Effective as of 08/29/2011, the MCW/FH HRPP office has made the following changes and additions to their policies, procedures and/or forms.

1. **New Process: Clinical Trial Contract and Informed Consent Document Comparison**
   With MCW/FH AAHRPP site visit in late March 2011, this review process was recommended by AAHRPP to be put in place at MCW/FH to review all clinical trial contracts with the informed consent document to ensure consistency in 4 areas:
   - Additional Costs to the Subject
   - Subject Compensation
   - Medical Treatment for study-related illness or injury
   - Compensation for study-related illness or injury
   Final IRB approval will be granted once the HRPP office has been notified the finalized contract is available for review & comparison.

2. **IRB Policy Revisions**
   - **IRB SOP: Submitting New Studies** – has been revised to note that all submissions require a protocol summary document to be uploaded in eBridge.
   - **IRB SOP: Modifications to an Approved Project** – has been revised to inform study teams & investigators when adding new study sites to their project
   - **IRB SOP: Institutional Authorization Agreements and Other Review Mechanisms for Multi-Center Studies** - Added additional reminders and language for study teams and Investigators to be aware and in compliance Froedtert Hospital

3. **Coordinated IRB Review Form (NEW):**
   This is a new form to help support Investigators to request a coordinated or single IRB review when a study may involve 2 or more of the following CTSI institutions:

<table>
<thead>
<tr>
<th>Blood Center of Wisconsin</th>
<th>Children’s Hospital of Wisconsin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Froedtert Hospital</td>
<td>MCW</td>
</tr>
<tr>
<td>Marquette University</td>
<td>Milwaukee School of Engineering (MSOE)</td>
</tr>
<tr>
<td>UW-Milwaukee</td>
<td></td>
</tr>
</tbody>
</table>

4. **eBridge Revision: Email Notification for Contract Finalization**
   A new email process has been enabled to notify both the IRB Office and Study Team/Investigators when a contract has been finalized with Grants & Contracts Office. This process will assist both Investigators/Study Teams and the HRPP office in being able to review and compare finalized contracts with the Informed Consent Documents prior to granting final approval.