Reporting Standards for *in vivo* Neural Interface Research (RSNIR) to Accelerate Interoperability, Clinical Integration, and Commercialization of NeuroTechnologies

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Overview (Objectives)

• WHY Standardize?
  ➢ Rationale for standardization of neural interface research reporting

• WHAT to Standardize (next)?
  ➢ Intro and scope of IEEE Working Group P2794 (RSNIR)

• WHO Are we?
  ➢ WG P2794 membership and constitution

• HOW are we doing it?
  ➢ WG Strategy and Segmentation
  ➢ Current & Upcoming Activity
  ➢ Input: How can you contribute?
WHY Standardize?

…what’s the need? … what’s the value?

→ to enable INTEGRATION!

1. Interoperability (Functional Integration)
   - Ecosystem of “plug & play” devices and systems
   - Functional/integrative neuroscience
   - Multimodal rehabilitation

2. Assimilation (Information Integration)
   - Personalized & evidence-based medicine
   - Systems neuroscience & multimodal rehab

3. Translation (Clinical & Commercial Integration)
   - Demonstration of value via rigorous validation and reporting
Innovative Research & Development Process

Knowledge

Hypothesis

Experimental Design → Execution

Engineering Innovation

Data Analysis & Interpretation

REPORTING (Publication)

Commercial Device Development

Clinical Practice

(Scientific Impact + Funding)
WHY Standardize Reporting?

→ High-quality, high-impact publications are a primary de facto objective for neurotechnology researchers

→ Rigorous experimentation and reporting is the way to validate, communicate, and translate the value of neurotechnology
  ➢ To scientific reviewers
  ➢ To funding agencies
  ➢ To (medical) device regulators
  ➢ To healthcare payers
  ➢ To device users (doctors, clinicians, patients)

→ Therefore, reporting standards can establish a broad incentive scheme for both neurotech researchers and device developers
  ➢ For researchers: via scientific publication review
  ➢ For commercial developers: via regulatory body review
Intro: IEEE Working Group P2794: Reporting Standards for *in vivo* Neural Interface Research (RSNIR)

- **WG P2794 Officers**
  - **Chair:** Zach McKinney – Scuola Superiore Sant’Anna
    (zmckinney@ieee.org)
  - **Vice Chairs:** Dennis McBride – NeuroRx, Source America
    Calvin Eiber – University of Melbourne
  - **Secretary:** Yu Yuan – Senses Global Labs & Ventures

- **Sponsoring Committee Representative:**
  - Carole Carey – C3-Carey Consultants, EMB/Std’s Com

- **IEEE Support Staff**
  - Tom Thompson
WG P2794 Affiliation

- **Sponsoring Society & Committee:** IEEE Engineering in Medicine & Biology Society/Standards Committee (EMB/Stds Com)
- **Outgrowth of IEEE Industry Connections Activity IC17-007:**  
  - NeuroTechnologies for Brain-Machine Interfaces (NT-BMI)
    - Scope of NT-BMI: provide summary & gap analysis of BMI landscape w. respect to standardization, as precursor for further BMI standardization
    - WG conception at BMI Standardization Workshop, BCI Society Meeting, May 24, 2018 -- Asilomar, CA (Chaired by NT-BMI Leadership)
- **Additional Active Working Groups** originating from NT-BMI
  - P2731 – Standard for Unified Terminology for Brain-Computer Interfaces
  - P2725.1 – Standard for Microwave Medical Imaging Device Safety
IEEE WG P2794: Reporting Standard for *in vivo* Neural Interface Research (RSNIR)

**WG Roster: 53 Total Participants**
- 37 Members (25 Voting, 12 Non-Voting)
- 13 Observers + 3 IEEE Staff

**Distribution of WG Participant Affiliations:**
(participants may list more than one affiliation type)

- Academic (or non-profit) Research Lab: 36
- Commercial Entity: 14
- Standardization Organization: 6
- Neural Interface End User: 5
- Other: 4
- Scientific Publication: 4
- Private Foundation or Advocacy Group: 2
- Healthcare Provider: 2
- Open-Source Platform Provider: 2
- Regulatory Body: 2
- Public Funding Agency: 1

→ **Seeking to increase neurotechnology stakeholder diversity!**
AIMS OF STANDARDIZATION of neural interface research reporting:

1. **Primary (direct)**: Improve the transparency, interpretability, reproducibility, and meta-analyzability of *in vivo* neural interface research (*human and animal*)

2. **Secondary (indirect)**: Facilitate convergence towards rigorous standard experimental methodologies, outcome measures, and easily aggregated neural data representation structures (file formats, etc.)

