Washington University in St. Louis

Human Research Protection Office
Box 8089
(314) 633-7400
Fax (314) 367-3041

In order to ensure an efficient review process the Human Research Protection Office (HRPO) has established target response times for the research community and HRPO staff.

Chart A provides a schedule of target response times and reminders for the research community. It is important to note that once a project or form is withdrawn due to non-responsiveness it cannot be reactivated. Instead, a new project or form must be submitted. This policy applies to new studies, modifications and continuing reviews.

Chart B lists the target review and response times that apply to the HRPO staff. This should serve as a useful guide outlining when you can expect to hear from HRPO. In addition, a glossary defining terms used within this document has been included.

Chart A: Target Response Times and Reminders for the Research Community

	Expected Response Time	1st automated reminder (sent via email)	2nd automated reminder (sent via email)	Personal Email from HRPO staff	Withdraw Form
Contingencies sent during the screening or expedited review process	Respond to contingencies within 7 calendar days*	7 calendar days after contingencies sent if no response*	14 calendar days after contingencies sent if no response*	21 days after contingencies sent if no response*	Withdraw project/form if not received within 3 business days of notification by personal email*
Contingencies from the full board committee when the study is "Approved Pending"	Respond to contingencies within 7 calendar days*	7 calendar days after contingencies sent with no response*	14 calendar days after contingencies sent with no response*	21 days after contingencies sent if no response*	Withdraw project/form if not received within 3 business days of notification by personal email*
Contingencies from the full board committee when the study is "Tabled"	Respond to contingencies within 7 calendar days*	7 calendar days after contingencies sent with no response*	14 calendar days after contingencies sent with no response*	28 days after contingencies sent if no response*	Withdraw project/form if not received within 3 business days of notification by personal email*

*When returning the project/form to HRPO ALL contingencies must be addressed.

Human Research Protection Office
Box 8089
(314) 633-7400
Fax (314) 367-3041

Important points to consider:

- After 21 or 28 days of non-responsiveness (depending on the status of the review) a personal email will be sent to the Principal Investigator (PI) and individuals listed as contact persons in myIRB. This email will provide notification that if a response to the contingencies is not received within 3 business days the project or form will be withdrawn.
- When responding to the automated or personal email it is important to keep the following in mind:
    - All contingencies must be addressed prior to returning the project/form to the HRPO staff.
    - If you have received communication from the HRPO staff with instructions to "hold in your inbox" you may disregard the automated email reminders. This may occur in the following examples (this is not an all inclusive list):
        - The study is being reviewed by another institutional committee and the IRB review cannot proceed until this approval has been obtained,
        - The study requires an Individual Investigator or IRB Authorization Agreement,
        - The investigator has been instructed to obtain a formal investigational drug or device determination from the FDA.
- Studies that require sponsor approval to contingencies will be held to the same target response times as described in this policy. Therefore, it is important to communicate these expected response times to your sponsor.

Chart B: Target Review and Response Times for HRPO Staff

	Review and Response Times	Comments
Administrative Screening (applies to all projects and forms)	1 business day	
Expedited review of new studies, continuing review and modifications	3 business days	
Screening for new studies, continuing review and modifications undergoing full board review	3 business days	
Triage of reportable events (REF)	1 business day	Actual review may occur several days later depending on the seriousness of the report.
Staff review of PI or delegate responses to contingencies	1 business day	
Minutes and contingencies from full board committee sent to investigator	2 business days from the date of the meeting	

Washington University in St. Louis

Human Research Protection Office
Box 8089
(314) 633-7400
Fax (314) 367-3041

Glossary of Terms:

Administrative Screening-All forms submitted via the myIRB system are initially processed by a Coordinator. During this administrative screening process we ensure basic elements and documents are included and make an initial determination as to whether or not the request requires review by the full board committee or if the request can be reviewed by expedited procedure.

Approved Pending - The project/form has been reviewed by the full board committee and is approved pending review and acceptance of the stated contingencies by the IRB Chair or by an individual designated by the Institutional Review Board (IRB).

Contingency - Any request for changes made during the screening or review process are called contingencies. This request can come from a HRPO staff person or the full board committee.

Continuing Review - Under federal regulation and HRPO policy all non-exempt human subject research must undergo review on a regular basis that is no greater than one year. Most commonly, the review period is set at one year. However, depending upon the complexity and risk involved in the study the review period may be shorter.

Delegate - The Principal Investigator (PI) may designate an individual(s) as a delegate within the myIRB system. By naming an individual as a delegate the PI gives that person the authority submit information in myIRB on their behalf. This not only includes forms such as modifications, continuing reviews or reportable events but also new studies.

Expedited Review - Federal regulations and HRPO policies allow certain types of research to be reviewed via expedited procedure (review). Expedited review does not mean fast or abbreviated. These studies are still subject to all of the requirements listed in the federal regulations and in HRPO policies. However, only one person (designated by the Executive Chair of the Washington University Institutional Review Board) must review the study or form.

Form – This term is used to describe the options for submission within myIRB. Once a new project is approved the following forms can be submitted: modifications, continuing review, modification/continuing review, reportable event, exception request and project closure.

Full Board Review - Research studies that do not fit within the federally designated expedited review categories must undergo review by the full board committee. This committee is comprised of individuals with various backgrounds and experience to promote complete and adequate review of human subject research.

Minutes - Federal regulations require the generation of minutes to document the review process that occurs during a full board committee meeting. The minutes includes regulatory determinations, contingency requests, and a summary of any disputed issues discussed during the meeting.

Human Research Protection Office
Box 8089
(314) 633-7400
Fax (314) 367-3041

Modification – Under federal regulation and HRPO policy all changes to human subject research must be reviewed and approved by the IRB prior to implementation unless the change is necessary to alleviate an immediate hazard.

Reportable Event - Unanticipated problems and noncompliance are considered reportable events. These events must be reported to the IRB via a Reportable Event Form (REF). See HRPO policies for more information on reporting requirements and timelines for reporting.

Screening – This term is used to define the process that occurs prior to a study or form being reviewed by the full board committee. The HRPO Analyst conducting this screening process ensures all information in the submission is complete, accurate and sufficient for the committee to make the necessary regulatory determinations.

Tabled - When the full board committee requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by 45 CFR 46.111 and 21 CFR 56.111, approval will be deferred pending subsequent review by the committee. The PI's responses must be reported back to the next convened meeting. The protocol and accompanying documents cannot be approved without a response from the PI and subsequent reconsideration, discussion, and vote by the committee.