

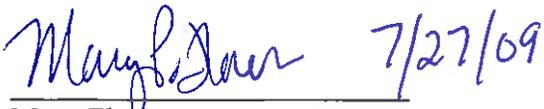
**DOCUMENTATION AND RECORD RETENTION STANDARD OPERATING
PROCEDURE**

**For NASA Johnson Space Center Institutional Review Board Committee for the
Protection of Human Subjects**

CPHS/SOP 001/2009_R1

July 16, 2009

SUBMITTED BY:

 7/27/09

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DOCUMENTATION AND RECORD RETENTION STANDARD OPERATING PROCEDURES

REVISION LOG

CPHS/POL 001/2009

REVISION NO	REVISION DATE	DESCRIPTION OF REVISION	PREPARED/REVISED BY
0	June 12, 2009	Original Document	Karen Mathes/Administrator, JSC IRB CPHS
1	July 16, 2009	Updated to reflect electronic retention of document	Karen Mathes/Administrator, JSC IRB CPHS

Documentation and Record Retention Standard Operating Procedures

I. IRB Record Documentation

The IRB Administrator will prepare and maintain documentation of the following:

A. IRB Research records to include:

- all original research proposals reviewed
- scientific evaluations, if any, that accompany the proposals
- approved consent documents
- applications for continuing review
- study progress reports and interim reports
- modifications
- adverse event or unanticipated problem report forms submitted by Investigators
- progress reports submitted by Investigators
- other reports such as page changes, protocol changes, adverse events etc.
- correspondence

B. IRB CPHS meeting minutes will be prepared, reviewed, and approved in a timely manner. Draft minutes will be available within 5 working days of the meeting date. Once signed by the Chair, and approved or amended by the members at a subsequent IRB meeting the minutes may not be altered. Final approved minutes are posted on the CPHS website in PDF format (<http://irb.nasa.gov> and <http://cphs.nasa.gov>).

IRB CPHS meeting minutes will include sufficient detail to document the following:

- The presence of a quorum throughout the meeting including the presence of one member whose primary concern is in a non-scientific area
- Attendance of members and alternates
- Approval of previous meeting minutes
- Discussion of expedited reviews and determinations
- Summary of the pertinent discussions of issues and resulting decisions
- Basis for requiring changes in or disapproving research
- Informed consent document was reviewed in accordance with applicable criteria and contains all of the required elements
- Risk level determination
- Contingent Approval Board recommendations
- Vote on reviewed proposals including the number voting for, against, and abstaining (with real or potential conflict of interest stated as the reason for abstention)
- When a member leaves the meeting and is unable to vote
- The frequency of continuing review of each proposal as determined by the IRB

- Any significant protocol-specific finding that may alter risk/benefit ratio
- Decisions regarding privacy including use or disclosure of protected health information, including HIPAA decisions

C. Current logs, audit reports, expedited reviews, continuing reviews and approval letters and correspondence between the IRB and Investigators are filed in electronic format and historical documents are stored in hard copy format. Statements of significant new findings are provided to the CPHS by PI's as part of the continuing renewal/protocol renewal application.

. Electronic records are stored electronically on a secure and password-protected server. Hard copy files are stored securely at the Wyle 1 Building, 1290 Hercules Ave, Suite 120, Houston, Texas, 77058. Files are in a badge access only area, past cipher locked doors, in locked office.

D. A roster of regular and alternate IRB members, along with Curriculum Vitae's, required completion of human subject research protection online training modules (CITI) and Conflict of Interest or Full Disclosure statements.

E. Standard Operating Policies and Procedures can be found at (<http://irb.nasa.gov> and <http://cphs.nasa.gov>) and include the following:

- Documentation and Record Retention Standard Operating Procedure (CPHS/SOP 001/2009)
- Full Committee Review Standard Operating Procedure (CPHS/SOP 002/2009)
- Expedited Committee Review Standard Operating Procedure (CPHS/SOP 003/2009)

II. IRB Record Retention

All JSC IRB records associated with specific research proposals are retained indefinitely. An off site storage facility shall be used to store archived materials. All records shall be accessible and available for inspection by authorized agency personnel at reasonable times in a reasonable manner

The CPHS office will conduct periodic self-assessment of IRB members and alternates to assure appropriate training. In addition, the CPHS office conducts human subject protection/safety training to government contractor employees and civil servant personnel with hard and electronic copies of sign-in sheets on-file.

The CPHS Office has the authority to develop, implement, and monitor the CPHS in accordance with federal, state and local law regulations. Policies and procedures will be reviewed annually to assure compliance with all regulations. The CPHS Office will track all changes to policies, procedures and guidance.

III. IRB Individual Protocol Records

The IRB Administrative Staff will prepare and maintain adequate documentation of IRB activities for each protocol under review. Each protocol is assigned a unique number and documentation is maintained in a separate file. The IRB records are organized to allow reconstruction of a complete history of all IRB actions related to the review and approval of the protocol and clearly indicate what the IRB actually approved.

Records for each protocol will include the following (as applicable):

- All materials required for a Full committee review as described:
<http://irb.nasa.gov/?p=apCreateNewApp>
- Documentation resulting from any review by the expedited procedure.
- Copies of all correspondence between the IRB and the investigators and key personnel, including substantive email communication as described in IRB Review Process – Communication of IRB Actions.
- Copies of study-related correspondence between the IRB and other entities, including regulatory authorities, other review committees and study subjects.
- Any additional documents deemed appropriate on a case-by-case basis.

IV. Access to Documents

The IRB Administrative staff will securely store and maintain these documents as required to protect the privacy and confidentiality of records. All electronic access to these files will be limited to authorized individuals, and the access by persons other than authorized individuals will be documented along with the purpose for which the files were accessed, and an audit trail kept of specific projects viewed or copied.

All records shall be accessible for inspection and copying by authorized representatives of Federal agencies or departments at reasonable times and in a reasonable manner. All other access to records shall be in accordance with applicable law and JSC policy.

Federal Regulations:

45 CFR 46.115

21 CFR 56.115

References:

OHRP Guidance on Written IRB Procedures – January 15, 2007.

<http://www.hhs.gov/ohrp/humansubjects/guidance/irbqd107.pdf>

FDA Information Sheets: Frequently Asked Questions: IRB Records

<http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBRecords>