Vendor has developed a new product introduction known as the ABC Solution. For the purposes of this clinical study, the Solution is configured with the following components:

- ABC Biosensor
- Seta Bridge Solution
- Android Tablet
- Database
- Clinical Research Solution (including Web Services and App)

The ABC Biosensor includes Bluetooth communication capabilities. ABC Biosensor sends the collected subject data wirelessly to the Seta Bridge Solution. The data from the Seta Bridge solution is stored in the Clinical Research Solution (CRS). The ABC Clinical Research Solution (CRS) is designed to support both the collection of subject measurements and evaluate the system performance in a clinical setting. The CRS consists of a database and an application running on an Android tablet. The database stores all data sent from the ABC biosensor to the Seta Bridge. The application displays data from the database to allow researchers to view specific reports from the database. When the ABC biosensor is launched on the market, it will connect through the Seta Bridge to a qualified backend system rather than to the CRS.

The ABC Biosensor Monitoring in the Emergency Department Observation Unit study has been developed to investigate the technical feasibility of installation, deployment, use, and performance of the ABC Solution to transmit biometric data from the ABC Biosensor to a backend system in a hospital setting.

As the sensor connects, it sends data over to the database such as rates of interruption or interference with other devices in the area, as well as the physiologic data from the device attached to the patient.

A database has been set up on a server within the PHS network. This database and server and being provided and set up by the sponsor.
1.0 Description of the Intervention Studied
The ABC Solution will be deployed in the Emergency Department (ED) Observational Unit (EDObs) at Brigham and Women’s Hospital and will enroll approximately 40 subjects. Enrollment for this study is expected to last approximately two months. During the study, subjects will wear the ABC Biosensor connected to the Seta Bridge and Clinical Research Solution throughout their length of stay in the EDObs.

The ABC Solution is a non-significant risk device. The individual components of the ABC Solution are described in the following sections.

1.1 ABC Biosensor
The ABC Biosensor (Figure 1) is currently under development. The device is a Class II device under product code MWI (cardiac monitor). ABC Biosensor is a chest-worn sensor that is intended to periodically collect, store, and transmit physiological data to a qualified system for use by healthcare professionals. The ABC Biosensor has dimensions of 96mm x 61mm x 7mm and weighs approximately 10 grams. The physiological data measured by the biosensor includes respiration rate and heart rate. In addition, the biosensor is intended to measure and wirelessly transmit contextual parameters consisting of activity level, activity type, and posture.

Figure 1: ABC Biosensor

1.1.1 Planned Intended Use
ABC Biosensor is a chest-worn sensor that is intended to periodically collect, store, and transmit physiological data to a qualified system for use by healthcare professionals. The physiological data measured by the biosensor includes respiration rate and heart rate. In addition, the biosensor is intended to measure and wirelessly transmit contextual parameters: activity level, activity type, and posture.

1.1.2 Planned Indications for Use
The biosensor is indicated for single use in the general care areas in the hospital. The biosensor is intended for patients who are 18 years of age or older. ABC biosensor is indicated for use as a physiological measurement device to aid in the treatment and management of patient condition by a healthcare professional.

1.1.3 Product Packaging and Shipment
The ABC Biosensor will be provided in individual packages for single use only. Devices will be labeled for investigational use only. Products will be either shipped or hand-carried by sponsor to the investigational site.

1.2 Clinical Research Solution (CRS) Web Services
The Clinical Research Web Services are the minimal services required to provision a biosensor, respond to queries about system health, and store data in a Clinical Research Database. The web services will be hosted on a PHS server.

1.3 Clinical Research Solution App
The Clinical Research Solution App is an Android-based tablet application used to manage subject association and display system performance data. The app will be installed on an Android tablet (described in 2.6).

1.4 Database Server
The Clinical Research Database is a structured query language (SQL) database that captures and stores data transmitted from the ABC Biosensor via the network. The server is a _____ running _____ OS.

1.5 Android Tablet
The Android Tablet is a commercial-off-the-shelf (COTS) Android tablet to run the user interface (UI) for the study (the Clinical Research Solution app, described in 2.4). It will be managed by study staff for the duration of the study. The model and OS are ____.

1.6 Number of Subjects
A maximum of 70 subjects will be enrolled at one investigational site. At sponsor’s discretion, enrollment may be discontinued after 40 evaluable subjects have been enrolled.

Subjects will be defined as evaluable if they have at least 12 hours of total wear, observation, a fully completed participant experience questionnaire and completed skin assessment.

1.7 Point of Enrollment
Subjects who sign the informed consent form and meet all inclusion criteria and none of the exclusion criteria will be enrolled. The point of enrollment is defined as when the ABC Biosensor is applied to the subject.

1.8 Study Duration
Each individual subject will participate in the study throughout their length of stay in EDObs or a maximum of 5 days (120 hours of wearing ABC Biosensor), whichever is shorter.

