**Post-IRB Approval Monitoring**
**Annual Calendar**

<table>
<tr><td rowspan="3">Pending Reportable Events</td><td>JAN</td><td>FEB</td><td>MAR</td><td>APR</td><td>MAY</td><td>JUN</td><td>JUL</td><td>AUG</td><td>SEP</td><td>OCT</td><td>NOV</td><td>DEC</td><td></td></tr>
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<tr><td colspan="13">Federal regulations governing human research require institutions to establish procedures for ensuring “prompt reporting” to the IRB and appropriate institutional officials about “any unanticipated problems involving risks to participants or others, as well as any serious or continuing noncompliance…”. In response to this requirement the UMCIRB has two SOPs titled “Unanticipated Problems Involving Risks to Participant and Others” and “Defining and Reporting Protocol Deviations”. Reporting is managed via ePIRATE. Known as ‘Reportable Events’; these may be created within ePIRATE by a study team member <u>but submitted only by the PI</u>. Reportable events should not linger in ePIRATE. A report of pending reportable events is run weekly and reviewed with a focus on those that have been in a pending state more than two weeks. For reportable events that are pending more than two weeks; an email notice will be sent to the PI to make him/her aware that they have a pending reportable event and should address it as soon as possible. Studies where there is repeated and continuing delay of submission of reportable events thereby violating the requirements of the SOPs noted above may be subject to a for-cause monitoring visit.</td></tr>
<tr><td rowspan="3">External Monitoring</td><td>JAN</td><td>FEB</td><td>MAR</td><td>APR</td><td>MAY</td><td>JUN</td><td>JUL</td><td>AUG</td><td>SEP</td><td>OCT</td><td>NOV</td><td>DEC</td><td></td></tr>
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<tr><td colspan="13">Funded studies may be monitored on a regular basis by the funding agency/sponsor or the agency’s designee (i.e., CRO, independent monitor, etc.). In fulfillment of its responsibility for ongoing review and approval of research, the UMCIRB conducts continuing review of research so that the study may continue past its current expiration date. As a part of its review, the UMCIRB requests that monitoring reports with unfavorable outcomes be submitted by the Investigator at the time of the continuing review. Funded studies where regular monitoring is conducted by the sponsor, or their designee will be randomly selected to provide the PAM office with a copy of all monitoring/audit reports received from the study sponsor or others to date. The PAM office will review the monitoring reports for any issues of concern that were not reported to the UMCIRB as required and will follow-up with the study team as needed on these issues.</td></tr>
<tr><td rowspan="3">ClinicalTrials.gov Registration</td><td>JAN</td><td>FEB</td><td>MAR</td><td>APR</td><td>MAY</td><td>JUN</td><td>JUL</td><td>AUG</td><td>SEP</td><td>OCT</td><td>NOV</td><td>DEC</td><td></td></tr>
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<tr><td colspan="13">Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires responsible parties to register clinical trials and submit summary results to ClinicalTrials.gov. The law applies to certain clinical trials of drug, biological, and device products and has been in effect since September 27, 2007. A report of studies will be run quarterly where the Investigator has indicated in ePIRATE that registration of his/her study on ClinicalTrials.gov is required. The studies captured in this report will be checked against the ClinTrials.gov website to ensure registration has been completed. If there are studies that should be registered but are not, follow-up with the investigator to determine the status of the study registration will be initiated by PAM staff.</td></tr>
<tr><td rowspan="3">Reported Conflict of Interest (COI)</td><td>JAN</td><td>FEB</td><td>MAR</td><td>APR</td><td>MAY</td><td>JUN</td><td>JUL</td><td>AUG</td><td>SEP</td><td>OCT</td><td>NOV</td><td>DEC</td><td></td></tr>
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<tr><td colspan="13">The UMCIRB requires full disclosure of any financial, professional, personal, and/or intellectual property interests, relationships, and affiliations by any study team member associated with human research activity. Any new conflict of interest (COI) that arises after the research begins and any changes in an existing COI must be reported to the UMCIRB at that time. Studies of PI’s reporting a COI will be pulled from ePIRATE on a quarterly basis for review to ensure that a current COI management plan is in place as required and that the COI is disclosed to study participants in the informed consent document if required. For studies where it is determined that the management plan is either missing or requires revisions and/or the consent document does not contain the required COI disclosure the PAM staff will notify the Investigator as well as the Office of Research Compliance if required.</td></tr>
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