



Collaborative Antiviral Study Group Ebrief

*US Department of Health and Human Services
The National Institutes of Allergy and Infectious Diseases*



Spring 2014

(Printer friendly version please [click here](#))

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Some have asked, "Who are we???"

As nearly all of you know, since the 1970s we (and you included) have been the Collaborative Antiviral Study Group (CASG). Under the CASG, which was one contract with NIH, re-competed and re-awarded for over 30 years, multiple studies were conducted. About 3 years ago, the NIH changed their funding methods and began requiring that each protocol be conducted under a separate contract. Subsequently, we were awarded five separate contracts for each of the current studies. From our view point, **we are all still the CASG**, but due to the divided contracts, the NIH does not classify us as the "NIH sponsored" CASG anymore (although we are still a collaborative group!). For that reason, you will sometimes see us refer to ourselves as the UAB Central Unit.

- Regulatory Issues
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- How Are We Doing?

DMID Studies

DMID 11-0067 Gan
Premie
DMID 11-0068
CMX-001 NeoNatal
DMID 11-0069
Valgan Toddler
DMID 11-0070
GeneXpert
DMID 11-0071 BK
Natural History
Adult

Forms

- Invoice Template

Contact Us

877-975-7280

We are very proud of all that we have accomplished together – all of us being the CASG. For that reason, we try to slip in the CASG name whenever we can...so you will still see this on some of our documents and on our website.

Thank ***you*** for being a part of the CASG (UAB Central Unit)!



Failed Screenings

Please remember that you must document on the website each month that you have “No Failed Pre-Screenings” or if you have “Failed Pre-Screenings.” Failed Pre-Screenings include pre-screened subjects who do not meet all the study criteria or who refused to sign informed consent. You will receive a reminder email at the end of every month to prompt you to enter this pre-screening data on the website. If you have any questions about the process, please contact

the Central Unit for help.



Password Access – Three Types

For the UAB Central Unit, you will need three different passwords and access. They are:

ONE - Electronic Data Entry System (**eDES**) **access** for viewing and printing protocol specific documents and for entering subject data into the eCRF: contact Sara Davis (sadavis@peds.uab.edu) or Christine Jenkins McCoy (CJMcCoy@peds.uab.edu).

TWO - For access to the **CASG CU Sharepoint**, contact Susan Branscum (sbranscum@peds.uab.edu).

THREE – For access to the **DMID CROMS** website to complete the training entitled Regulatory File Document Guidelines and Source Documentation Standards for DMID Clinical Studies contact Susan Branscum.



Refresh!

We have recently noted that when trying to assist sites with the eDES, problems arise with access. We have found that sometimes your computer is 'remembering' the web address incorrectly if you have previously bookmarked the site. If you bookmark the page, please refresh each time you open it. Or enter the eDES from the CASG home page

<https://www.uab.edu/medicine/peds/casg>

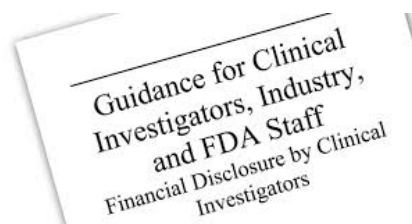
or the eDES login <https://casgcu.soph.uab.edu/Portal/PortalLogin.aspx>.

DMID 11-0070 GeneXpert Study

Clinical Administrator's Note

Investigators and Study Coordinators, we thank you for your continuous work to achieve activation status and begin recruiting and enrolling participants in this very important study. The goal is to enroll 12,500 participants over the next 18 months or so. In order to achieve this goal, we need all sites actively enrolling participants. Here at the Central Unit we will do our best to decrease the number of delays related to database training, sub-contracts, and regulatory issues that are within our control. So, we are reaching out to encourage you to achieve activation status as soon as possible and join us in this uphill journey to reach our goal to successfully enroll this study.

- Ilet Dale RN, BSN, MScM, CCRP



Regulatory Issues



Financial Disclosure: -- **NEW – NEW – NEW:** The **original** financial disclosures will be maintained at your site. Please keep your **original** financial disclosures in a secure location and create a Note to File identifying where the financial disclosures are located and in whose custody. Place this Note to File in your Project Notebook behind the tab labeled “CV, Medical License, HSP Certificate and Financial Disclosure.”



