Nokia Sensing XCHALLENGE
Competition Summary
17 February 2014

1. BACKGROUND

Sensors and sensing are magnificent windows into ourselves, enabling expansive views of human health, emotion, and the surrounding environment. Why is sensing needed? By capturing and interpreting information about us, sensing has the ability to detect disease and confirm sickness or wellness with minimal intrusion and maximum convenience.

Sensing can measure and monitor our vital signs, brain activity, five senses, systems of the human body, as well as our emotions, at any time of day, or over periods of time. How does this happen? A "signal," reading, or metric about us is captured by a sensing mechanism—traditionally a testing instrument, but today it can be a wearable device or wireless technology. Once this data is available from sensing mechanisms, sophisticated software algorithms can analyze and interpret the data to assess our state of health and being. These powerful sensing technologies enable exponential growth in our awareness and knowledge about us. Sensing thus lays the foundation for a mobile health revolution that will transform healthcare into what it must become: highly personalized for the unique needs of each individual.

Medical laboratories and medical institutions have traditionally been the only means for obtaining quantified measures of health. The few exceptions include home pregnancy and glucose tests, which are bought over-the-counter and are widely used by consumers.

Laboratories provide accurate results, yet are inadequate for a number of reasons:

- Some health conditions and diagnoses are subjective with no current means for quantification, relying mainly on physician interpretation which can vary among clinicians;
- Even simple tests require a doctor's order and a corresponding office visit, and results are delivered to the doctor rather than the person, limiting accessibility a basic tenet of healthcare;
- The cost of acquiring measurements of health is subject to both inefficiencies and inequities in our healthcare system;
- The use of testing is limited to known measures, correlations and causations of human conditions;
- Environmental, emotional or external elements that significantly impact health are often not measured; and
- Measurement occurs only at the specific point in time that a person happens to visit a facility; one-time measurements made infrequently may not represent overall health.

Even a physician's knowledge and years of training are limited when interpreting incompletely understood or unavailable information. Sensing enables healthcare to move into a "precision" realm that is quantifiable, repeatable, and more reliable. This disruptive innovation in the way we get

information about ourselves uses technology as the primary method for assessing health instead of human judgment, overcoming a key barrier to taking the first step in healthcare—knowing the status of our health. Sensing-enabled detection and measurement thus makes healthcare and the means for understanding health more reliable, accessible to many more people, available at a lower cost, and faster than ever before possible.

Advances in many areas of science, technology and design can be leveraged for health sensing. Intriguingly, even everyday metrics such as body temperature or facial movement can be extraordinarily insightful indicators of health. Collection and aggregation of sensor-derived information can then uncover patterns, incidences, and conditions that otherwise cannot be seen. Many of these technologies have been envisioned or are in some stage of development in research labs, academic institutions, "garage" workshops, or in start-up back burner projects in companies.

To realize the potential of new and existing sensing technologies, an impetus for their emergence is needed. The Nokia Sensing XCHALLENGE incentivizes the acceleration and application of these much-demanded sensing mechanisms to human-centric domains of health:

SENSING DOMAIN	**DOMAIN DEFINITION**	**EXAMPLES OF SENSORS (non-exhaustive)**
Biosensors	Any device that uses specific biochemical reactions to detect chemical compounds in biological samples for the purpose of detecting or measuring a specific disease state or health condition.	Lab-on-a-chip, polymerase chain reaction **(**PCR), non-invasive blood sensing, salivary diagnostics, Circulating Nucleic Acids (CAN) and DNA analytics.
Imaging	Physiological imaging that incorporates radiology, nuclear medicine, investigative radiological methods, ultrasound, endoscopy, (medical) thermography, medical photography, and microscopy.	Magnetic resonance imaging (MRI), computed tomography (CT) and positron Emission tomography (PET) scanning, Ultrasound imaging.
Environmental	Detection and characterization of the world outside of the human organism, including pollution, water or airborne allergens and UV light intensity among other conditions relevant to human health.	Sensors that detect biological pathogens, chemical or allergenic agents including the presence of food-borne pathogens. Detection of hazardous radiation levels.

