**IRB Protocol Review Sheet for Convened Initial Review**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Number: | 2016C0123 | **PI:** | Smith |

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| --- | --- | --- |
| **DETERMINATIONS** |  | **CONSENT/HIPAA (check all that apply)** |
|  |  |  |  |  |
|  | Approved |  |  | No Waivers, Alterations, or LAR Consent |
|  |  |  |  |  |
|  | Requires Modifications – \*provide comments |  | x | Waiver of Consent |
|  |  |  |  |  |  |
| x | Deferred – \*provide comments |  |  | Alteration of Consent |
|  |  |  |  |
|  | Disapproved – \*provide comments |  |  | Waiver of Consent Documentation |
|  |  |  |  |
|  |  |  | Waiver of Parental Permission |
|  |  |  |  |
| **POPULATIONS (check all that apply)** |  |  | Alteration of Parental Permission |
|  |  |  |  |  |
| x | No Special Populations |  |  | Waiver of Parental Permission Documentation |
|  |  |  |  |  |
|  | Approval for Pregnant Women/Fetuses |  |  | Waiver of Assent |
|  |  |  |
|  | Approval for Children |  |  | Consent by Legally Authorized Representative |
|  |  |  |  |
|  | Approval for Prisoners |  | x | Waiver of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Adults with Decisional Impairment |  | x | Partial Waiver of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Non-English Speaking Subjects |  |  | Alteration of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Non-Viable Neonates |  |  |  |
|  |  |  |  |  |
|  | Approval for Neonates of Uncertain Viability |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **LEVEL OF RISK** |  | **NONCOMPLIANCE (check all that apply)** |
|  |  |  |  |  |
|  | Minimal risk |  | x | N/A |
|  |  |  |  |  |
|  | Greater than minimal risk |  |  | Unsubstantiated |
|  |  |  |  |  |
|  |  |  |  | Minor (not serious, not continuing) |
|  |  |  |  |  |
| **NEXT REVIEW DATE** |  |  | Serious |
|  |  |  |  |  |
| x | One year |  |  | Continuing |
|  |  |  |  |
|  | Other – specify: |  |  | Refer to IRB Investigative Committee |
|  |  |  |  |  |
|  |  |  |  | Refer to another university review process |
|  |  |  |  |  |
|  |  |  | Determination pending/ Further information required |
|  |  |  |  |
|  |  |  | Corrective actions(s) required – \*provide comments |

**\*COMMENTS/MODIFICATIONS:**

|  |
| --- |
| SUMMARY:* Study purpose:
* Funding source (funded/unfunded/sponsor name):
* Study treatment and intervention(s) and duration of study:
* Planned enrollment number:
* Special populations (if any):
* Informed consent process and HIPAA authorization
* Monitoring process
* Incentives

 [describe any additional findings]COMMENTS:[Reviewer describes any necessary modifications or concerns]**EXAMPLE:**SUMMARY:The purpose of this unfunded study is to investigate functional biomarkers and examine the expression of molecular targets that can help define rheumatic autoimmune diseases in patient populations that share pathogenic mechanisms. The study will prospectively enroll 50 adults with autoimmune disease and a control group of 50 adults without autoimmune disease. The investigators also plan to obtain retrospectively archived specimen from healthy individuals that are not participating in the prospective portion of the study; these specimen will be obtained from pathology archives or from tissue procurement. Subjects in the autoimmune disease group will be asked to provide tissue and oral mucosa biopsies. Subjects in the control group will be asked to provide either tissue or oral mucosa biopsies. Informed consent and HIPAA authorization will be obtained from the subjects in the prospective phase and waivers of consent and HIPAA authorization were requested for the retrospective portion. A partial waiver of HIPAA authorization for recruitment purposes was also requested, which is appropriate. The PI will monitor the study for any adverse events; a DSMB will not be used. Subjects will not be paid for participation.COMMENTS:General:* It isn’t clear in the material provided if the investigators are trying to create a repository in addition to studying specific molecular targets. If a repository is being created, a separate study for the repository activities versus the research question must be submitted and the current submission revised accordingly.

Informed consent:* Section 3/page 2 does not fully describe all samples which will be collected and should be revised to include urine and stool in addition to blood and saliva samples.
* Section 11/page 9 includes a statement that payments are considered taxable income, however, there are no subject payments in this research.
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|  | Jane Doe |  | 7/1/2016 |  |
|   | IRB Reviewer |  | Date |  |