

# New Interventional Study Checklist

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

If you have any questions about the process or forms, please contact Ebany Martinez-Finley, Director, Research, at [emartinez41@phs.org](mailto:emartinez41@phs.org) or 505-923-7854.

If you are requesting an **expanded access/ compassionate use protocol** or other **investigator-initiated study**, please contact Dr. David Arredondo (with the protocol packet) before continuing work on your submission.

## To Request Review and Approval of a New Interventional 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 6 and submit to the Institutional Review Board (IRB). Include your completed *Operational Approval Determination form* in your submission packet.

- (2) Contact Lori Galves ([lgalves@phs.org](mailto:lgalves@phs.org) or 505-923-8518) in Finance to prepare or contract for a Medicare Coverage Analysis (MCA).

- (3) Complete the *Interventional Study Operational Approval Form* [\[link\]](#), including the clinical / operations approval section.

- (4) Submit the *Interventional Study Operational Approval Form* to Ebany Martinez-Finley, Director, Research at [emartinez41@phs.org](mailto:emartinez41@phs.org) or 505-923-7854.

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

- (5) Once you've received approval (and a signed copy of your request), work with Finance to negotiate/ finalize the study budget with the sponsor (if necessary).

- (6) 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 *Operational Approval Form* (if required)

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

- (7) The Clinical Trial Agreement and negotiated budget can be submitted to Network Contracting for review/ negotiation while under review by the PHS IRB. Contract will not be fully executed without proof of IRB approval.

- (8) Open the study and initiate all necessary work with Patient Billing, Finance, Informatics, and other clinical departments.