3. **Tertiary (downstream)**: Promote increased interoperability and clinical capability in the field of neurotechnology

*Reference: IEEE Project Authorization Request (PAR) 2794, §5.4 – Purpose*
Working Group Scope: Reporting Standard

Official Scope, defined by IEEE Project Authorization Request (PAR) 2794:

“This Standard defines the essential characteristics and parameters of in vivo neural interface research studies (including clinical trials) to be reported in peer-reviewed scientific and clinical literature, including both minimum reporting standards and best-practice guidelines.”

NOT Included in Scope (… potential downstream effects…)

- Specification of Neural Interface system design features, configurations, or performance parameters
- Explicit requirements on experimental methodology
- Use of specific neurodata file formats and data structures
Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

- not a currently recognized standard term

This expansive definition could be interpreted to include:

- Brain-Computer Interfaces: EEG, ECoG, Intracortical Arrays
- Peripheral Nerve Interfaces: invasive, non-invasive
- Neuroimaging: fMRI, fNIRS, MEG, optogenetics
- Indirect Neural Modalities: electromyography (EMG), electrooculography (EOG), etc.
- Neuromodulation: DBS, spinal cord stimulation, peripheral nerve stimulation, focused ultrasound… FES??
→ Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

➢ Fundamental Balance (Tension) between:

1. Want to create a standard with enough technological specificity to be useful to neurotech researchers & developers; AND

2. Want to create a Standard that serves as a framework enabling coherent communication between experts (engineers, researchers, clinicians, etc.) in different fields of expertise!

➢ “Looking for a system to describe and manage complexity”
Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

→ Working Solution: distinguish between 2 (3) different domains of scope:

1. The **Physical Interface (Technological) Scope**: the set of all technologies to which our Standard may apply

2. The **Application Scope**: The set of all (research) uses of NIx technology to which our Standard may applies

3. (TBD…) +: **Epistemological (Informational) Scope**: The set of all aspects of NIx research to which our Standard applies
Physical Interface (Technological) Scope – As defined thus far by WG:

- **Definitively Include:** “systems that record or modulate *biological signals directly in neural tissue*”

- **Potentially Include:** “systems that record or modulate *biological signals of neurological origin*” (including EMG, EOG, etc.)

- **Exclude:** systems measuring *motor output* (e.g. IMUs, eye tracking, MoCap) that don’t directly measure *biosignals*
(Potential) Epistemological Scope *(to be refined...)*:

- Experimental methodology and outcome measures
- Recording configurations and parameters
- Cognitive aspects & ontology
- Signal processing, neurodata feature extraction, and standard file formats
- Data analysis and statistical analysis methods
- Data aggregability and shareability
- Data security?
- NeuroEthics?
QUESTION relating to Epistemological Scope:

To what extent can and should the reporting requirements and guidelines established by our Standard be formulated to influence experimental methodology and NIx system design/performance themselves?

DECISION: Our Standard will remain officially agnostic regarding experimental methods, choice of outcome/performance measures, NIx system design, and NIx configuration parameters.

- ...rather, we will simply specify the aspects of methodology and NIx system design/configuration that must be reported in 2794-compliant documents
- ... prescriptive requirements will be left to the resulting scientific & neurotech community consensus, and the policy decisions of scientific publishers and device regulators.
WG P2794 – Scope of Standardization

→ Benefits of “Design & Methods-Agnostic” Policy:

1. NO CONSTRAINT on Innovation
2. Minimize barriers to adoption & adherence
3. Improved longevity of Standard: applicability (& extensibility) to new devices and methodologies not yet in existence
4. Accelerate discovery & innovation via improved quality of experiments, results, and information sharing
5. Accelerated commercial development (via regulatory approval) via rigorous, development-aligned research practices
   - Minimize project failures due to flawed study design or execution
   - Reduce barriers to translational research & commercial development
WG P2794 – Group Organization (Strategy)

→ Challenge #2: How to segment our WG into working sub-groups?