Note to File: Please remember to use the DMID Note to Study File format. The DMID *Guidelines for Writing Notes to the Study File* is located on the password protected side of our website (<https://casgcu.soph.uab.edu/Portal/PortalLogin.aspx>). Once you have logged into the website, look on the left-hand side under Document, Forms, and Note to File Guidelines.

Subcontract Invoicing Reminder

Now that two studies (DMID Gan Premie/11-0067 and GeneXpert/11-0070) are (finally!) actively enrolling and two other studies (Valgan Toddler/11-0069 and BK Natural History/11-0071) should be doing so shortly, we wanted to remind you of several things related to invoicing for the subcontracts.

1. As specified in your subcontracts, sites should be **invoicing monthly** based on the PI/Study Coordinator effort and other possible costs that are chargeable to the study. We understand that up until now, this has been a confusing process for many, either because there was no ongoing activity at your site and, thus, no effort to charge, or because your site subcontract was still “in process” at one stage or another due to the NIH’s protocol approval delays and no cost extensions. However, since the majority of sites have been activated for the Gan Premie/11-0067 protocol, and a large number have been activated or are close for the Genexpert 11-0070 study, you should be invoicing for effort involved in screening, training, regulatory activity, etc. on a regular basis.
2. Please make sure that invoices contain all of the information provided on the sample invoice (attached) including the period dates, site certification statement and signature. Also, **please**

make sure that you verify the contract number, subcontract and invoice number (i.e. all of the red xx on the template). Because all of the numbers attached to the different contracts are almost identical, it is easy to confuse the studies and mix up charges for one study by putting them on a form for another study (which has happened with more than one institution).

3. In addition, please make sure you and/or your finance office lists charges on the invoices using ONLY the categories provided in the subcontract and template (i.e. salary/fringe, other direct costs such as administrative or pharmacy fees and “per subject” costs). We do not provide support for consulting, travel or other items not listed in the executed agreements.
4. Finally, based on the experience we now have with the highest enroller for the GeneXpert/11-0070 study (LSU), we are changing the invoicing method a little for this study only. What we now plan on doing is printing an enrollment report for your site at the end of each period that includes basic information such as the enrollment date, PID # for each subject and total number enrolled. We will send this to you for verification, sign off and use as documentation for the formal payment invoice to be sent by your institution. Hopefully, this will make it easier for everyone, but please don't hesitate to let us know if you have questions or suggestions.

If you have questions about invoicing, please contact Mary Wyatt Bowers (mwbowers@peds.uab.edu).

You can link to a printer friendly version of the Invoice Template under Forms on the left-hand menu.

Page: _____ Word Count: 1,000,000

[View Cart](#) & [Checkout](#)

Wages: _____

Researcher's Institution: _____

Downloaded by guest from <http://www.cambridge.org/core>. <http://www.cambridge.org/core>. <http://www.cambridge.org/core>

(TUM)	Approved/Reviewed by	Examination
	Current period	Signature in date

History

- Foreign
- Other direct costs

Additional notes:

Subject placement

8204 • J. Neurosci., July 26, 2006 • 26(30):8197–8204

*All items shown are subject to availability

Subcontractor hereby certifies that each submitted invoice reflects accurate, sufficient and verifiable expenses incurred in accordance with the period of performance and budget of the Subcontract.

Subventricular region



Spring Training

eDES training for the BK Study and Valgan Toddler Study will be offered later in the Spring or early Summer. If you need training for the GeneXpert Study or GanPremie Study, please contact Liz Paton (epaton@peds.uab.edu) for materials.

So, how are we doing???

PROTOCOL	SITE	ENROLLMENT	ENROLLMENT GOAL
Gan Premie	Univ of South Florida	1	32
GeneXpert	UAB	12	12,500
	LSU	38	
	Metro Health	9	
	Utah	2	
Gan Toddler	Version 1 sent to sites		
BK Natural History	Pending		
CMX HSV	Pending		

A little CASG
humor...



To remove your name from our mailing list, please [click here](#).

Questions? Contact the CASG at 877-975-7280

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