SAMPLE FOR-CAUSE AUDIT NOTIFICATION CHECKLIST

FOR USE BY THE REVIEWING IRB REQUESTING THE AUDIT

STUDY TITLE: _____

PRINCIPAL INVESTIGATOR: _____

PARTICIPATING SITE FOR AUDIT: _____

SITE INVESTIGATOR: _____

RELYING INSTITUTION POINT OF CONTACT: _____

SPONSOR: _____

Funding Sources *(check all that apply)*: ☐ Industry Sponsor ☐ Foundation ☐ Government/NIH ☐ Internal Funds

Type of Study: ☐ Drug/Biologic ☐ Device ☐ Tissue/Sample Repository ☐ Genetics ☐ Vaccine
☐ Questionnaire ☐ Chart Review/Database ☐ Other: _____

WHAT CONCERNS PROMPTED THE REQUEST FOR AN AUDIT?

☐ Reviewing IRB has reason to suspect serious or continuing noncompliance or unanticipated problem involving risk to subjects or others based on information received in a submission or upon report of an investigator or other member of the study team.

☐ Report of concerns from a third party (e.g., participant or sponsor complaints, institutional official request, or government agencies (e.g., FDA, NIH, OHRP).

☐ Reason to need verification that the Research is being conducted in accordance with the IRB-approved protocol [including known/suspected issues with study conduct, data integrity, etc].

Comments and additional information:

DOCUMENTS AND INFORMATION THAT THE REVIEWING IRB REQUESTS TO BE REVIEWED IN ORDER TO MAKE A DECISION REGARDING NON-COMPLIANCE? (include relevant subject selection and/or percent of records to be reviewed where applicable)

☐ Current Protocol in use by site

☐ Current Consent Documents in use by site

☐ Investigator/Study Team Training Documentation

☐ Source Documentation *(Specify)*: _____

☐ Other (e.g., Relying Institutions Policies, Study Manuals, Investigator Brochures, Notes to file, Adverse Event and Deviation logs, etc.) *(Specify)*: _____

☐ Additional information *(Specify)*:

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Time frame in which the audit should be conducted and communicated back to the Reviewing IRB.

How will information and documents, including relevant policies if necessary, be communicated between the Reviewing IRB and the Relying Institution (e.g., Reviewing IRB Institution's electronic system, summary report of submissions, pdf/zip file of relevant documents)*?

Will the Reviewing IRB or the Relying Institution be responsible for performing the audit? If a shared responsibility, specify what aspects will be audited under the direction of the Reviewing IRB and what aspects will be audited by the Relying Institution. In addition, specify if self-assessment by the Relying Site PI or Relying Site Study Team may be used to satisfy the review request.

** Secure file transfer requirements, if any, should be followed as per IRB-approved protocol and policies of Reviewing IRB and Relying Institution.*

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