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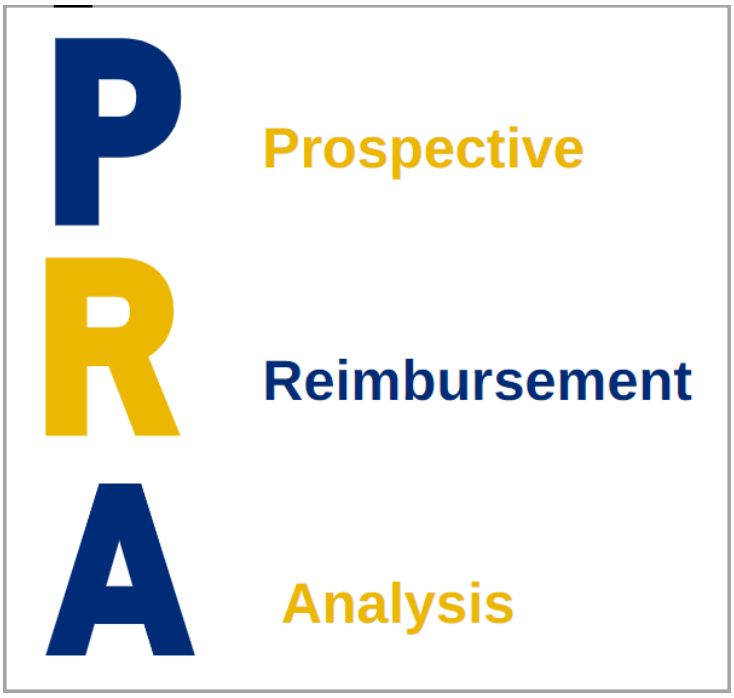
Research Billing Buzz

A Newsletter from the Office of Clinical Research Billing Compliance

Volume 5 August 2019

The Prospective Reimbursement Analysis



In this Issue

In our last issue, we discussed the importance of research billing compliance and we went over Medicare's clinical trial coverage. In this instalment of *Research Billing Buzz* we will discuss the Prospective Reimbursement Analysis in a little more depth.

What is a PRA?

The Prospective Reimbursement Analysis (PRA) is a systematic review of a clinical research study protocol, draft contract and sponsor budget, proposed Informed Consent Form (ICF) cost language and other study documents, such

as Notice of Grant Award (NOGA), Investigator's Brochure (IB) and information regarding the FDA status of the investigational item(s) for the determination of cost delineation (research vs. standard clinical care) of items and services performed as part of consenting subject's participation in the clinical research or clinical trial.

What is the PRA Used For?

The PRA has many uses, among these is budgeting, build of research order sets and treatment plans and compliant billing.

Remember that the PRA is a document internal to Hopkins.

Who Develops the PRA?

The PRA is developed by the office of Clinical Research Support Services (CRSS) within the Office of Research Administration (ORA).

When is a PRA Needed?

