

<b>TITLE:</b>	<b>Pre-Review</b>
<b>PURPOSE:</b>	Process to Pre-Review a submission to the IRB or a determination whether an activity is exempt Human Research or is not Human Research
<b>RESPONSIBILITIES:</b>	HSPP Staff

**PROCEDURES:**

Submissions to the IRB not following the Submission Requirements as outlined in HSPP Guidance are returned without review to the Principal Investigator and any alternate contact with a message explaining why the submission is being returned.

Submissions lacking the following items, as appropriate, should be returned to the PI:

- A conflict of interest resolution by the IRC or ERC.
- All required signatures.
- Any required documents.
- Site authorizations as applicable.
- Scientific review letter or signature from the University of Arizona Cancer Center Scientific Review Committee.

If the submission is regarding existing Human Research, confirm that the project has active IRB approval.

Review the submission materials for completeness and write a pre-review based on the 'Pre-review' guidelines in the Operations Manual.

If the IRB requires changes to a submission, changes must be submitted to the IRB within 30 days of the pre-review email that is sent to the PI. If a response to the IRB or additional information is not provided within 30 days of the pre-review email, the submission will be withdrawn. If the PI decides after the submission has been withdrawn that they want the items to be reviewed then the submission will need to be resubmitted to the IRB and depending on signature dates it may require that new signatures be obtained.

Evaluate the most likely level of review:

- If the submission can be handled as a Non-Committee Review and the investigators and research staff are not Restricted, follow "SOP-041: Non-Committee Review Preparation."
- If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope (See SOP-022: IRB Meeting Preparation).

**MATERIALS:**

- Operations Manual

**REFERENCES:**

None

**REVIEW/REVISIONS:** From 10/01/2010 version: Modified reference to remove W304 as it was integrated into each application form.  
From 08/01/11 version: Updated process to reflect current practice; Deleted reference to the VA.  
From 01/2014 version: Renumbered from P&P-021.  
From 3/2015 version: Addition of pre-review return policy