

# Charter

The Implantable Brain-Computer Interface  
Collaborative Community (iBCI-CC)



**Executive summary:** The goal of the iBCI-CC is to foster collaboration among diverse stakeholders, including researchers, clinicians, medical device manufacturers, patient advocacy groups, and people with lived experience, to accelerate the development, safety and efficacy evaluation, and access to iBCI technologies.

**Vision:** We envision a future where iBCIs improve the lives of individuals, empowering each user of an iBCI to lead a fuller and more independent life.

**Mission:** The iBCI-CC is an inclusive organization that seeks to advance the field of iBCIs through a platform that develops and uses harmonized approaches to drive continuous innovation and equitable access to iBCIs by:

1. Utilizing regulatory science tools to support evidence-generation and inform the community about topics relevant to iBCIs,
2. Creating inclusive platforms for addressing complex problems, and
3. Convening diverse stakeholders to enable discussion and education of each other and the broader community.

**About Us:** The iBCI-CC brings together a broad range of stakeholders in the pre-competitive space, focused on addressing challenges and harnessing opportunities related to iBCI innovation. The iBCI-CC aims to foster collaboration among stakeholders, including people with lived experience of neurological injury or disease, researchers, clinicians, medical device companies, patient advocacy groups, ethicists, regulators, federal agencies, and research support organizations. In addition, the iBCI-CC will create a platform that will lead to enhanced evidence to support regulatory tools for evaluation, identifying efficient approaches for accelerated delivery, thereby ensuring individual users can thrive in society with this transformative technology.

**Scope:** Implantable Brain Computer Interfaces are medical devices whose recording elements are implanted under the scalp or in the intracranial space, including with intravascular, epicortical, and/or intraparenchymal electrodes. iBCIs sense signals from the brain, interpret that brain activity (e.g. via software), and facilitate restoration or rehabilitation of function to improve users' quality of life. For the purposes of initial focus, deep brain stimulation devices along with other brain stimulation technologies are outside the initial scope of the iBCI-CC. The evaluation component of the iBCI-CC will assess value and performance of the iBCI-CC. The iBCI-CC uses regulatory science tools that develop methodologies, data analysis, and frameworks to support evidence generation that leads to increased understanding of practical and valuable approaches for evaluating products and processes related to implantable brain-computer interfaces.

## **1.0 Meetings:**

All Regular meetings of the iBCI-CC will be open to all Members and the public, promoting transparency and inclusivity. Regular meetings are intended to provide updates on recent activities and to coordinate the scope of collective efforts. Regular meeting minutes will be taken and shared publicly.

### **1.1 Regular Meetings:**

Regular meetings may be held on such date and at such time as designated by the Convener from time to time and stated in the notice of the meeting. At least one Regular meeting shall be held annually. Regular meetings may be held in-person or remotely. Notice of Regular meetings will be provided at least fourteen days in advance of the meeting. Notices will be provided via the website and email to the Members. The meeting agenda for Regular meetings will be determined and set by the Convener in collaboration with the Charter Signatories. The agenda will be designed to address key topics, updates on ongoing workgroups and projects, and any new issues or challenges that need to be discussed.

### **1.2 Special Meetings:**

Special meetings may be requested by a Charter Signatory at any time; notice of the time and place of each Special meeting will be provided at least three days in advance of the meeting.

### 1.3 Quorum:

A quorum is defined as 75% of the Charter Signatories, whether present in-person or remote, at any properly called Regular or Special meetings of the Members.

### 1.4 Voting:

The iBCI-CC will aim to reach consensus on all substantive questions without requiring a formal vote. Voting will only take place when a quorum is established. The iBCI-CC should only conduct a vote to resolve a substantive issue after the Convener has determined that all available means of reaching consensus through technical discussion and compromise have not succeeded and that a vote is necessary to break a deadlock. In this case the Convener shall record in the meeting minutes: an explanation of the issue being voted on, the decision to conduct a vote to resolve the issue, the outcome of the vote, and any formal objections. Voting shall take place by Members with voting rights (Section 3.2). Final votes are determined by simple majority. All dispute adjudication will be exercised before the full community. The only exception to Section 1.4 appears in Section 5.0 regarding amendments to the Charter.

## **2.0 Workgroups:**

To facilitate advances and innovation in implantable brain computer interfaces, the iBCI-CC believes in distributing tasks across Workgroups consisting of stakeholders who have expertise, interest, and/or willingness to develop and deliver clear recommendations on important issues for further discussion and deliberation by the broader iBCI-CC. Workgroups will disseminate project information and updates through educational outreach, scientific presentations, and by making all resources broadly and publicly available. These Workgroups address topics that include but are not limited to:

- User Priorities/Preferences and iBCI Use Cases
- Clinical Study Endpoints
- Clinical Practice Guidelines
- Payor Interactions and Device Categorization
- Modular Components, Interoperability, and ISO/Other Standards

- Public Messaging, BCI Education, and Regulatory Science Education that could support policy
- Ethics, Neural Data Privacy, and Data Security

### **3.0 Membership:**

#### **3.1 General Conditions of Membership:**

Any individual or organization with a demonstrated interest in the cause of the iBCI-CC, as enumerated in the Mission, may apply for membership in the iBCI-CC. Members are encouraged to actively participate and contribute to the community's goals and projects, with the understanding that a minimal level of engagement is required to maintain membership status. The iBCI-CC aims to have a membership of diverse stakeholders, including patient advocacy organizations, industry representatives and leading researchers among our members. Members are expected to actively participate in meetings, provide input and feedback. A Member may withdraw from the iBCI-CC at any time by providing written notice to the Convener. As a condition of membership, all Members agree to abide by the iBCI-CC's Code of Conduct. Violation of the Code of Conduct will result in membership being revoked as outlined in the Code of Conduct policy. This process will be overseen by Charter Signatories.