- Sub-group segmentation would ideally (but not necessarily) reflect the organization of the final standard…

- Vertical (technology-based) vs. Horizontal (application or research aspect-based) Hierarchy?
WG Segmentation … via NIx taxonomy?

\{NI\} The set of all neural interfaces

- Sensory Prostheses
- Brain/Computer Interfaces
- Stimulation Neuromodulation
- Recording Neuro-imaging
- Implantable
- "Pure" Neuroimaging (e.g. diagnostics)

IEEE WG P2794: Reporting Standard for *in vivo* Neural Interface Research (RSNIR)
Challenge #2: How to segment our WG into working sub-groups?

- Sub-group segmentation would ideally (but not necessarily) reflect the organization of the final standard…

- **Vertical** (technology-based) vs. **Horizontal** (application or research aspect-based) **Hierarchy**?
Challenge #2: How to segment our WG into working sub-groups? ...

- **SOLUTION:** Segment WG based on distribution of member expertise

- WG Member expertise survey:

  - **How technology (modality)-specific is your expertise?**
    - 1: 2 (9.5%)
    - 2: 2 (9.5%)
    - 3: 7 (33.3%)
    - 4: 5 (23.8%)
    - 5: 5 (23.8%)

  - **How broad is your subject area expertise?**
    - 1: 4 (19%)
    - 2: 7 (33.3%)
    - 3: 6 (28.6%)
    - 4: 3 (14.3%)
    - 5: 1 (4.8%)
Challenge #2: How to segment our WG into working sub-groups? ...

- **SOLUTION:** Segment WG based on distribution of member expertise
  → 6 sub-groups total: 5 technology-oriented (“vertical”) groups:
    - EEGs for BCI
    - Invasive BCIs (intracortical, ECoG)
    - Peripheral Neural Interfaces
    - Neuroimaging
    - Neuromodulation
  
  … + **“Horizontal Integration” group**, to coordinate & harmonize others

- Tentative plan to develop Standard with a modular, layered architecture, that enables referencing of requirements in a 3 domains of scope (tech-based, application-based, research epistemology-based)
YOUR INPUT ENCOURAGED!! ... and Thank You!

• Via direct WG Participation
  - Seeking to increase NeuroTech stakeholder diversity
    - Scientific Publishers
    - (Medical) Device Regulators
    - … + Clinicians? … End-Users?

• By Sharing your Experience: First-hand descriptions of use cases for our Std and testimonials of its potential value to you
  - How would the proposed Standard improve your NeuroTech research, development, or quality assurance capabilities?
  - How has the lack of standardization in this area presented a challenge or barrier to your past efforts?
Current & Future WG Activity

• **Physical Interface-Oriented ("Vertical") Groups**: Generate list of epistemological aspects to be reported, to make the Standard useful.

• **Horizontal Integration Group**: Inventory and gap analysis of existing reporting standards, best-practice guidelines, and initiatives
  - Clinical trial and meta-analysis reporting guidelines & initiatives (CONSORT, FAIR, PRISMA, EQUATOR, etc.) re: NeuroTech specificity
  - Neurodata-specific standardization initiatives: Neurodata Without Borders, INCF, COBIDAS, Brain Imaging Data Structure (BIDS), NeuroImaging Data Model (NIDM)
  - Standard data structures & file formats – e.g. XDF, HDF5
  - Open source platforms & tools for Neurotech interoperability – e.g. OpenBCI, Lab Streaming Layer, BCI2000, OpenVIBE
  - Other NeuroTech Stds Working Groups – eg. IEEE P2731 (Unified BCI Terminology)
  - Clinical Neurophysiology Data and Electronic Health Record formats? – e.g. MEF3

  ... then develop our Standard to address the gaps!
Current & Future WG Activity

• Upcoming WG-Related Events
  • RSNIR Workshop at IEEE Systems, Man, Cybernetics (SMC) Conference (Bari, Italy, Oct 6-9, 2019)
  • Next Teleconference: Wed, Sept 25 – 15:30-17:00 CET (9:30-11:00 EDT)

➢ To learn more, provide input, or participate:
  ➢ RSNIR public web page: https://sagroups.ieee.org/2794/
  ➢ Direct Contact: z.mckinney@ieee.org; y.yuan@ieee.org