



## Financial Newsletter

### Year 10 - Issue 001

Hello IMPAACT CTU PI's, CRS Leaders, CTU and CRS Coordinators, Financial and Administrative Contacts:

Welcome to grant year 10! IMPAACT received the notice of award from NIH/NIAID on November 27, 2015. Our team is diligently working to ensure you receive all subagreements in a timely manner. This newsletter explains all of the changes that will occur in Year 10.

Please feel free to contact me if you have any questions.

Thank you

Jackie Lizotte, MBA  
Assistant Director IMPAACT Finance & Contracts

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### YEAR 9 FINAL INVOICES

Now that grant year 9 has ended, it is urgent for each site to submit all final invoices for protocol funding to Johns Hopkins University by the specified date provided in your subagreement. The JHU team will be sending reminder e-mails during the first week in December to ensure that your team is aware of the urgent deadlines. JHU is not able to pay any invoices received after the due date due to the volume of invoices and reporting deadlines.

## CHANGES TO SUBAGREEMENTS IN YEAR 10

Each site will receive a Master Member Agreement (MMA) modification, Protocol Specific Task Order (PSTO) modification(s), and Significant Financial Interest (SFI) form if applicable. These items will be issued in one e-mail message. Please note that JHU will execute agreements upon receiving all requested materials.

Changes have been made to MMAs and PSTOs to reflect new terms and conditions listed in the notice of award and Uniform Guidance policy updates which became effective on December 1, 2015.

Changes include:

- MMA Section I: Section I has been updated to reflect the need for an IMPAACT Member Institution (IMI) to coordinate with JHU and NIAID regarding any media communications which describe projects or programs funded in whole or in part with U.S. federal money.
- PSTO Section 1.6: Section 1.6 has been updated to reflect all new registrations and deregistrations according to DAIDS-ES as of mid-November.
- PSTO Section 4: Section 4 has been updated to reflect all authorized payments to your site with the exception of CTI (CTI is now referenced in Section 7, if applicable).
- PSTO Section 4.10.1: Section 4.10.1 has been updated to state that all PF invoices should be submitted via e-mail to [impaact-subs@jhmi.edu](mailto:impaact-subs@jhmi.edu).
- PSTO Section 6: Section 6 has been updated to reflect lists terms regarding CTU and CRS fiscal responsibilities. Specifically:
  - The CTU will have the primary responsibility for all PF accounting.
  - IMI must provide, at a minimum, quarterly information on actual grant expenditures to the CTU.

## PROMISE – YEAR 10 CHANGES

### 1077BF, 1077FF, and 1077HS Reimbursement

Follow up in 1077BF and 1077FF is expected to be completed by September 30, 2016; follow up in 1077HS is expected to be completed by August 31, 2016. Reimbursement will only occur for those visits occurring on or before these dates.

### 1077BF, 1077FF, and 1077HS Increased Per Participant Pricing

1077BF, 1077FF, and 1077HS per participant prices have been increased in grant year 10 to account for those additional participants now on triple ARVs. All prices listed below reflect direct costs per mother-infant pair per year.

1077BF – The previously approved per participant price for 1077BF mother-infant pairs was \$3,250; it has been increased to \$3,436.

1077FF – The previously approved per participant price for 1077FF mother-infant pairs was \$2,505; it has been increased to \$2,691.

1077HS – The previously approved per participant price for 1077HS participants was \$1,566 (International) and \$2,148 (Domestic & Brazil); it has been increased to \$1,731 (International) and \$2,458 (Domestic & Brazil).

#### START Visit Completion

All Step 2 Entry and Step 2 +4 visits are expected to be completed by November 30, 2015. However, with recognition that sites may not be able to fully control this timing, reimbursement will be provided for all such visits completed by January 31, 2016. Reimbursement will only occur for those visits occurring on or before this date.

#### P1084s Closure

All scheduled follow up visits are expected to be completed by November 30, 2015, and all participants should be off study. P1084s per participant costs are not billable in grant year 10 and have been removed from your cost and payments.

#### Close Out

The IMPAACT Management Oversight Group (MOG) is currently working on preparing PROMISE site-specific study close out costs for activity occurring after August 31, 2016, for 1077HS sites, and September 30, 2016, for 1077BF and 1077FF sites. Information will be disseminated to sites on or before January 31, 2016.

### **P1078 – CHANGES TO PER PARTICIPANT PRICING**

All sites currently registered for Protocol P1078 will have two per participant reimbursement amounts reflected on their year 10 cost and payments grid. For any sites who enroll more than 75 pairs, the per participant price will increase by 10%. The first 75 pairs will be reimbursed at a rate of \$3,650 direct costs per year and any additional pairs enrolled will be reimbursed at a rate of \$4,015 direct costs per year. Once the site has reached the 75 pair threshold, Alexis Henninger will send a list of PIDs who are considered part of the first 75 enrollments as well as a list of the PIDs over the 75<sup>th</sup> enrollment.

### **HUMAN SUBJECTS (HS) AND GOOD CLINICAL PRACTICE (GCP) BI-ANNUAL AUDIT**

As stated in our notice of award, NIAID requires that we maintain valid human subjects (HS) and good clinical practice (GCP) certifications for both key personnel and any clinical research site personnel who have more than minimal involvement with the conduct of the research (performing study evaluations or procedures or providing intervention) or more than minimal study conduct-related contact with study subjects or confidential study data, records, or specimens. Any other personnel with minimal involvement in the conduct of the research or minimal conduct-related contact with the participants (e.g. drivers, couriers, clerical and administrative staff etc.) should receive training emphasizing the protection of participant privacy and confidentiality.

By January 15, 2016, each site will be receiving a request from Erin Infanzon to update all HS/GCP information. Sites will be required to fill out an Excel spreadsheet to include all personnel currently working on the project. It is the responsibility of each CRS to add the names of all individuals currently receiving support from UM1A1068632-10 and to provide valid certificates in order to ensure proper compliance.

## UPCOMING NEWSLETTER TOPICS

- Please submit any request for newsletter topics to Jackie Lizotte – [jlizott1@jhmi.edu](mailto:jlizott1@jhmi.edu)

## IMPAACT FINANCIAL STAFF LISTING

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