

# IBC Ceded Review Request Form

## Purpose of this form

To facilitate centralized review of research and reduce the burden on Harvard Catalyst investigators who propose to conduct research in multiple locations, investigators conducting research at more than one site may submit this form to request review by a single Institutional Biosafety Committee (IBC). The request will be considered by the relevant IBCs and a decision will be made on a case-by-case basis. Additional review may be required. Acceptance of the cede review request does not indicate IBC approval. A separate IBC Application will be required and additional training may also be required.

## When to use this form

Investigators should use this form before submission of an IBC application and when the research is ready for IBC review. For research that has previously been reviewed and approved, this form may also be used to request review by a single IBC by adding new sites to an existing protocol. This form is designed to support requests for single IBC review among the signatory institutions of the Harvard Catalyst Common Reciprocal IBC Reliance Agreement. However, the form may be used to request reliance with Harvard Catalyst investigators and non-signatory institutions. Reliance will be considered on a case-by-case basis.

## Definitions

**Overall Principal Investigator (PI):** Overall Principal Investigator has the ultimate responsibility for the conduct of research to ensure subject safety and data integrity for research that will be carried out collaboratively among two or more institutions. Collaborators may be from other institutions outside of Catalyst.

**Collaborating PI and/or Site Investigator (Site PI):** The Site Investigator is responsible for the conduct of research at the institution where s/he is employed. Unless the Overall PI is cross-credentialed, at least one Site PI is required for each site participating in multi-center research.

**Relying and Reviewing Institution/IBC:** When an institution cedes its IBC review to another institution's IBC, the institution that cedes review is called the "Relying Institution" and the institution that accepts the review is called the "Reviewing Institution."

## Application process

The application **must** include at least one Harvard Catalyst investigator. The Overall PI (or designee) should complete this form and submit completed form to the IBC of the Institution where the Overall PI is Primarily Employed (this is the institution where you receive your paycheck). Although investigators may have appointments at multiple institutions, investigators are usually considered "an employee" or a "workforce member" of one institution. The institution from which the investigator receives his/her paycheck is generally considered the institution of primary employment. For Harvard University employees, this would be the School at which the primary appointment is held.

For consideration, the following information is requested:

- Name and contact information of Overall PI as well the collaborators
- IBC requested to be the reviewing IBC and why
- Title and brief description of your research.
- The sites where the research will be conducted. Should you request consolidated review with a non-Harvard Catalyst site, please be aware that should cede be granted, additional review requirements and agreements will be required.
- The activities which will be conducted at each site.

**Please note that items marked with a \* are required.**

**When the form is complete, please email it to all IBC contacts for the participating sites (see Appendix A).** Once a request is submitted, all institutions indicated as participating will be notified of the request. The IBCs will consult with each other to determine whether a single IBC review is appropriate and, if so, which IBC should be the Reviewing IBC. While the application allows a specific IBC to be requested, the IBCs retain the right to determine which IBC is most appropriate for review, including a determination that the request is not appropriate for consolidated or single IBC review. Once your request is received, you should hear from an IBC contact within five business days. For any questions about the status of a submitted application please contact the designated IBC contact from the PI's home institution.

See Appendix A for the list of IBC contacts.

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## 1. NAME AND CONTACT OF INDIVIDUAL COMPLETING THIS FORM

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**First Name:\***

**Last Name:\***

**Email (Please use the institutional email address):\***

**Phone:\***

**Institution:**

*If Other Institution, please include institution, collaborator and contact information:*

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## 2. OVERALL PRINCIPAL INVESTIGATOR, IF DIFFERENT FROM ABOVE

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**First Name:\***

**Last Name:\***

**Email (Please use the institutional email address):\***

**Phone:\***

**Institution:**

*If Other Institution, please include institution, collaborator and contact information:*

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## 3. REQUESTED IBC\*

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### 2.1. WHICH IBC DO YOU REQUEST AS THE REVIEWING IBC:

(H = Harvard COMS; P = Partners IBC; See Appendix A for details)

Beth Israel Deaconess Medical <sup>H</sup>

Harvard Medical School <sup>H</sup>

Massachusetts Eye and Ear <sup>H</sup>

Boston Children's Hospital

Harvard T. H. Chan School of Public Health <sup>H</sup>

Massachusetts General Hospital <sup>P</sup>

Brigham and Women's Hospital <sup>P</sup>

Harvard School of Dental Medicine <sup>H</sup>

McLean Hospital <sup>P</sup>

Dana-Farber Cancer Institute

Harvard Faculty of Arts and Science <sup>H</sup>

Schepens Eye Research Institute <sup>H</sup>

Forsyth Institute

Joslin Diabetes Center <sup>H</sup>

Spaulding Rehabilitation Hospital <sup>P</sup>

Other institution *Include institution, collaborator and contact information:*

**3.1. THIS IBC IS REQUESTED TO BE THE REVIEWING IBC BECAUSE (CHECK ALL THAT APPLY)\***

- |                                     |  |
|-------------------------------------|--|
| Institution of Primary Employment   | Research infrastructure considerations (i.e. lab space, equipment) |
| Feedback from IO, IBC chair, others | Expertise considerations (i.e. IBC experience, science expertise)  |
| Confidentiality/privacy concerns    | Concerns regarding oversight needs                                 |

**3.2. EXISTING APPROVALS**

If this research has already been approved by an IBC, and you are requesting an additional site(s) be added to your existing IBC approval, please note here.

