New Observational Study Checklist

Use this checklist to guide you through the process of requesting review and approval of a new observational/ data study. This process applies to studies conducted at all PHS facilities, with PHS patients, or by a PHS employee EXCEPT those opened in conjunction with the NM Cancer Care Alliance (NMCCA).

If you have any questions about the operational approval process or forms, please contact Ebany Martinez-Finley, Director, Research, at emartinez41@phs.org or 505-923-7854

To Request a New Observational/ Data Research Study:

☐ (1) Fill out the *Operational Approval Determination form* [link].

- If Operational Approval is required, continue to step 2.
- If operational approval is not required, skip to step 5 and submit to the Institutional Review Board (IRB). Include your completed *Operational Approval Determination form* in your submission packet.

☐ (2) Complete the *Observational Study Operational Approval Form* [link].

☐ (3) Submit the *Observational Study Operational Approval Form* to Ebany Martinez-Finley, Director, Research, at emartinez41@phs.org or 505-923-7854.

Ebany will facilitate administrative review/ approvals and submit to the Clinical Research subcommittee for operational approval.

☐ (4) Once you've received approval (and a signed copy of your request), work with Lori Galves, Manager, Research & Sponsored Awards, in Finance to negotiate/finalize the study budget with the sponsor (if needed). 505-823-8518 or lgalves@phs.org

☐ (5) Once you've received approval (and a signed copy of your request), submit your study review request to the IRB through IRBNet.

If you have questions about the IRB submission process, please contact the Human Research Protections Office at 505-841-1436. You can find more information about the IRB on the PHS.org IRB web page.

Include the:

- *Operational Approval Determination form* and
- signed *Observational Study Operational Approval Form* (if required)

in your IRB submission packet. This can be done concurrently with budget negotiations.

☐ (6) The Clinical Trial Agreement (CTA) and negotiated budget may be submitted to Network Contracting for review/ negotiation (if necessary) while the study is under review with the IRB. The CTA will not be fully executed until proof of IRB approval is provided.

☐ (7) Open the study and begin research activities.