P1752 Working Group Meeting

Sponsored by IEEE Engineering in Medicine & Biology (EMB) Standards Committee

Please mark your attendance at: https://tinyurl.com/yc3oxg6q (see chat window)

11 December 2018

Teleconference
This document shows attendance from previous calls [https://tinyurl.com/yc3oxg6q](https://tinyurl.com/yc3oxg6q) (link in the chat window of join.me). **If you attended the call, please verify that your name is listed**
- If not, email simona@openmhealth.org

**Put your name and affiliation in the chat window for attendance today.**
- If your name is not listed, or if you are joining only via phone, please email simona@openmhealth.org with “P1752 WG call” as subject

Attendance is important for determining voting rights, so please remember to “check in”

Voting rights are granted according to the P&P after attending two consecutive calls and by explicit request to the Secretary
IEEE Patent Policy
Participants have a duty to inform the IEEE

- Participants shall inform the IEEE (or cause the IEEE to be informed) of the identity of each holder of any potential Essential Patent Claims of which they are personally aware if the claims are owned or controlled by the participant or the entity the participant is from, employed by, or otherwise represents.

- Participants should inform the IEEE (or cause the IEEE to be informed) of the identity of any other holders of potential Essential Patent Claims.

Early identification of holders of potential Essential Patent Claims is encouraged.
Ways to inform IEEE

• Cause an LOA to be submitted to the IEEE-SA (patcom@ieee.org); or

• Provide the chair of this group with the identity of the holder(s) of any and all such claims as soon as possible; or

• Speak up now and respond to this Call for Potentially Essential Patents

If anyone in this meeting is personally aware of the holder of any patent claims that are potentially essential to implementation of the proposed standard(s) under consideration by this group and that are not already the subject of an Accepted Letter of Assurance, please respond at this time by providing relevant information to the WG Chair.
Other guidelines for IEEE WG meetings

- All IEEE-SA standards meetings shall be conducted in compliance with all applicable laws, including antitrust and competition laws.
  - Don’t discuss the interpretation, validity, or essentiality of patents/patent claims.
  - Don’t discuss specific license rates, terms, or conditions.
    - Relative costs of different technical approaches that include relative costs of patent licensing terms may be discussed in standards development meetings.
      - Technical considerations remain the primary focus
  - Don’t discuss or engage in the fixing of product prices, allocation of customers, or division of sales markets.
  - Don’t discuss the status or substance of ongoing or threatened litigation.
  - Don’t be silent if inappropriate topics are discussed ... do formally object.

Patent-related information

The patent policy and the procedures used to execute that policy are documented in the:

• **IEEE-SA Standards Board Bylaws** (http://standards.ieee.org/develop/policies/bylaws/sect6-7.html#6)

Material about the patent policy is available at http://standards.ieee.org/about/sasb/patcom/materials.html

If you have questions, contact the IEEE-SA Standards Board Patent Committee Administrator at patcom@ieee.org
Determination of Quorum

https://tinyurl.com/yc3oxg6q
Approval of Agenda

1. Attendance
2. Call for Patents
3. Approval of agenda and of prior minutes (if quorum present)
4. Updates from subgroups
5. Discussion: upcoming activities
6. Other business
Approval of Prior Minutes

(11/27)
Update: Physical Activity and Mobility (PA&M) Schema Subgroup
Physical Activity & Mobility (PAM) Sub-group

1. We discussed on how the PA schema needs to be structured
   • Higher level that encompasses various PAs
   • OR should it be just another schema that is applied in parallel to other schemas.
   • Important properties for PA Schema
     • Intensity
     • Cadence
     • Open properties

2. Next Meeting: Thursday Dec 13, 2018 (11am to 11:45am Eastern Time)
"$schema": "http://json-schema.org/draft-04/schema",
"description": "This schema represents some measure of one physical activity.",
"type": "object",
"properties": {
  "activity_name": {
    "description": "The SKMEDX code represents Physical activity (observable entity)",
    "type": "string",
    "title": "activity_name",
    "optional": false
  },
  "length_unit_value": {
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    "type": "number",
    "title": "length_unit_value",
    "optional": false
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  "unit_value": {
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    "title": "time_frame",
    "optional": false
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    "title": "cadence",
    "optional": false
  },
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    "description": "The calories burned during the activity.",
    "type": "number",
    "title": "kcal_burned",
    "optional": false
  },
  "distance": {
    "description": "The distance traveled during the activity.",
    "type": "number",
    "title": "distance",
    "optional": false
  },
  "count": {
    "description": "The number of steps taken during the activity.",
    "type": "number",
    "title": "count",
    "optional": false
  },
  "effective_time_frame": {
    "description": "The effective time frame during the activity.",
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    "optional": false
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"definitions": {
  "activity_name": {
    "description": "The SKMEDX code represents Physical activity (observable entity)",
    "type": "string",
    "title": "activity_name",
    "optional": false
  },
  "length_unit_value": {
    "description": "The SKMEDX code represents Physical activity finding (finding)",
    "type": "number",
    "title": "length_unit_value",
    "optional": false
  },
  "unit_value": {
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    "title": "unit_value",
    "optional": false
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    "type": "number",
    "title": "time_frame",
    "optional": false
  }
}
Update: Sleep Schema Subgroup
Sleep Schema Subgroup Update (pg. 1)

