

**HOSPITAL FOR SPECIAL SURGERY**

**Institutional Review Board**

**IRB SUBMISSION REQUIREMENTS**

eCAP is the acronym for the HSS electronic Clinical Application Portal. All of the Services at HSS use eCAP for submission of their clinical research protocols.

The eCAP Home Page is accessed via the following links:

Internet access: <http://www.hss.edu/institutional-review-board.asp>

Intranet access: http://intranet.hss.edu/research/IRB

eCAP Account: Contact Yang Zhou (zhouy@hss.edu) to have an eCAP account created for you. Provide her with your name, department, e-mail address and study role (study staff, co-investigator, coordinator) or questions about log in.

eCAP training: Contact Charles Castel (castelc@hss.edu) in the IRB Administration Office.

There are **eCAP Quik Guides** available to guide you through creating, revising and submitting a protocol for CRP and IRB review at this [link](http://intranet.hss.edu/research/IRB/index.htm).

Contact Barbara Bosco, Manager, Clinical Review Panels, x1914, (boscob@hss.edu)  for questions relating to the CRPs.

**OVERVIEW OF THE IRB SUBMISSION PROCESS**

The submission process for review of human subject research protocols is divided into two segments:

* Scientific Preview and Approval (Parts I & II)
* IRB Review and Approval (Part III)

**Scientific Pre-Review**

The Scientific Clinical Review Panels (CRPs) review research protocols prior to submission to the IRB. The CRPs focus on:

* assessing feasibility of a study,
* the research questions and outcomes,
* study design,
* data being collected,
* sample size and data analysis

This is done to ensure that the scientific methodology is sound so investigators will be able to answer their research questions at the conclusion of the study and to ensure that it will be publishable.

**NOTE: Be sure to upload the sponsor protocol for externally-sponsored studies.**

**SCIENTIFIC PRE-REVIEW**

*All protocols must be pre-reviewed and approved by the appropriate Departmental Clinical Pre-Review Panel****.***

***Complete Parts I & II of the eCAP Smartform, upload appropriate documents and submit it to your appropriate Clinical Review Panel for scientific review.***

**NOTE:**

**Only the PI can submit a new protocol to the CRP.**

**The Smartform is ‘locked’ upon submission to the CRP.**

*Please consult the list below for the Chairpersons and contact individuals to obtain information for submission requirements and deadlines.*

There are 10 CRP’s:

**Orthopaedic CRP:** Dr. Jo A. Hannafin is the Chair; Barbara Bosco is the Administrator, x1914

**Rheumatology CRP**: Dr. Lisa Mandl is the Chair; Carey Ford is the Administrator, x1698

**Arthroplasty CRP**: Dr. Douglas Padgett is the Chair; Amethia Joseph is the Administrator, x8757

**Radiology CRP**: Dr. Ted Miller is the Chair; Roseann Zeldin is the Administrator, x1025

**Rehabilitation CRP**: Mary Murray-Weir is the Chair; Gwen Weinstein-Zlotnick is the Administrator, x1660

**Anesthesia CRP**: Dr. Jacques YaDeau is the Chair; Jodie Curren is the Administrator, x2946

**Physiatry CRP:** Dr. Ellen Casey is the Chair, Jennifer Cheng, PhD, is the Administrator, x6870 **Neurology CRP:**  Dr. Ronald Emerson is the Chair; Douglas Williams is the Administrator, x1046

**Nursing CRP**: Patricia Quinlan is the Chair, Shanelle O’Rourke-Brown is the Administrator, x1191

**Education/Social Work CRP:** Dr. Laura Robinson is the Chair; Titilayo Ologhobo is the Administrator, x 2185

Information regarding meeting dates and submission deadlines for the Clinical Review Panels is available at this [link](http://intranet.hss.edu/research/IRB/83.htm).

A **biostatistician** is also assigned as a member of each CRP. It is advisable **to set up a consultation** **for statistical assistance** with a study early in the process of writing it. Download and complete the study intake form which can be found at this [link](http://www.hss.edu/epi-biostats-intake). A statistician will be assigned to assist you with sample size calculation, statistical analysis, controls, randomization, etc.

**There are several exceptions to the rule regarding CRP review of a protocol:**

* Studies that only involve the **retrospective review of existing data** bypass the CRP and are submitted directly to the Research Service Chief for sign off. Once the Research Service Chief signs off via ECAP then the study goes directly to the IRB for review and approval. Be sure to select the “Expedited Retrospective Chart Review” button under Section #7 on the first page of the eCAP application.
* Case Reports also go directly to the IRB for review – use the “Expedited Retrospective Chart Review” selection for your case report.
* Studies that qualify for Exempt Review also bypass the CRP and go directly to the Research Service Chief for sign off. Once the Research Service Chief signs off via ECAP then the study goes directly to the IRB for review. If you need help in deciding which Exempt Category to choose, contact the IRB Office at x2456 or x2939.