SENSING DOMAIN	DOMAIN DEFINITION	EXAMPLES OF SENSORS (non-exhaustive)
Kinematics	Measurement of human movement through space; absolute geographic position, velocity, and acceleration for the purpose of identifying the health status and function of individuals.	Inertial measurement units (IMU) involving any level of biomechanics, motion tracking, orientation, or activity classification to indicate relative health and wellness.
Behavioral	Measurement of data describing mood and emotion with sensors that offer greater accuracy, reliability and frequency than is currently feasible with self-reporting and surveys.	Voice recognition, facial patterns, motion detection, sweat. Can include galvanic, auditory, visual, and behavioral clues about human mood and emotion.
Physiology	The quantitative measurement and visualization of physiological states including vital signs, traditional and non-traditional measures of health.	Electrocardiography (ECG), electroencephalography (EEG), electromyography (EMG), body temperature, levels of relative consciousness and related.

The potential for health sensing is stunning. The examples of sensing mechanisms and their applications below represent a mere fraction of incredible advancements to be seen in our lifetimes.

- **PCR or rapid PCR:** PCR or polymerase chain reaction is a technology used in molecular biology to test and analyze DNA. PCR can be used for many health assessment applications such as the detection of genetic disorders, bacteria, or viruses (including AIDS).
- **Nanotechnology:** 'Nanotech' refers to purposeful engineering of matter at scales of less than 100 nm to achieve size-dependent properties and functions that radically affect engineering, electronics, biotechnology and health care. Nanotech can be applied to many facets of sensing. For example, miniaturized molecular devices can be created to contain Nano-sized fluorescent dyes that can be used to detect substances such as glucose or sodium, telling us information needed to treat diabetes or dehydration.
- **Medical imaging technologies:** Sophisticated medical equipment such as MRI, ultrasound and CT scanning enable us to see images of the structures and organs in our bodies-- with obvious benefit. It would be advantageous to develop medical imaging capabilities that can be used in individual doctor's offices and even at our homes. These new sensing technologies could be for example using the infrared capabilities on a camera phone to confirm Lyme disease rash or skin cancer.

- **Motion sensing:** MEMS accelerometers, gyroscopes and magnetometers are becoming pervasive—they are already embedded in many cell phones—and can detect motion to tell us much about body position and our state of being. For example, motion sensors can determine if a person is standing or lying down. An algorithm analyzing an elderly person's body position over time would know their typical sleeping hours, and that an abrupt change from standing to lying down could indicate a fall and/or need for an alert. Perhaps combined with another technology that measures heart rate patterns, sensing could be used to tell us both state of health and its cause.

- **Facial expression and speech analysis:** These sensors have the ability to capture and quantify our expressions and intonations (or lack of them). Once our smiles or frowns and speech patterns can be measured objectively, they can be used to reliably confirm depression and other emotional conditions. An important part of this technology will be pattern recognition to determine normal vs. unusual, combined with factors such as social circumstances, sleep, activity levels, medication and other compounding physiological conditions.

- **Lab-on-a-chip:** A lab-on-a-chip is a miniaturized microfluidic device that can be as small as the size of a postage stamp and made of materials as inexpensive as paper. With this technology, traditional testing that used to be conducted in mostly in laboratories can be done on location with a disposable, very low cost chip (under $1 per test) that gives immediate results, and has the ability to measure/ identify multiple conditions with a single drop of blood or body fluid.

- **Galvanic Skin Response:** Galvanic Skin Response is our skin's ability to conduct electricity and activate our sweat glands. Exercise or hot weather causes us to sweat, but sweat can also be a result of physiological conditions that go hand-in-hand with an abnormal heart rate. Galvanic skin response sensors are typically non-invasive and have great potential for at-home use.

