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# SWOG Financial Agreements: What You Need To Know

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## 1. What types of financial agreements does SWOG utilize for site payments?

SWOG uses two primary types of financial agreements when processing site payments – Purchase Service Agreements (PSA's) and fixed-price agreements. Each site will have two PSA's – one with the Group Chairs Office and one with SWOG-CTP. Additionally, each site will also need to establish a fixed-price agreement for both NCTN and NCORP studies. More information about each type of agreement is below:

- **Fixed-Price Agreements:** the NCI now mandates that SWOG (and the other cooperative groups) utilize fixed-price agreements for *federal* study activity. These are not just vendor agreements; instead, they are established subawards that last the duration of the respective grant cycle and allow for payments to be made to the site for specific federal study activity. There are two separate fixed-price agreements that a site must execute:
  - **NCTN Fixed-Price Agreement:** covers federal funding listed on NCTN studies
  - **NCORP Fixed-Price Agreement:** covers federal funding listed on NCORP studies
- **Purchase Service Agreements:** in addition to the fixed-price agreements, sites must also establish a PSA between the participating site/institution and SWOG. As mentioned above, because SWOG deals with both federal and non-federal study payments, there are actually two separate PSA's that a site must complete:
  - **SWOG-CTP (The Hope Foundation):** covers non-federal payments
  - **SWOG GCO (OHSU):** covers federal payments not covered under SWOG's main NCTN and NCORP grants (payments such as PCORI, RO1, etc.)

Unlike more traditional subawards, there is no invoicing required or payment schedule; instead, payments are triggered via federal study activity that is listed on a given funding memo (funding memos also clearly state whether a study is NCTN or NCORP). Because fixed-price agreements are only required for federal funding, site's must only complete one set of agreements (NCTN and NCORP) with SWOG GCO (meaning they are not required for non-federal funding via SWOG-CTP).

## 2. Who should I contact to execute these various agreements for my site?

The primary contact for federal and non-federal funding on SWOG studies is listed on each of the study funding memos (and also listed below). When your site is ready to establish these required agreements, please reach out to the appropriate contact and they will work with you to get all of the necessary information completed and the agreement executed. Please be sure to include a copy of your site's W-9 when reaching out to both SWOG GCO and SWOG-CTP.

### Federal Funding Questions Contact:

TBD

Grants & Contracts Coordinator

Oregon Health & Science University (SWOG GCO)

Phone: (503) 494-5514

[FedSitePayments@swog.org](mailto:FedSitePayments@swog.org)

### Non-Federal Funding Questions Contact:

Mariela Pucci

Sr. Accounting Specialist

SWOG-CTP and The Hope Foundation

Phone: (734) 998-7174

[Finance@thehopefoundation.org](mailto:Finance@thehopefoundation.org)

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## SWOG Site Payments Frequently Asked Questions (FAQ)

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### **1. Where do I find information on payment amounts and instructions for each study?**

Payment amounts and instructions are listed on each individual study's funding memo. The funding memo for each study is available on the CTSU website ([www.ctsu.org](http://www.ctsu.org)) under the 'funding information' tab.

In addition to the standard federal and non-federal amounts, funding memos may also include line item amounts such as "Federal Other\*" or "Federal DCTD Special." More information on these payments (such as eligibility, physical payment, etc.) can be found in the "Study Specific Notes" section.

### **2. Do sites need a contract or scope of work with SWOG?**

Beginning on March 1<sup>st</sup>, 2019, all sites that receive (or could receive) payments directly from SWOG will need separate fixed-price subawards for NCTN and NCORP funded study activity. The old process involved Purchase Services Agreements (PSA); however, per the NCI mandate, this process will now transition to fixed-price subawards. Non-federal study activity will continue to flow through SWOG-CTP on the PSA each site has with them.

Additional federal funding outside of the NCTN and NCORP grants (RO1, etc.) will continue to be distributed through the current PSA with SWOG at OHSU. Additional federal funding will indicate a separate funding source on the study funding memo.

*Please review page one of this packet titled "SWOG Financial Agreements: What You Need to Know" for more details.*

### **3. Do sites need to invoice SWOG for study activity?**

SWOG does not typically make study activity payments to sites from an invoice. Payment for study activity is automatically triggered as indicated on the study's funding memo.

Some funding items may require an invoice; however, such a request is not typical. The notes section for each such item will indicate if an invoice is required.

### **4. How are payments triggered?**

Payment triggers for each study activity are listed on the study's funding memo.

Generally, federal base intervention payments are triggered by the enrollment of the patient. Federally-funded biospecimen and other ancillary payments from federal funding are usually triggered by entering the submission dates in the 'Funding' tab in OPEN on the CTSU website.