**Reviewing IBC:**

**Review/Protocol #:**

**Review Date:**

**Additional Notes:**

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**4. RESEARCH INFORMATION**

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**4.1. TITLE OF RESEARCH PROJECT (PLEASE INCLUDE BELOW)\*:**

**4.2. BRIEF DESCRIPTION\*:**

Please describe in lay terms the proposed study and the study methods. An IBC representative may also request additional supporting documentation.

**4.3 RESEARCH SPECIFICS\***

Type of study	Containment	Other
Laboratory study	Does the study require a BL3 facility?	To your knowledge are other approvals required for this research?
Animal	No      Yes	No      Yes
Lab (Bench)	Does the study involve a select agent(s) or a biological toxin(s) subject to the National Select Agents Registry Program managed by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA). The current list of toxins is available at: <a href="http://www.selectagents.gov/index.html">http://www.selectagents.gov/index.html</a> ?	<i>If yes, please indicate:</i>
Other		IACUC
Human clinical trial	No      Yes	Please name the Reviewing IACUC:  IRB Please name the Reviewing IRB:  Other Please name:

**4.4. THE SITES INVOLVED IN THIS RESEARCH ARE (CHECK ALL THAT APPLY)\*:**

Beth Israel Deaconess Medical <sup>H</sup>	Harvard Medical School <sup>H</sup>	Massachusetts Eye and Ear <sup>H</sup>
Boston Children's Hospital	Harvard T. H. Chan School of Public Health <sup>H</sup>	Massachusetts General Hospital <sup>P</sup>
Brigham and Women's Hospital <sup>P</sup>	Harvard School of Dental Medicine <sup>H</sup>	McLean Hospital <sup>P</sup>
Dana-Farber Cancer Institute	Harvard Faculty of Arts and Science <sup>H</sup>	Schepens Eye Research Institute <sup>H</sup>
Forsyth Institute	Joslin Diabetes Center <sup>H</sup>	Spaulding Rehabilitation Hospital <sup>P</sup>

Other institution *Include institution, collaborator and contact information:*

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**5. COLLABORATORS AND RESEARCH ACTIVITIES\***

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In the following section, for each site listed above please list your collaborator(s) and explain the research activities at each site

**5A. NAME AND CONTACT OF COLLABORATING PI(S)/SITE INVESTIGATOR (S)**

**First Name:\***

**Last Name:\***

**Email (Please use the institutional email address):\***

**Phone:\***

**Institution:**

*If Other Institution, please include institution, collaborator and contact information:*

Activities/procedures that will be conducted at this site:

**5B. NAME AND CONTACT OF COLLABORATING PI(S)/SITE INVESTIGATOR (S)**

**First Name:\***

**Last Name:\***

**Email (Please use the institutional email address):\***

**Phone:\***

**Institution:**

*If Other Institution, please include institution, collaborator and contact information:*

Activities/procedures that will be conducted at this site:

**5C. NAME AND CONTACT OF COLLABORATING PI(S)/SITE INVESTIGATOR (S)**

**First Name:\***

**Last Name:\***

**Email (Please use the institutional email address):\***

**Phone:\***

**Institution:**

*If Other Institution, please include institution, collaborator and contact information:*

Activities/procedures that will be conducted at this site:

**5D. IF ADDITIONAL COLLABORATORS, PLEASE LIST BELOW**

(Include: first name, last name, email address, phone, and institution; if necessary include additional collaborator information in separate document):

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## APPENDIX A: IBC CONTACTS

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### **Boston Children's Hospital**

Despina Felis

Despina.Felis@childrens.harvard.edu

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### **Dana Farber**

Karen Byers

Karen\_Byers@dfci.harvard.edu

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### **Forsyth Institute**

Kathy Eklund

KEklund@forsyth.org

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### **Harvard COMS**

Rebecca Caruso

Rebecca\_Caruso@hms.harvard.edu

Web: <http://hms.harvard.edu/departments/committee-microbiological-safety>

#### **Please note that Harvard COMS conducts IBC review for the following institutions:**

Beth Israel Deaconess Medical Center, Joslin Diabetes Research Center, Harvard Medical School, Harvard School of Dental Medicine, Harvard T.H. Chan School of Public Health, Harvard University Faculty of Arts and Sciences, Massachusetts Eye and Ear, Schepens Eye Research Institute.

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### **Partners Healthcare IBC**

Ryan Schlimgen

rschlimgen@partners.org

Web: [http://resadmin.partners.org/RM\\_Home/Research\\_Support\\_Depts/Research\\_Oversight/PIBC/About/AboutPIBC.aspx](http://resadmin.partners.org/RM_Home/Research_Support_Depts/Research_Oversight/PIBC/About/AboutPIBC.aspx)

#### **Please note that Partners Healthcare IBC conducts IBC review for the following institutions:**

Brigham and Women's Hospital, Inc., Massachusetts General Hospital, McLean Hospital Corp., Spaulding Rehabilitation Hospital Network.