- **Temperature:** Temperature is a seemingly mundane measure of health, but its significance can be greatly elevated with highly sensitive sensors that continuously measure body temperature. Sophisticated software can analyze hundreds or even thousands of measurements *per minute* to determine a woman's typical temperature and fluctuations. These subtle increases in body temperature can be a non-invasive, non-drug dependent means of determining fertility.

- **EKG/ECG and EEG:** EKGs or ECGs (electrocardiographs) have been used in hospitals and emergency rooms for decades, but the equipment needed to measure health patterns is generally used once a person is already sick. EEG (electroencephalography) is another technology that is used to measure brain waves and is currently limited to medical institutions. New sensing mechanisms can make electrical sensing technologies like these portable and readily available. Faster treatment of heart conditions and brain malfunction becomes possible, along with an ability to identify unexpected conditions that reveal themselves with newly pervasive measurement.

- **Olfactory:** Electronic noses can elevate a human's mediocre ability to smell to that of a well-trained dog… and beyond. Receptors sensing gas chromatography, ion mobility spectrometry, and electrophoresis can be used to measure not only blood and breath alcohol content, but blood glucose, bacterial infections and even some cancers— based on odorant compounds in a persons' breath.

- **Environmental sensing:** Environmental factors such as air quality, UV exposure, air-borne pathogens and allergens or drinking water quality strongly influence our quality of life. Sensors that can give us a real-time indication of these factors or the presence in the environment that trigger respiratory distress will significantly improve people's lives by enabling them to manage Asthma by identifying patterns and frequency of attacks, learning more about triggers, and controlling symptoms—leveraging and supplementing traditional care in a doctor's office.

The ultimate goal of the $2.25 Million Nokia Sensing XCHALLENGE is to incentivize teams to develop sensors and sensing technologies to capture health data in a way that is impactful, convenient, scalable, and accessible.

It is anticipated that the Nokia Sensing XCHALLENGE will build a sensor and sensing ecosystem that will support and expand upon that developing for the Qualcomm Tricorder[1] XPRIZE, whose goal is make it possible for an individual to assess their health state with a desirable, understandable, mobile solution. The Qualcomm Tricorder XPRIZE will integrate advances in sensing technology, artificial intelligence, cloud technology, mobile platforms, and user networks.

The second Nokia Sensing XCHALLENGE has a total prize purse of $1,125,000 USD. From this total, up to six (6) awards are available:

A $525,000 USD Grand Prize will be awarded to the team with the best achievement during Final Round Judging as determined by the Judging Panel and the Crowd Panel using the judging criteria herein (see Table 2 below for Final Round scoring details).

Up to five Distinguished Prizes, each valued at $120,000 USD, will be awarded to up to five teams with the best achievement in Final Round Judging as determined by the Judging Panel using the judging criteria herein.

Bold and capitalized terms not defined herein bear the definitions in the **Master Team Agreement**, which will be available to teams that have registered their Intent to Compete.

2. GUIDING PRINCIPLES

The XPRIZE Foundation has designed the Nokia Sensing XCHALLENGE so that it adheres to the following principles:

- Achieve our main goals: stimulate innovation to capture health-related sensor-based data in a fast, convenient, and accessible way, building an ecosystem of available technologies for integrated solutions such as those anticipated in the Qualcomm Tricorder XPRIZE
- Stimulate the development of new options in measuring and understanding human health
- Be simple to understand and easy to communicate
- Remain independent, non-partisan, and technology neutral, treating competitors with equality and fairness
- Attract a balanced set of donors, sponsors, and partners to help competitors succeed
- Provide many opportunities for recognition so that it is worthwhile to compete whether or not a team places first
- Make heroes out of the competitors and winner(s) through widespread exposure, media coverage, and a significant cash award
- Challenge existing beliefs, policies, infrastructure, or laws that inhibit progress
- Educate the public on key issues related to consumer-driven healthcare technologies

The Nokia Sensing XCHALLENGE organizers and sponsors are entering into this competition in good faith. We expect and require the same attitude from all competitors and participants, so that together we can provide the most favorable experience for all.