1.9 Methods and Timing of Assessing, Recording, and Analyzing Study Endpoints
Investigator and subject assessments will be conducted using standardized questionnaires and forms provided by Vendor and entered in DATABASE electronic data capture system. This is their internal data system. At the end of the study period, patients complete a survey. The tablet is set up in order for the patient to complete – the RA enters the patients study ID and provides the tablet to the patient to compete. The RA does as well (study ID put into that). The sponsor is providing 2-3 android devices for this purpose, which will be locked in a research office when not in use.

All data analysis will be conducted by Vendor.
2.0 Treatment of Subjects and Study Procedures

2.1 Treatment of Subjects
The ABC Solution is not intended to provide any treatment or provide a diagnosis of any health condition during this study.

Subjects will wear the ABC Biosensor for duration of their stay in the EDObs unit. At the conclusion of their participation, they will complete a questionnaire regarding their experience with the ABC Biosensor.

2.2 Study Procedures

2.2.1 Informed Consent
Potential subjects are given the most current IRB-approved informed consent form to read. They will be provided ample time for review and an opportunity to ask questions about the study. If they agree to participate, they will sign the consent form and be given a copy of the signed document for their records. The original informed consent form will be filed at the site. All components of the consent process will be documented. Only after informed consent has been obtained, may the study procedures begin.

Subjects who consent to participate in the study will receive a wristband identifying them as study participants.

2.2.2 Eligibility Screening
Review the inclusion criteria to ensure the subject meets all inclusion criteria. Review the exclusion criteria to ensure the subject does not meet any of the criteria.

2.2.3 Medical History and Demographics
Once consent is obtained and eligibility is confirmed, site staff will collect a brief medical history that will include demographics, history of skin condition, and relevant respiratory or cardiac conditions. If any past medical history issues arise, the investigator will determine if subject is eligible for the study.

2.2.4 Skin Assessment and Preparation
The subject's upper left chest area will be assessed before the ABC Biosensor is placed. Skin must be clear of any rashes, abrasions, and openings.

To prepare the skin for ABC Biosensor placement, dry, dead epidermal layers of skin must be removed, along with any natural oils, dirt, skin moisturizer, fake tan, body powder, sweat, etc.

Prepare the skin using the following steps:
- Trim excess hair with electric trimmer (do not shave the hair with razor blade as this could lead to skin irritation or abrasions)
- Clean the skin thoroughly using a mild unscented soap (such as Dove sensitive skin unscented) and allow to air dry. Ensure that any oil, lotion, residue, or debris is completely removed.
- Use a skin preparation pad or paper (such as M4606A ECG Skin Prep Paper) to abrade the skin and remove dry skin.

2.2.5 ABC Biosensor Placement
The ABC Biosensor should be kept in the sealed package and opened immediately before use to prevent hydrogel from drying. Do not use if hydrogel is dry.
Site staff will remove the device backing and place the ABC Biosensor in the upper left chest (Figure 2).

**Figure 2: ABC Biosensor Placement**

The identification number of the ABC Biosensor and associated subject ID will be recorded on the subject log. Excel spreadsheet on an PHS SFA.

The ABC Biosensor package will be kept at the site and the device will be placed in the original package following completion of the study.

If ABC Biosensor becomes detached prior to end of study participation period, study staff will use their judgement to determine whether a second biosensor will be placed.

### 2.2.6 ABC Biosensor Pairing

Site staff will assign and pair the ABC Biosensor to the Clinical Research Solution using the Vendor ABC CRS App on the provided Android tablet.

The user will log into the app using a provided username and password.

They will add a new subject and enter their study-assigned unique Subject ID.

The user will follow the prompts on the screen to assign the biosensor. This will include scanning (QR code using the tablet camera) the biosensor label, confirming the sensor assignment, powering on the sensor, and applying the sensor to the subject.

**Figure 4: App Screenshot (Scan biosensor label to associate biosensor with the subject)**

**Figure 5: App Screenshot (Activate and place the new biosensor)**

### 2.2.7 Assigning new ABC Biosensor to Existing Subject

If a ABC Biosensor needs to be replaced, first disconnect the current sensor. Follow previous steps to assign the new biosensor to the subject. Disposed after each use.

**Figure 6: App Screenshot (Disconnect Current Sensor)**
After disconnecting the current sensor, follow the previous steps to assign the new biosensor to the subject.

2.2.8 Participant Experience Questionnaire
Subjects will complete a questionnaire (Appendix I: Participant Experience Questionnaire) at the follow up visit that rates the overall experience and level of comfort of the ABC Biosensor.

3.0 Assessment of Performance
Data stored in the Clinical Research Database will be analyzed by Vendor to determine the percentage of data collected from the biosensor with a valid signal quality index as well as the percentage of data transmitted to the database in real time versus data lost vs data stored locally on the sensor and uploaded retrospectively.

