing Name & Address, Type, Number of Copies, and Mail Description. A red box highlights the 'Mail Description' field, and a red arrow points to the 'Mailing Name & Address' field.

STEP 4: Enter Key Personnel

- Click Key Personnel tab
- Click Employee Search icon
 - Enter Last Name, First Name or User Name and click Search button
 - Click Return Value for appropriate search result
 - Select Proposal Role
 - Click Add Person button
- Repeat steps for all Key Personnel on the project

NOTE: One Principal Investigator is required on all Proposal Development documents

NOTE: Do NOT answer the Certification Questions unless you are listed as a Principal Investigator or Co-Principal Investigator; these questions should be completed when the Proposal Development document routes

- Enter Combined Credit Split information
- Click the Default Distribution button if 100% credit will be distributed to the prime Principal Investigator and Lead Unit and the calculations will automatically populate

The screenshot displays the 'Proposal Development Document' interface. The 'Key Personnel' tab is active, showing a search area with 'Employee Search' and 'Non-employee Search' options, and a 'Proposal Role' dropdown menu. Below this is a table for 'Combined Credit Split' with columns for 'Intellectual' and 'F&A Revenue'. The table lists 'Carter, Tracey L.' as the Principal Investigator with 100.00 credit split. A 'default distribution' button is highlighted at the bottom of the table.

	Intellectual	F&A Revenue
Carter, Tracey L.	100.00	100.00
IN-HEMO - HEMATOLOGY/ONCOLOGY	100.00	100.00
UA-RSCH - RESEARCH ADMINISTRATION	0.00	0.00
Unit Total:	100.00	100.00
Totals		
Investigator Total:	100.00	100.00

STEP 5: Enter Special Review

- Click Special Review tab
- Select Type of Human Subjects
- Search or Enter IU Protocol ID if applicable OR
- Select Approval Status of Not Yet Applied if IU Protocol ID has not yet been created
- Enter Comments if applicable
- Click Add button
- Repeat steps for all Protocols on the project

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
Initiator: loader Created: 08:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel **Special Review** Custom Data Abstracts and Attachments Questions Budget Versions Permissions Proposal Actions Medusa

Special Review

	* Type	* Approval Status	IU Protocol ID	Application Date	Approval Date	Expiration Date	Exemption #	Actions
Add:	select	select					E1 E2 E3	add
	Human Subjects	Not yet applied						delete

Comments:

save reload close

STEP 6: Enter Custom Data information

- Click Custom Data tab
- Enter Account ID(s) if Account Number(s) exists in KFS
- Select Grant Services Team of CTO

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
Initiator: loader Created: 08:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review **Custom Data** Abstracts and Attachments Questions Budget Versions Permissions Proposal Actions Medusa

Document was successfully saved.

Additional Project Data

Additional Project Data

Full Group Name: Additional Project Data

Date Assigned (Format MM/DD/YYYY):
Negotiation ID:
Record Resides With: select
Grant Services Team: CTO
Grant Services Administrator: select
APPS: Yes No
Proposal Contract Officer: select
CO Review Complete (Format MM/DD/YYYY):
Internal VPR Administrative Deadline Missed: Yes No
Internal VPR Technical Deadline Missed: Yes No
ADR: select
Account ID(s): 4500011
Limited Submission Number:
Subject to Alternative Minimum Wage (EO 13658): Yes No

save reload close

Step 7: Attach Contract, Budget or other applicable documentation AND Add Notes

- Click Abstracts and Attachments tab
- Show Internal Attachments panel
- Select Attachment Type of Clinical Trial Contract/Budget
- Enter Description
- Browse and Attach file
- Click Add button
- Repeat steps for Clinical Trial Protocol if applicable
- Add any additional attachments necessary
- Show Notes panel if any internal notes should be added to Proposal Development document
- Enter Note Topic
- Enter Note
 - If anyone from the department would like to be included in the correspondence with the Sponsor, the following Note should be added:
 - Enter Note Topic of, "Contact Person"
 - Enter Note Text of, "Please include {insert name and email} on all correspondence with the sponsor."



Please attach the following documents as available:

- Agreement (CTA/Amend in Word Version)
- Sponsor Budget (Draft is OK)
- Clinical Trial Protocol
- Informed Consent Document (Draft is OK)
- Internal Budget (Draft/Estimate)

Proposal Development Document			Doc Nbr: 47583902	Status: In Progress
			Initiator: tcarter	Created: 08:21 AM 03/21/2016
			Sponsor/S2S: GOG CORPORATION/None	PI: Carter, Tracey L

Proposal | S2S | Key Personnel | Special Review | Custom Data | **Abstracts and Attachments** | Questions | Budget Versions | Permissions | Proposal Actions | Medusa

[expand all](#) | [collapse all](#)

Proposal Attachments (0) [show](#)

Personnel Attachments (0) [show](#)

Internal Attachments (1) [hide](#)

Add Internal Attachments						
Posted Timestamp	Uploaded By	* Attachment Type	Description	File Name	Actions	
add:		select:		Browse... No file selected.	add	
1: 03/21/2016 01:13 PM	Carter, Tracey L	Clinical Trial Contract/Budget	Draft Contract	Aa_TEST.pdf	view replace delete view/edit rights	

[download all](#)

Abstracts (0) [show](#)

Notes (2) [hide](#)

Notes xx					
Posted Timestamp	Author	* Note Topic	* Note Text	Actions	
add:				add	
1	Carter, Tracey L	Important Note	This is an important note for the CTC office.		
2	Carter, Tracey L	Contact Person	Please include Joe Smith (jsmith12345@iu.edu) on all correspondence with the sponsor.		

