

## Use of WCG IRB, Inc./Advarra for Multi-Site Research

If you are an NIH Intramural Research Program investigator and you are using NIH funds to pay for IRB services from either Advarra or WCG IRB please read and follow the instructions below. If you are using NIH funds, you may pay for the services either by creating a new task order on an existing contract known as the “S4 contract” or alternatively by setting up a new contract through your ICs contracting office. You may not pay for the services using a P-card, as with that mechanism the necessary terms and conditions that flow to the vendor will not be in place.

If an external non-NIH entity (for example a pharmaceutical company) is paying for the IRB services these instructions do not apply.

### **Paying for services using the existing S4 contract mechanism**

The Office of Human Subjects Research Protections has put a contract in place with WCG IRB, Inc. (formerly WIRB) and Advarra, to provide additional IRB review support for multi-site research. The contract put in place by OHSRP is only for use by NIH Intramural investigators when the intramural program is conducting the research. It is **NOT** to be used to pay for IRB services for non-NIH sites, even if the NIH is serving as the sponsor or is funding the research.

- The contracts with WCG IRB, Inc. and Advarra have been set up as a subcontract to our prime contract with Guidehouse. This contract is part of the S4 contract, led by COR Lionell Davis. Specific contract language was used and approved by the NIH Office of the General Counsel when setting up the contract with WCG IRB, Inc. and Advarra.
- To start the process of using the contract, please reach out to Haley Esser ([haley@bccdc.net](mailto:haley@bccdc.net)). Haley is the lead person in the S4 Project Management Office (S4 PMO). Haley will provide further information and may connect you with other individuals on her team who will help you set up your agreement and obligate your funds to be paid to WCG IRB, Inc. or Advarra.

You will need to set up a new task order on the S4 for your specific project. When your task order is awarded, it will clearly state the dates for the period of performance. Haley Esser will provide Guidehouse with the necessary information so Advarra or WCG invoices can be paid.

- Ensure that you use the funds obligated for WCG IRB, Inc. or Advarra within the period of performance of the contract. If your protocol plans change such that the commercial IRB services are no longer needed, please inform Haley so that she can discuss with you the possibility of submitting a funding de-obligation request through the contract office.

### **Paying for services using another contract mechanism**

You may set up a separate contract with WCG or Advarra to pay for services. If you choose to do so, please follow the instructions below.

- Contact Haley Esser (lead person in the S4 Project Management Office) to obtain the contract language that has been used in our previous contract. This contains important terms and conditions that should be included in your contract. This language has been vetted by OHSRP and OGC.

The NIH IRP already has a master reliance agreement with these entities. This agreement is separate from the contract and is the authority for them to review for the NIH. Do not negotiate a new reliance agreement.

- Should you have any questions during this process, please reach out to the following:
  - Contract questions: Haley Esser email: [haley@bccdc.net](mailto:haley@bccdc.net)
  - Reliance and multi-site research questions: [NIH-Reliance-sIRB@nih.gov](mailto:NIH-Reliance-sIRB@nih.gov)

Thank you, and if you have any additional questions, please send an email to [IRB@od.nih.gov](mailto:IRB@od.nih.gov).