#### **3.2 Members:**

The iBCI-CC has two classes of memberships: Charter Signatories and General Members (collectively, the "Members").

##### **3.2.1 Charter Signatories:**

Charter Signatories are the sole voting class of Members in the iBCI-CC. Each Charter Signatory shall have one vote and is a signatory on the Charter. Additional Charter Signatories may be added at any time upon the unanimous consent of the then-current Charter Signatories. Charter Signatories will be reviewed on an annual basis.

##### **3.2.2 General Members:**

As set forth in Section 3.1, any individual or organization is eligible to apply for General Membership. General Members are key contributors to the activities of the iBCI-CC. As

determined by the Convener, General Members may participate in or lead Workgroups and committees of the iBCI-CC. General Members have no voting rights in the iBCI-CC.

### 3.3 Convener:

The Convener for the iBCI Collaborative Community is responsible for providing general oversight, administrative and operational support, financial management, and ensuring compliance with the community's objectives. Mass General Brigham (MGB) serves as the Convener for the iBCI-CC on record.

The Convener also assumes various responsibilities, including providing general oversight to ensure the smooth functioning of the iBCI-CC. Furthermore, the Convener ensures that all activities of the iBCI-CC align with the charitable mission, fostering a cohesive and purpose-driven collaboration within the community. An amendment to the relationship with the Convener must be approved by a unanimous vote by the iBCI-CC Charter Signatories.

### 3.4 Roles and Responsibilities:

- 3.4.1 **Members:** Members as defined in section 3.2 may be a member of any stakeholder group, with documented expertise or experience, with an interest in implantable brain computer interface innovation and development. Members must be approved to join the iBCI-CC and must actively participate in at least one Workgroup.
- 3.4.2 **Convener:** The Convener, as defined in section 3.3, has the primary responsibility is to serve as the organizer and administrator of the collaboration, carrying out the preliminary and follow-up tasks to establish and maintain the collaboration. The Convener's task may include:
  - Clarifying the purpose of the collaborative leadership effort
  - Developing and maintaining a list of potential stakeholders to invite to the iBCI-CC
  - Managing the membership and Workgroups
  - Addressing the financial and legal structures of the iBCI-CC.

The Convener is instrumental in administering the collaborative leadership and does not serve as the facilitator. The Convener may work with non-members on administrative and operational aspects of the iBCI-CC, but core iBCI-CC activities will be completed by Members.

#### 4.0 Goals:

The iBCI Collaborative Community will strive to achieve the following goals, which include but are not limited to:

- enable the potential of implantable Brain Computer Interfaces using regulatory science approaches,
- train and educate stakeholders in pre-competitive regulatory science relevant to iBCIs,
- promote, collaborate, and advocate in dialogue with payers including public and private healthcare insurers to support a pathway to reimbursement,
- facilitate clinical progress in the field of implantable BCIs,
- accelerate harmonized exchange of information and curate the necessary levels of scientific evidence to drive regulatory and reimbursement decisions, and
- simplify and clarify iBCI human subjects research regulatory processes and authorities across federal funding agencies and FDA.

##### 4.1 Project Goals:

The collaborative community aims to develop regulatory science tools, familiarize the community about regulatory pathways and guidances, and facilitate the development of integrated solutions for implantable BCIs from inception to clinical implementation to commercial market availability. The iBCI-CC will dissolve once people living with conditions that may benefit from the use of iBCIs in the U.S. and abroad have available a range of safe, effective, solutions for implantable BCIs.

##### 4.2 Project and Workgroup framework:

The iBCI-CC has *Projects*, conducted by *Workgroups*. *Workgroups consist of Members who work collaboratively on a Project, or who work collaboratively on more than one*

*Project that share a common theme or area of interest. Workgroups are approved by consensus (or, if necessary, vote) of Charter Signatories.*

Workgroups and their Projects strive to:

- integrate end-user perspectives by including people with lived experience and patient advocates;
- investigate and develop methods and tools to help specify risks and benefits in the precompetitive phase;
- help delineate the order of events to enable clinically meaningful and patient reported outcome measures (PROMs);
- make available relevant resources that can shorten the development of iBCIs such as ground-truth data sets and regulatory tools;
- understand the regulatory pathways and inform evidence-based tools to address key scientific and device development questions in the precompetitive space.

The iBCI-CC will make materials publicly available and share links to relevant organizations to help all stakeholders.

The iBCI-CC will focus initially on regulatory and translation issues in the United States.

## **5.0 Charter amendments:**

This Charter may be altered, amended, or repealed, in whole or in part, by unanimous approval of the then-present Charter Signatories, given a quorum is met.

## **6.0 Framework Evaluation:**

The iBCI-CC strives to assess its effectiveness through evaluating the inclusion of a wide range of stakeholders, output in terms of educational materials and guidelines, and proactive public information sharing of challenges to progress in the field. Our ultimate evaluation factor is the progress of iBCI technologies reaching the people who may benefit. We will continuously adjust our framework to drive successful innovation.

## Charter Signatories

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1. Jennifer French, M.B.A.  
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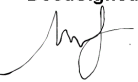
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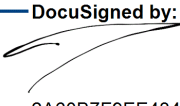
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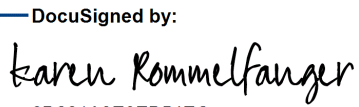
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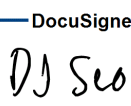
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