[save](#) | [reload](#) | [close](#)

Step 8: Complete Questions

NOTE: The Proposal Development document cannot route until all questions are complete

- Click Questions tab
- Show Proposal Questions panel
- Answer every question that displays

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
 Initiator: tcarter Created: 08:21 AM 03/21/2016
 Sponsor/SZS: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments **Questions** Budget Versions Permissions Proposal Actions Medusa

Document was successfully saved.

Proposal Questions (Complete)

Questions

Does this application reflect a change in grantee institution from that indicated on a previous application? Yes No

Does the proposed project involve human embryonic stem cells? Yes No

Is proprietary/privileged information included in the application? Yes No

Check "No" if no inventions were conceived or reduced to practice during the course of work under this project. Check "Yes" if any inventions were conceived or reduced to practice during the previous period of support. Yes No

Will new space or remodeling be required for this project? Yes No

Are other IU campuses, schools, or units involved? If Yes, add unit(s) to Other IU Unit(s) subpanel in the Organization/Location panel of the Proposal tab. You do not need to add additional units for a Co-PI or PI/Multiple. Additional units are required for Key Personnel who are not in the lead unit. Yes No

Does this project have an international connection: that is, collaboration with internationally-based colleagues or institutions; significant activity outside the United States; or pertain topically to countries, regions or populations outside the United States? (Used by the International Affairs Office.) Yes No

Are human or non-human primate anatomical substances used (includes tissues, cells, and fluids)? Yes No

Buttons: save, reload, close

Step 9: Enter Budget (contact the Office of Clinical Research (ocr@iu.edu) with any questions regarding budget calculations, rates, etc.)

- Click Budget Versions tab
- Enter Name
- Click Add
- Click Open

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
 Initiator: tcarter Created: 09:21 AM 03/21/2016
 Sponsor/SZS: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments Questions **Budget Versions** Permissions Proposal Actions Medusa

Budget Versions (07/01/2016 - 06/30/2019)

Name	Version #	Direct Cost	F & A	Total	Budget Status	Final	Actions
GOG Budget	1	0.00	0.00	0.00	select	<input type="checkbox"/>	open, copy
Residual Funds:							
Cost Sharing: 0.00							
Unrecovered F&A: 0.00							
Comments:							

Buttons: save, reload, close

- Update Period 1 End Date to Project End Date
- Delete any Periods beyond Period 1
- Enter Direct Cost and IRB/OCR fees in Direct Cost field
- Enter Indirect Cost in F&A Cost field
 - F&A Cost = 36% of total, excluding any IRB/OCR fees
- Click Save

- A message will populate stating, “Changing the budget period dates will result in changes being made to line item expenses and recalculation of the budget. Do you want to proceed?”
- Click Yes

Budget Document Doc Nbr: 47583902 Status: SAVED
Initiator: tcarter Created: 08:21 AM 03/21/2016
Budget Name: GOG Budget Version #: 1

Budget Versions Parameters Rates Summary Personnel Non-Personnel Distribution & Income Modular Budget Budget Actions

[return to proposal](#)
* required field

Budget Overview

Project Start Date: 07/01/2016
Project End Date: 06/30/2019
Total Direct Cost Limit: 0.00
Budget Status: Incomplete
Final?
On/Off Campus: Default

Modular Budget?
Residual Funds:
Total Cost Limit: 0.00
Uncovered F & A Rate Type: MTDC
F&A Rate Type: MTDC
Submit Cost Sharing?

Comments:

Budget Periods & Totals

Budget Periods	Period Start Date	Period End Date	No. of Months	Total Sponsor Cost	Direct Cost	F&A Cost	Uncovered F&A	Cost Sharing	Cost Limit	Direct Cost Limit	Actions
Add:	<input type="text"/>	<input type="text"/>		0.00	0.00	0.00	0.00	0.00	0.00	0.00	<input type="button" value="add"/>
1	07/01/2016	06/30/2019	12.0	0.00	100000	80000	0.00	0.00	0.00	0.00	<input type="button" value="delete"/>
2	07/01/2017	06/30/2018	12.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	<input type="button" value="delete"/>
3	07/01/2018	06/30/2019	12.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	<input type="button" value="delete"/>
Totals	07/01/2016	06/30/2019	36.0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	<input type="button" value="recalculate"/>

generate all periods calculate all periods default periods save reload close

- Click Final? checkbox
- Select Budget Status of Complete
- Click blue Return to Proposal button

Budget Document Doc Nbr: 47583902 Status: SAVED
Initiator: tcarter Created: 08:21 AM 03/21/2016
Budget Name: GOG Budget Version #: 1

Budget Versions Parameters Rates Summary Personnel Non-Personnel Distribution & Income Modular Budget Budget Actions

• Document was successfully saved.