**IRB REVIEW**

*After the scientific pre-review panel has reviewed and approved your protocol*

***complete Part III, upload the consent form(s) and any additional documents and submit the protocol to the IRB for review*** *.*

**NOTE:**

**Only the PI can submit a new protocol to the IRB**

**The Smartform is ‘locked’ upon submission to the IRB.**

***Protocols that qualify for Full Board Review are due on the 1st of every month****.*

***Protocols that qualify for Expedited Review can be submitted at any time.***

*If you have any questions, call the IRB Administrative office at ext. 2939 or 2456.*

**TIPS:**

If your study involves minors, be sure to upload a completed Assent Form for Child Participation in a Research Study to the SmartForm, as well as the Informed Consent form with a Parent/Legal Guardian signature. The Assent form should be written at the appropriate age level, i.e. 7 – 12 years old or 13 – 18 years old.

The HIPAA Waiver form is embedded in the eCAP new protocol application (Section 3.71).

Consult the HIPAA Compliance Project/Research/Research Policy and Forms on the HSS intranet to determine the appropriate authorization form or HIPAA waiver (Full/Partial/Alteration) for your protocol. Please contact Ms. Andrea Ansorge, Vice-President for Corporate Compliance and Internal Audit at x2398 if you have questions or need advice.

**Financial disclosure** **forms must be completed for all professional personnel listed on the protocol. Potential conflict of interest must be reviewed and mitigated by the Conflict of Interest Committee for Research (COIC) before it is reviewed by the IRB.** HSS policy provides that an investigator or Research Staff member may not participate in human subjects research when he/she or a member of their Immediate Family has a Financial Interest in the organization sponsoring the research or that makes the drug, biologic, or device that is being researched, unless the researcher receives the approval of the Conflict of Interest Committee for Research, and then only on the conditions approved by the COIC.  If you have, or any investigator listed on the protocol has, a Financial Interest in the study, it must be disclosed to the COIC which will work with you or the investigator to prepare a statement to disclose the Financial Interest in the informed consent form.  Please contact the COIC members responsible for human subjects research (Vincent Grassia, Vice President, Research Administration, x2261, and Dr. Robert Hotchkiss, Director of Clinical Research, x1964) with any questions about this.

Documents that may be included in a submission:

* Consent and Assent Forms
* Genetic testing consent form (if applicable) AND Research Authorization
	+ **Please note, the genetic testing consent is NOT combined with the Research Authorization. Therefore, the Research Authorization must be submitted separate from the consent.**
* Financial Disclosure Forms for **ALL** study team members.
* Questionnaires, data collection forms, advertisements, recruitment letters/scripts, Investigator Brochures, sponsor protocols, etc., that will be utilized with the study.

**Institutional Registries**

There are 9 Institutionally-Sponsored Registries: Anterior Cruciate Ligament Reconstruction, Cartilage Repair, Total Shoulder Arthroplasty, Hip Pain and Preservation, Foot & Ankle, Hip and Knee Joint Replacement, Osteolysis Tissue, Physiatry, Scoliosis.

Each of the Registries has a Steering Committee that is responsible for reviewing and approving proposals to access data in the registries. Form 5A (a paper form) is used for proposals to access and review Registry data. Once the Registry Steering Committee approves a study it can begin without IRB review and approval. However, if a study involves collecting additional data that does not exist in the Registry, the proposal will also have to be reviewed and approved by the IRB. Choose “Existing Registry” in the Study Design Question #7 on the first page in eCAP. Complete the SmartForm and upload the Approved Form 5A and submit it to the IRB for review. Be sure to include information on the additional data that is being collected, as well as information regarding the statistical analysis that will be done on this additional data.

For Registry data requests, please refer to the “Guidelines for Requesting Registry Data for Research Proposals” on the [Forms and Guidelines](http://intranet.hss.edu/research/IRB/62.htm) webpage.

All the material, including the ***HSS Human Subjects Protection Policies and Procedures*** are

available on the Clinical Research Administration webpage on the [HSS Intranet](http://intranet.hss.edu/research/IRB/).

Click on this link for the [HSS Patient Registries](http://intranet.hss.edu/research/185.htm) webpage.