These metrics will be assessed by the sponsor reviewing event logs from the Clinical Research Web Services in combination with the patient and RA survey responses from the Vendor system.

4.0 Case Report Forms (DataBase)

4.1 Source Documentation, Reporting, and Maintenance
Source Documentation is the original collection of subject/study data. If source data is captured more than once at different time points (e.g., date of birth is often captured more than once on different documents), the later collection is corroborating source documentation. Source documents will have adequate study/site and subject identifiers and must be legible. A blue or black pen should be used to document source data. A pencil should never be used.

4.2 Data Reporting to Sponsor
Data will be collected by means of recording/writing on source documents or by direct data entry into the DATABASE electronic data capture system. Only staff that have been delegated by the Principal Investigator will be able to enter or make changes to data in the case report forms.

5.0 Data Handling and Record Keeping

5.1 Data Management System
All clinical data will be entered into DATABASE, a 21 CFR Part 11-compliant electronic data capture (EDC) system provided by the Sponsor. It is an internet-based EDC system for reporting clinical data to the Sponsor (eCRFs). All subjects who consent to participate will be registered in the EDC system. The data will be housed within a secure server and accessible only to the sponsor, study personnel, and investigators. Access to the EDC system will be secured through logins managed by a system administrator and appropriated training will be provided. The EDC system provides the capability to perform data management activities within a consistent, auditable, and integrated electronic environment (data security, data entry, data validation). Data entries and modifications will be recorded via an audit trail. If the data manager or study monitors identify data errors or inconsistencies, they will generate queries that will be sent to the study staff. After queries are resolved, the database will be locked, and the data will be imported into a statistical software and analyzed by biostatisticians.

The DATABASE EDC system only applies to the clinical data collected on study case report forms. Data from the ABC Biosensor (heart rate, respiration rate, activity type, activity level, posture) will not be entered into DATABASE EDC.
### 6.0 Appendices

#### Appendix I: Participant Experience Questionnaire

<table>
<thead>
<tr>
<th>Participant Experience Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Please circle the most appropriate answer for questions 1-3 according to the following scale:</strong></td>
</tr>
<tr>
<td>1. <strong>None:</strong> Not present</td>
</tr>
<tr>
<td>2. <strong>Minimal:</strong> Present but barely noticeable</td>
</tr>
<tr>
<td>3. <strong>Mild:</strong> Noticeable but discomfort is tolerable</td>
</tr>
<tr>
<td>4. <strong>Moderate:</strong> Discomfort is enough to interfere with routine activities</td>
</tr>
<tr>
<td>5. <strong>Severe:</strong> Discomfort is significant and the ABC Biosensor was removed</td>
</tr>
<tr>
<td><strong>Scale</strong></td>
</tr>
</tbody>
</table>

| 1. **I experienced discomfort during the placement of the device.** |
| If 4 or 5 is given, please explain: |
| 1 | 2 | 3 | 4 | 5 |

| 2. **I experienced discomfort during the time I was wearing the device.** |
| If 4 or 5 is given, please explain: |
| 1 | 2 | 3 | 4 | 5 |

| 3. **I experienced discomfort during the removal of the device.** |
| If 4 or 5 is given, please explain: |
| 1 | 2 | 3 | 4 | 5 |

**Use the following scale to answer question 4:**

| 1. Completely disagree |
| 2. Somewhat disagree |
| 3. Neither agree or disagree |
| 4. Somewhat agree |
| 5. Completely agree |

| 4. **I was inconvenienced while wearing the device.** |
| If 4 or 5 is given, please explain: |
| 1 | 2 | 3 | 4 | 5 |

| 5. **The power button clicking was noticeable.** |
| Yes | No |

| 6. **I would wear the device again.** |
| Yes | No |

| 7. **Do you have any additional comments regarding the experience of wearing the device?** |
Appendix II: Device Adhesion Assessment

Adhesion Assessment Instructions
Use the pictogram (shown below) to record the level of adhesion of the device to your skin on a scale of 1-5.

1. Device is fully attached to skin
2. Device is starting to peel within the blue area
3. Device is starting to peel within the red area
4. Device is starting to peel within the green area
5. Device has completely detached from skin

<table>
<thead>
<tr>
<th>Device Adhesion</th>
<th>Day 1 (24 hours)</th>
<th>Day 2 (48 hours)</th>
<th>Day 3 (72 hours)</th>
<th>Day 4 (96 hours)</th>
<th>Day 5 (120 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date DD/MMM/YYYY</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Adhesion Assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did any of the following cause detachment (Yes/No)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clothing</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sleeping</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Showering</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Excessive Perspiration</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Removed from self</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
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</tr>
<tr>
<td>Other</td>
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eCRF info table