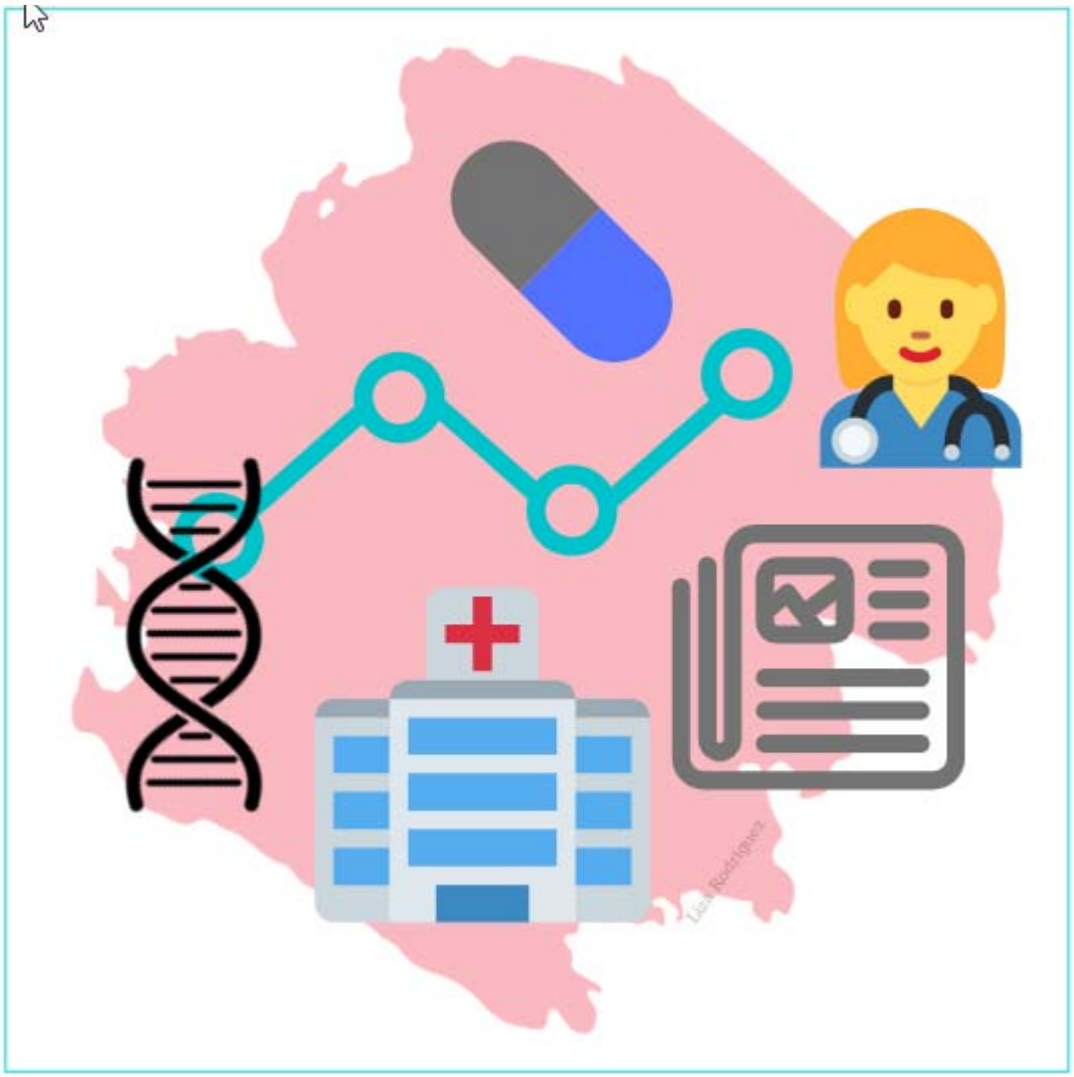
All study applications submitted through eIRB are reviewed for PRA determination by CRSS.

PRAs are necessary for all research studies that have *the potential* to generate a Johns Hopkins Medicine patient bill and require participants to sign an ICF.

Note that the study might need a PRA even if all costs are covered by the study to ensure that participants are not billed inappropriately.

Who Approves the PRA?

The Principal Investigator (PI) has final approval of the PRA.



What do I do if Something Changes in my Study?

If your Protocol changes, please make sure to submit it to the IRB as soon as possible. This will trigger a re-review by CRSS as the study might need a new PRA.

What can I do to Help?

- Work with your CRMS Analyst to answer their questions and provide all documents requested.
- Make sure that you closely review your Draft and Final PRA.
- Remember that the services listed in the PRA should all be included in your budget.
- Submit changes in research promptly to the IRB so the PRA can be updated on time to avoid billing errors.

Need Help?

If you need help, have questions or want to suggest topics for future newsletters you can email us at:

CLINIRESBILLING@exchange.johnshopkins.edu

For more information, visit the **Research Revenue Cycle Website**

Research Rev Cycle Website

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