

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Electronic Submission and Review Process Category: IRB Review Process	

I. Policy Statement

Parkview Health Institutional Review Board (PH IRB) has created an electronic database and has launched an email submission and electronic review process. As of April 15, 2011, paper submissions are no longer accepted by the PH IRB Office; hand written signatures are no longer required on PH IRB forms; and all research matters for review shall be submitted electronically to the PH IRB.

PH IRB maintains an electronic copy of study records on a Parkview Health (PH) password-protected, secure, network server. Study records may include, but are not limited to, submissions for review, reviewed research proposals and their associated application and report materials; and any pertinent correspondence between the IRB and the Investigator. All electronic records are backed up nightly as part of Parkview Health Information Services' standard procedures. These records are kept indefinitely.

II. Definition of Terms

Electronic Database: A collection of any data that is organized so that its contents can easily be accessed, managed, updated and stored electronically. This includes, but is not limited to, the storing of information in documents created or stored in Microsoft's Word, Excel, Access, Outlook, and/or SharePoint.

Logon: A unique, specific, confidential credential that identifies the person as a legitimate and authorized user of the computer and/or electronic system.

III. Procedure

- A. Until such time that all pertinent PH IRB Policies and Forms can be updated, this Policy supersedes all other PH IRB Policies and Forms to the extent that they may refer to paper copies, submissions, or requirements for signatures on IRB forms.
 - Signature lines on PH IRB forms may be completed by typing the appropriate name(s) and date on the signature and date lines.
- B. All research submissions to PH IRB shall be conducted by email. Other electronic media may be used under special circumstances.
- C. Email and other electronic accounts, passwords and logons shall not be shared.
- D. Usernames, passwords and logons are provided to individuals for their exclusive use. Sharing of this information is not appropriate. Logging onto the system or sending email under another person's identity to submit, review, or approve documents is considered the same as falsifying a hand written signature on a research application and related documents.

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Electronic Submission by Email Process:

- A. The Principal Investigator (PI) of a clinical trial or research project is ultimately responsible for all aspects of the study, including submissions to the IRB. The PI must approve each submission that is sent to the IRB.
- B. All IRB-related submissions and documents shall be submitted by the Investigator, or their designee(s), to PH IRB, by using email. Other electronic media may be used under special circumstances.
- C. To download and complete the appropriate forms, go to the PH IRB web site, irb.parkview.com. An electronic copy of the completed application should also be kept in the Investigator's records.
- D. All supporting materials (e.g. survey instruments, consent forms, subject materials) must be clearly labeled and submitted as either Word documents or PDF files along with the application.
- E. Word documents or original PDF documents are preferred over scanned PDF files. Please do not submit a scanned PDF file unless there is no other option.
- F. Forward the application and supporting documents as email attachments to the PH IRB Office.
- G. An email response shall be sent in return notifying the Investigator of receipt of the application, and of any revisions or additions that may be necessary.
- H. Submissions to PH IRB shall no longer be rubber-stamped and dated as "Received", as the email date and time shall serve as this documentation.
- I. After PH IRB review and approval, Review Certificates shall be sent electronically and shall serve as notice of approval and/or acknowledgement. Paper documents shall no longer be provided or rubber-stamped as "Approved". Exceptions may be made to accommodate special circumstances.

Investigator Statement of Compliance

- A. Submission of an application shall serve as assurance that the following statements are true, regardless of whether they have been added to all appropriate PH IRB Forms:
 - 1. By submitting this form, the Principal Investigator assures that all information provided is accurate. He/she assures that procedures performed under this project will be conducted in strict accordance with federal regulations and PH IRB policies and procedures that govern research involving human subjects. He/she acknowledges that he/she has the resources required to conduct research in a way that will protect the rights and welfare of participants and that he/she will employ sound study design which minimizes risks to subjects. He/she agrees to submit *any* change to the project (e.g. change in Principal Investigator, research methodology, subject recruitment procedures, etc.) to the IRB in the form of an amendment for IRB approval prior to implementation except where necessary to eliminate apparent immediate hazard to the

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subjects. Any changes relating to Conflict of Interest will be reported immediately to the PH IRB. Any unanticipated problems involving risks to human subjects or others will be reported to the IRB immediately.

2. The Principal Investigator certifies that he/she has reviewed this IRB Application and ensures that all materials are accurate and complete.
 3. My typed name below shall have the same force and effect as my hand written signature.
- B. The PI's name and/or designee(s), or other name(s), and dates, shall be typed on "signature" lines on all submission forms forwarded to the IRB.

PH IRB Member Review Process

- A. Research applications and documents for review shall be available electronically to PH IRB Members for each IRB meeting through a designated, password-protected, secure site on a PH server.
- B. Members shall have adequate advance notice prior to the Meeting date that all documents have been uploaded and are ready for review.
- C. Members shall use their unique logon to access the documents.
- D. IRB Meetings shall be conducted with electronic documents. Paper documents shall no longer be provided. Exceptions may be made to accommodate special circumstances.

IV. References

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