Non-federal funding and additional federal funding (non-NCTN or NCORP) payment triggers are listed in the notes section for each type of submission or activity. Usual payment triggers include submission of data into SpecTrac or submission of a particular activity form. SWOG encourages each site to review the funding memo for payment triggers prior to opening a study.

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### **5. Are biospecimen and other ancillary submission payments made per submission or per enrollment?**

Payments for biospecimen and other ancillary submissions are usually paid as a one-time payment per enrollment for the amount listed of each specific type of submission or activity. The one-time payment will be triggered with the first time point, unless otherwise stated on the funding memo.

Some study activities will have payments at multiple time points and are triggered accordingly. In this case, the activity time points and payment amounts will be listed on the funding memo under the 'study component description' column in the table and/or in the notes for that particular funding activity.

### **6. Are the activity payments for submission of biospecimens and other ancillary items such as images meant to cover the cost of the procedure or test for the patient?**

Not usually. Biospecimen and imaging submission payments are usually meant to cover the cost to the site associated with the submission (i.e. labor, supplies, postage or shipping, etc.).

If a study has a non-standard of care procedure or test, the funding for the study should include a payment to cover the cost of that procedure and test. This information is available on the study's funding memo, coverage analysis and protocol. SWOG encourages each site to review the funding memo, coverage analysis, protocol, and evaluate their local coverage prior to opening a study.

### **7. How long does it take to receive payments?**

Payment for study activity is typically mailed to the site within 1-3 months from the date of the payment trigger. Some payments may take longer depending on the funding source for that particular activity.

Please contact the Group Chairs Office ([FedSitePayments@swog.org](mailto:FedSitePayments@swog.org)) if your site has missing federal payments for activity past 6 months. Conversely, please contact Mariela Pucci ([Finance@thehopefoundation.org](mailto:Finance@thehopefoundation.org)) for missing non-federal payments.

### **8. Where do the payment checks come from?**

Payments for study activity will be paid to the site from the NCTN Group credited with the enrollment. If SWOG is credited with an enrollment, payments will be distributed as described below:

Main members and affiliates – Federal payments will be distributed by OHSU, the fiscal manager for SWOG's federal grants. Payments for non-federal funds are distributed by SWOG-CTP.

Components of main members or affiliates – Both federal and non-federal funds will be distributed to the site by the site's main member or affiliate. Please contact the head CRA for the site's main member or affiliate for specifics details.

LAPS and NCORP sites – Most federal funding for study activity for LAPS and NCORP sites will be available to the site via their grants with NCI. Please contact your site's LAPS or NCORP grant coordinator for more information. Federal funds that are not part of the site's LAPS or NCORP grant, as well as Non-federal funds, will be distributed as indicated above for main members and affiliates.

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## SWOG Site Payments Frequently Asked Questions (FAQ)

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### **9. How does SWOG determine where payment checks are mailed?**

The payee address is determined during the subaward agreement process. If the payee address changes for your site, please notify the funding contacts for both federal and non-federal funding.

### **10. How are payments handled if a site participates in a study from a different NCTN group?**

If a site participates in a non-SWOG led study through NCTN and credits SWOG for the enrollment, the federal and non-federal funds are typically distributed by SWOG.

The federal funds, in this case, will be paid through SWOG's own grant; consequently, federal funds will generally be paid within the same time period as with SWOG led trial participation.

The non-federal funds are passed from the Lead NCTN Group to the credited NCTN Group for distribution. Consequently, non-federal funds will likely take longer to distribute than SWOG trial participation.

### **11. Who should I contact if I have questions?**

The contact for federal and non-federal funding is listed on each of the study funding memos. Currently the contacts are as follows:

#### Federal Funding Questions Contact:

TBD

Grants & Contracts Coordinator

Oregon Health & Science University (SWOG GCO)

Phone: (503) 494-5514

[FedSitePayments@swog.org](mailto:FedSitePayments@swog.org)

#### Non-Federal Funding Questions Contact:

Mariela Pucci

Sr. Accounting Specialist

SWOG-CTP and The Hope Foundation

Phone: (734) 998-7174

[Finance@thehopefoundation.org](mailto:Finance@thehopefoundation.org)

#### NCA or General Funding Questions Contact:

SWOG Funding Team

[Funding@swog.org](mailto:Funding@swog.org)

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# National Coverage Analysis (NCA)

- What is a Clinical Trials Coverage Analysis?
  - A coverage analysis is a review of all tests, procedures, and interventions associated with a clinical trial (CT) to determine which ones are 'billable' and which are 'not billable' to a third party payer against the national guidelines and coverage rules
- Who performs the NCA's?
  - The Clinical Trials Support Unit (CTSU) creates the NCAs for NCTN and NCORP trials
- Why are NCA's performed?
  - NCAs are intended to be a **guide** for the sites as they consider their participation in SWOG trials
  - Sites should still make sure to do their own local coverage analysis (LCA) using their local coverage determinations
- Where can you find NCA's?
  - Once completed, official NCAs are posted on the CTSU dashboard

## How Do We Determine What's Billable? CMS NCD for Routine Costs in Clinical Trials (310.1)

- “Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:
  - The investigational item or service, itself unless otherwise covered outside of the clinical trial;
  - **Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient** (e.g., monthly CT scans for a condition usually requiring only a single scan); and
  - **Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.”**

<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true>

# What to Look for in an NCA?

- Cost categories
- CPT codes
- Study calendar
- Justification and comments
- Legend



# Sample NCA Document

Procedure	Sample CPT Codes	Pre-random	Within 7D after random	Within 30D after random	Beginning Within 14D after random	Within 14D after PCI completion	At Day 90 after random	At Day 180 after random	At Day 270 after random	At Day 360 after random	At Day 450 after random	At Day 540 after random	At Day 630 after random	At Day 720 after random	Off MRI Surveillance prior to 24 months	Follow Up after 24 months	Justification and Comments	
<b>EVALUATION &amp; MANAGEMENT</b>																		
History and Physical Exam		M					M	M	M	M		M		M	M	M	Physical Exams at workup and during follow up would be considered conventional care to monitor disease/ progression. NCCN guidelines for Small Cell Lung Cancer (SCLC) v 1.2019 supports H&P follow up Q3 mo during yrs 1-2, Q6 mo during yr 3, then annually (SCL-6). Medical records must document medical necessity and support level of E&M performed. To be billable, evaluation must be done by a healthcare provider (MD, DO, NP) as part of a physical exam.	
Weight & Performance Status		M																
Toxicity Notation	99201-99205, 99211-99215, G0463				M	M	M											
Administer cognitive function testing	n/a		S				S	S		S		S		S	S			Study paid per funding sheet
Radiation therapy materials submission via TRIAD for review by IROC Rhode Island	n/a					NB												Would be considered staff time
Quality of Life Questionnaires (see Section 15.4)	n/a				NB		NB	NB	NB	NB				NB	NB			Would be considered staff time
Imaging Submission (see Section 15.2)							NB	NB		NB							Would be considered staff time	
Monitoring for survival and disease status	n/a														NB	NB	Would be considered staff time	
<b>LABORATORY</b>																		
Serum creatinine for calculated creatinine clearance	82565						M	M	M	M		M		M			It would be considered conventional care to assess kidney function prior to the use of contrast dye for imaging in patients with a history of cancer/chemotherapy treatment. Medical records must document medical necessity. (Per protocol section 9, testing is to be done within 14 days prior to each MRI).	
venipuncture	36415, 36951, 36952			M*			M	M	M	M	M*	M	M*	M			Would be considered conventional care. *Note per protocol section 15.3, the research blood specimen is to be collected only if a SOC blood draw is scheduled. If the patient does not have a standard of care blood drawn at a research blood specimen time point, do not collect the research sample.	
<b>SPECIMENS</b>																		
blood specimen submission	36415, 36951, 36952			S*			S	S	S	S	S*	S	S*	S	S		Sponsor paid per ICF and funding sheet. *Note per protocol section 15.3, the research blood specimen is to be collected only if a SOC blood draw is scheduled. If the patient does not have a standard of care blood drawn at a research blood specimen time point, do not collect the research sample.	

**Legend**  
 RC = Routine cost for a QCT and billable to Medicare/government payer/commercial payers  
 S = Sponsor paid/provided per study funding sheet  
 NB = Non-billable item  
 M = Billable as conventional care in a non QCT or in a clinical trial that does need to qualify for coverage





# Questions on NCAs?

- Visit the CTSU website to view active study NCAs and funding memos
- Email [funding@swog.org](mailto:funding@swog.org) with questions

# SWOG Membership Categories and Funding

## Who funds and distributes study site funding to Payee Member Sites?

Payee Member Sites	NCTN Federal Study Activity	NCORP Federal Study Activity*	Non-Standard Federal Payments**	Non-Federal Payments**
<b>Main Member (MM) Affiliate of MM Site LAPS Aligned Affiliate (LAPS AA)</b>	Credited Group	Credited Group	<b>Funded by:</b> Study Sponsor Group  <b>Distributed by:</b> Credited Group	<b>Funded by:</b> Study Sponsor Group  <b>Distributed by:</b> Credited Group
<b>LAPS Main Member</b>	LAPS grant	Credited Group		
<b>NCORP or NCORP MU Main Member</b>	NCORP grant	NCORP grant		

\*Includes Quality of Life/Patient Reported Outcomes (QOL/PRO) substudies embedded into NCTN studies

\*\*Funding is paid by the Study Sponsor Group to the Credited Group for distribution to the Payee Member Site