



**Financial Newsletter  
Issue 001**

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

The IMPAACT Finance Group at Johns Hopkins University is pleased to provide you with our first newsletter. We will be sending newsletters out as new information becomes available or changes are made to current procedures.

Please continue to send all protocol funds inquiries to [IMPAACT-Subs@jhmi.edu](mailto:IMPAACT-Subs@jhmi.edu) rather than individuals. All staff members have access to this e-mail address and you will receive a faster reply.

We welcome your feedback and comments.

Thank you

Jackie Lizotte, MBA  
Assistant Director IMPAACT Finance & Contracts

**IN THIS ISSUE...**

- **IMPAACT New Team Member**
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**WELCOME ANNA DENT!**

I would like to welcome **Anna Dent** to the IMPAACT finance team at JHU. Anna joins our group from Johns Hopkins University, School of Public Health, where she worked for 7 years in both pre and post award sponsored activities.

We are thrilled to have her join the team. We are currently in the process of transitioning protocol funds site management activities (except for pharmaceutical studies) to Anna and hope to have her fully up and running soon.

## PROMISE INVOICE DO'S AND DON'TS

We have received many inquiries on billing PROMISE participants beginning December 1, 2014. The IMPAACT team is actively working with all of you to answer your questions. In addition to the cost and payments section of your task order, we have put together a set of Do's and Don'ts to assist you with your monthly invoices:

1. PIDs entered in the PID logs must be for those on study for at least 48 weeks. Do not bill JHU for a PID that is not yet in follow up. Since PROMISE completed enrollment 11/30/14, protocol funds for new enrollments prior to this date were included in your Y8 protocol funds ending 11/30/14.
2. PIDs entered in the PID logs must be billed at the requested milestone. JHU should only be invoiced for the FIRST visit following week 48, 96, 144, and so on. We validate this information with the data management center's (DMC) monthly data reports, so if we see that the first visit has already taken place in the current follow up year, we cannot pay the current follow up year costs again; as they would've already been paid in your prior year protocol funds.
3. Payment for 1077BF, 1077FF and P1084s are for mother-infant pairs; so bill only for the mother's PID. Please remove all PIDs that belong to the infant to simplify the review process.
4. If a CRF was not submitted until the month following the visit, the visit will not appear on the DMC report until the following month; therefore, you cannot invoice for this visit until the following month.
5. If a follow up visit did not occur in the month being billed, the PID will not appear in the DMC report. We cannot validate a PID for payment if it does not show up in the monthly DMC report.
6. Payments will not be made for any participants who are off protocol.
7. Please add a note at the bottom of your PID log if your site encounters special situations:
  - a. There is a case of twins - bill twice for the same mother PID.
  - b. The mother passes away – bill for the infant PID.

## HUMAN SUBJECTS AND GOOD CLINICAL PRACTICE CERTIFICATION 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.

Over the next month, Erin Infanzon will be contacting each CRS to request updated certificates for any personnel currently listed with expired certification dates and to add any newly hired personnel to the database. It is the responsibility of each CRS to add the names of all individuals currently receiving support from UM1AI068632-09 and to provide valid certificates.

## UPCOMING NEWSLETTER TOPICS

- Financial Staff Photos, Bios, and Work Duty Listings
- IMPAACT Annual Meeting Appointment Times and Information
- Changes to Uniform Guidance – How will it affect you?

## IMPAACT FINANCIAL STAFF LISTING

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