[return to proposal](#)
* required field

Budget Overview

Project Start Date: 07/01/2016
Project End Date: 06/30/2019
Total Direct Cost Limit: 0.00
Budget Status: Complete
Final?
On/Off Campus: Default

Modular Budget?
Residual Funds:
Total Cost Limit: 0.00
Uncovered F & A Rate Type: MTDC
F&A Rate Type: MTDC
Submit Cost Sharing?

Comments:

Budget Periods & Totals

Budget Periods	Period Start Date	Period End Date	No. of Months	Total Sponsor Cost	Direct Cost	F&A Cost	Uncovered F&A	Cost Sharing	Cost Limit	Direct Cost Limit	Actions
Add:	<input type="text"/>	<input type="text"/>		0.00	0.00	0.00	0.00	0.00	0.00	0.00	<input type="button" value="add"/>
1	07/01/2016	06/30/2019	36.0	180,000.00	100,000.00	80,000.00	0.00	0.00	0.00	0.00	<input type="button" value="delete"/>
Totals	07/01/2016	06/30/2019	36.0	180,000.00	100,000.00	80,000.00	0.00	0.00	0.00	0.00	<input type="button" value="recalculate"/>

generate all periods calculate all periods default periods save reload close

Step 10: Submit Proposal Development document

- Click Proposal Actions tab
- Show Data Validation panel
- Click Turn on Validation button
 - If any Errors generate, click Fix button and fix all issues
 - If any Warnings generate, click Fix button, review all issues and fix appropriate issues

NOTE: Errors must be corrected prior to submission; Warnings should all be reviewed but are not required to be fixed

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
Initiator: toa:ter Created: 08:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments Questions Budget Versions Permissions **Proposal Actions** Medusa

Document was successfully saved.

Data Validation

You can activate a Validation check to determine any errors or incomplete information. The following Validations types will be determined:

- errors that prevent submission into routing
- warnings that serve as alerts to possible data issues but will not prevent submission into routing
- errors that prevent submission to grants.gov

turn off validation

Validation Errors

Sponsor & Program Information (1)

- Sponsor deadline date has not been entered.

Fix

Warnings

No Warnings present.

Grants.Gov Errors

No Grants.Gov Errors present.

Unit Business Rules Errors

No Unit Business Rules Errors present.

Unit Business Rules Warnings

No Unit Business Rules Warnings present.

- Click Submit button

Proposal Development Document

Doc Nbr: 47583902 Status: In Progress
Initiator: toa:ter Created: 08:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments Questions Budget Versions Permissions **Proposal Actions** Medusa

Document was successfully saved.

Data Validation show

Proposal Hierarchy show

Print show

Copy to New Document show

Route Log show

Notifications show

Ad Hoc Recipients show

Super User Action show

submit save reload close cancel

Proposal Development document has now been submitted into routing. To view route log, show Route Log panel. The Actions Taken and Pending Action Requests will display. Show Future Action Requests panel to view future route chain. This document will route to the Office of Clinical Research for final approval.

Proposal Development Document Doc Nbr: 47583902 Status: In Progress
Initiator: lcarter Created: 08:21 AM 03/21/2016
Sponsor/S2S: GOG CORPORATION/None PI: Carter, Tracey L

Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments Questions Budget Versions Permissions **Proposal Actions** Medusa

Document was successfully saved. expand all collapse all
* required field

Data Validation show

Proposal Hierarchy show

Print show

Copy to New Document show

Route Log hide

⚠ This is a non-production environment (Staging)

Route Log refresh

ID: 47583902 hide

Title		Proposal Development Document - CTC, New GOG Corp/Immunogen Contract; Proposal No: 87201; Due Date: 2016-03-31; PI: Carter, Tracey L; Sponsor: GOG CORPORATION	
Type	Proposal Development Document	Created	08:21 AM 03/21/2016
Initiator	Carter, Tracey L	Last Modified	03:36 PM 03/21/2016
Route Status	SAVED	Last Approved	
Node(s)	Initiated	Finalized	

Actions Taken hide

Action	Taken By	For Delegator	Time/Date	Annotation
SAVED	Carter, Tracey L		09:54 AM 03/21/2016	

Pending Action Requests hide

Action	Requested Of	Time/Date	Annotation
IN ACTION LIST COMPLETE	Carter, Tracey L	09:54 AM 03/21/2016	

Future Action Requests show