**FORM “P2”**

**HU IRB Form: Post Approval Monitoring**

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| **Title of Project**: Click here to enter text. | | |
| **Review Date:** Click here to enter text. | | |
| **Principal Investigator**:  Click here to enter text. | **Department**: Click here to enter text. | |
|  | **Email**: Click here to enter text. | |
| **IRB Number:**Click here to enter text. | **Phone:** Click here to enter text. | |
| **Approval Date:** Click here to enter text. | **Expiration Date:** Click here to enter text. | |
| **POST APPROVAL MONITOR REVIEWER** | | |
| **Position** | | **Name** |
| ORRC Staff (Name) | | Click here to enter text. |
| IRB Chair | | Click here to enter text. |
| IRB Co-Chair | | Click here to enter text. |
| IRB Member (CTSA Research Subject Advocate) | | Click here to enter text. |
| IRB Member (Others) | | Click here to enter text. |

*The overarching goals of the Post Approval Monitoring (PAM) process are to: ensure that the rights and well fair of research subjects, and the quality and integrity of research at HU; identify educational and support needs of the HU research community; ensure compliance with federal, state, local and institutional regulations and guidelines; and identify areas of our research infrastructure and that may benefit from the improvement of our research policies and procedures.*

The HU IRB will use this form to perform random “post approval monitoring” of protocols. It will work in tandem with the currently ongoing monitoring of IRB protocols by the Research Subject Advocate of our Clinical Research Unit (CRU) who is now an IRB member. The quality control and educational utility of this form is emphasized. Independent and unsolicited reporting is also encouraged. Selected protocols will have this assessments performed prior to the annual review of related consent documents. In addition to complying with appropriate management of violated regulatory requirement, findings from this review will also inform subsequent review intervals of the protocols.

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| **Principal Investigator** | | | | | | | | |
| **Notification of Review** | | | | | **Date Notified:** Click here to enter text. **By Email Telephone** | | | |
| **Meeting Schedule** | | | | | **Planned Date of Review:** | | Click here to enter text. | |
|  | | | | | **Place of review:** | | Click here to enter text. | |
|  | | | | | **Planned Attendees:** | | Click here to enter text. | |
| **Regulatory Documents Reviewed** | | | | | | | | |
| **Document Reviewed** | | | | | **Date of Reviewed** | **Approval Date** | | **Expiration Date** |
| Click here to enter text. | | | | | Click here to enter text. | Click here to enter text. | | Click here to enter text. |
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| **Communications** | | | | | | | | |
| **YES** | | | **NO** | | Study-related communication with IRB properly filed | | | |
| **YES** | | | **NO** | | Study-related communications with sponsors properly filed | | | |
| **YES** | | **NO** | | | Study-related communications with DSMB properly filed | | | |
| **Comments:** Click here to enter text. | | | | | | | | |
| **Subjects’ Selection and Study Progress** | | | | | | | | |
| **Number selected for review** | | | | | **Number =** Click here to enter text. | | | |
| **Total enrolled** | | | | | **Number =** Click here to enter text. | | | |
| **Total approved** | | | | | **Number =** Click here to enter text. | | | |
| **YES** | | | | **NO** | **Informed consent current** | | | |
| **YES** | | | | **NO** | **Informed consent obtained and properly documented** | | | |
| **YES** | | | | **NO** | **Reviewer observed informed consent process (may defer to RSA)** | | | |
| **YES** | | | | **NO** | **Satisfied with the process observed (If not may recommend additional education)** | | | |
| **Comments:** Click here to enter text. | | | | | | | | |
| **Recruitment Methods and Materials**  **Select methods used and determine whether consistent with approved consent document** | | | | | | | | |
| **Yes** | **No** | | | | **Media Advertisements** | | | |
| **Yes** | **No** | | | | **Internet** | | | |
| **Yes** | **No** | | | | **Flyer/Posters** | | | |
| **Yes** | **No** | | | | **Mailed Letters** | | | |
| **Yes** | **No** | | | | **Telephone** | | | |
| **Yes** | **No** | | | | **Direct Mailing** | | | |
| **Yes** | **No** | | | | **Others: Describe** Click here to enter text. | | | |
| **Compensations**  **Determine methods used and whether consistent with consent document** | | | | | | | | |
| **Yes** | **No** | | | | **Gift Certificates** | | | |
| **Yes** | **No** | | | | **Money** | | | |
| **Yes** | **No** | | | | **Research Cards** | | | |
| **Yes** | **No** | | | | **Others:** Click here to enter text. | | | |
| **Research Methods** | | | | | | | | |
| **Yes** | **No** | | | | **Unreported protocol violation/deviation** | | | |
| **Yes** | **No** | | | | **New study procedure introduced without IRB approval** | | | |
| **Comments:** Click here to enter text. | | | | | | | | |
| **Risks** | | | | | | | | |
| **Yes** | **No** | | | | **Unanticipated problems** | | | |
| **Yes** | **No** | | | | **Newly identified risks already to the IRB** | | | |
| **Yes** | **No** | | | | **Appropriate file protection and secured office location** | | | |
| **Yes** | **No** | | | | **Appropriate computer protection** | | | |
| **Institutional and Investigators’ Issues** | | | | | | | | |
| **Yes** | **No** | | | | **Office or laboratory space concerns and general support** | | | |
| **Yes** | **No** | | | | **Change in study leadership** | | | |
| **Yes** | **No** | | | | **Lack of support** | | | |
| **Yes** | **No** | | | | **Complaints (Please describe)** Click here to enter text. | | | |
| **SUMMARY COMMENTS** | | | | | | | | |
| Click here to enter text. | | | | | | | | |

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| --- | --- | --- |
| **SIGNATURE** | | |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **REVIWER’S NAME** | **SIGNATURE** | **DATE** |