- **Quantitative sleep measure schemas:**
  1. Review/Discuss the drafted schemas presented in the subgroup meeting via emails, slack (Josh has added the group);
  2. Signing up and drafting the remaining proposed schemas;

- **Qualitative sleep measure schemas:**
  1. Reviewed/Consolidated qualitative sleep measures (spreadsheet);
  2. Modifying the spreadsheet based on the discussions with Dr. White on Dec. 7, 2018 (select questionnaire, define use cases);
  3. Reviewing the existing Open mHealth framework for subjective measures;
Next Step

Quantitative sleep measure task group:
---Review/Discuss the drafted schemas;
---Complete the drafting for the remaining proposed schemas;

Qualitative sleep measure task group:
---Complete consolidating the selected qualitative sleep measures and use cases;
---Review/Discuss the spreadsheet to reach consensus;
---Review/Evaluate the existing framework from Open mHealth;
---Draft/Discuss qualitative sleep measure schema (start with one);
Discussion: Minimum Metadata (continued)
Minimum Metadata Categories

• Datapoint ID and Schema ID

• Source Provenance – from what did this datapoint come from (Static provenance)

• Acquisition Provenance – how was this datapoint acquired (Dynamic provenance)

• Defer for later
  • Processing provenance – how was this datapoint computed
  • Data sharing permissions and record
  • Context (some elements may end up in above categories)
### Source: What Do We Need to Know?

<table>
<thead>
<tr>
<th>Metadata Category</th>
<th>Needs</th>
<th>Properties (bold = required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>What device/app?</td>
<td>name, manufacturer/publisher, model</td>
</tr>
<tr>
<td></td>
<td>What hardware platform?</td>
<td>{iOS, Android, WatchOS, Wear OS, ....} OS version</td>
</tr>
<tr>
<td></td>
<td>What firmware/algorithm of the device/app?</td>
<td>Firmware name, firmware version, reference url (e.g., dates of versions, validation details)</td>
</tr>
<tr>
<td></td>
<td>Which individual device/app?</td>
<td>ID, ID Type (e.g., UDI)</td>
</tr>
<tr>
<td></td>
<td>Type of source sensor(s) (if any)</td>
<td>e.g., PPG</td>
</tr>
<tr>
<td></td>
<td>What is the sensor hardware platform?</td>
<td>What chip is in the device?</td>
</tr>
</tbody>
</table>

**Notes:** Device/app refers to hardware devices and software as a medical device (SaMD).
# Acquisition: What Do We Need to Know?

<table>
<thead>
<tr>
<th>Metadata Category</th>
<th>Needs</th>
<th>Properties (bold = required)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acquisition</strong></td>
<td><em>how was the datapoint acquired?</em></td>
<td><strong>source_creation_datetime</strong></td>
</tr>
<tr>
<td></td>
<td>When was this datapoint created at the source?</td>
<td>date-time schema represents a point in time (ISO8601). Timezone is UTC unless otherwise specified</td>
</tr>
<tr>
<td></td>
<td>Was the datapoint sensed or self-reported?</td>
<td><strong>modality</strong></td>
</tr>
<tr>
<td></td>
<td>What is the placement of the datapoint source?</td>
<td>(in relation to the body)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>{body location} and {laterality} and {laterality dominance}</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(not in relation to the body) Geolocation, named location,, etc.</td>
</tr>
</tbody>
</table>

**Notes:** Body location to include finger, wrist, chest, head, ears, feet, waist, neck, stomach, eye/gaze, hip, ankle
Future Work
Next Steps: Metadata

- We will revise full set of proposed minimal metadata properties
- We will follow up with FDA on UDI
- We will conduct one-on-one conversations with WG members to more deeply understand your use cases

Do you have hands-on experience with using mHealth data? Do you have hands-on experience handling metadata to summarize/visualize it?

- Contact us! Plan to schedule 30 minute calls over December and January
  - ida@openmhealth.org or simona@openmhealth.org
Summary of Action Items
Future Meetings
Upcoming Meetings

• Main WG
  • January 15, 2019: 8 AM (Pacific)

• Sleep subgroup
  • January 8, 2019 8:30am to 9:30 am (Pacific)

• PA&M subgroup
  • December 13, 2018 11 to 11:45 am (Eastern)
  • January 3, 2019 11 to 11:45 am (Eastern) [to be confirmed]
Adjournment