1*TRICORDER is used under license and a trademark of CBS Studios, Inc.*

3. WHO CAN PARTICIPATE?

The competition is open to competitors globally. To be eligible to compete and claim any award, a team must be an **Eligible Entity**, as defined in the Master Team Agreement, and must otherwise comply with all the terms of the Master Team Agreement. The Master Team Agreement also contains a number of restrictions on potential entrants that are intended to prevent conflicts of interest. Potential teams are also subject to these restrictions. Further, current employees of Nokia Corporation or any of its group of companies (or respective members of their immediate families) may neither participate in nor have financial interest in any team.

The competition is void in those countries where prohibited or restricted by law. XPRIZE reserves the right to limit, or restrict upon notice, participation in the competition to any person or entity at any time for any reason.

Teams may withdraw as set forth in the Master Team Agreement.

4. COMPETITION STRUCTURE

Competition information will be available in the following documents:

- **Competition Summary** (this document) – Informational document that provides a high-level description of the prize competition
- **Competition Guidelines** – Detailed document that describes the general requirements and parameters of the competition and are binding on teams as referenced in, and as part of, the Master Team Agreement.
- **Master Team Agreement** – Legally binding contract that contains the requirements of the competition. All competing teams must sign this in order to compete for a Purse.
- **Rules and Regulations** – Document detailing the testing protocols, specific rules, dates/times, and other details that will govern the Competition and will be binding on teams.

The second Nokia Sensing XCHALLENGE is a 16-month, fixed-date competition and will occur in two rounds. The **Competition Calendar** is available in the **Competition Guidelines**.

Qualifying Round will take place during the second and third quarters of 2014.

Final Round will take place during the third quarter of 2014 and will determine the Grand Prize and Distinguished Prize winners.

XPRIZE encourages teams to merge, reorganize, collaborate and/or share technical assets during the course of the **Competition** in order to create the most effective submissions with the highest likelihood of winning a Purse, subject to the terms and conditions in the Master Team Agreement. Teams cannot withdraw and enter into the Competition as a new team.

5. COMPETITION GOALS

The goal of the $2.25 Million Nokia Sensing XCHALLENGE is to incentivize teams to develop sensors and sensing technologies to capture health data in a way that is impactful, convenient, scalable, and accessible

All Entries will be judged on the following criteria:

Qualifying Round:

- **Accuracy:** Is it accurate, reliable and effective in collecting meaningful data?
- **Technical innovation:** What type of technology is used to collect and report data?
- **Human factors:** How much consideration is there for the user of the application?
- **Originality and creativity:** How unique and novel is the solution?
- **Portability:** Does it meet the need for personal mobility?
- **Relevance:** Is it relevant to a prevalent public health need?
- **Integration:** Can the submission easily integrate, using hardware and/or software, with other sensing devices and/or handheld interpretive devices to enable a complete "solution"?
- **Multi-functionality:** Can the submitted solution discern an array of diagnostic data about an individual or situation with one device or process?
- **Submission:** How complete is the submission? What is the quality and level of clarity

Final Round:

- **Accuracy and Consistency:** Is it accurate, reliable and effective in collecting meaningful data?
- **Demonstration Quality:** Is the demonstration of functionality and use credible and compelling?
- **Technical Innovation:** What type of technology is used to collect and report data?
- **Crowdsourcing:** The submission will be presented to participants for their evaluation as part of a crowdsourcing evaluation process.
- **Human Factors:** How much consideration is there for the user of the application?
- **Market Opportunity:** How likely will the submission succeed in the commercial marketplace?
- **Originality and Creativity:** How unique and novel is the solution
- **Packaging, Portability & User Experience:** The final form of the submission will be reviewed and evaluated

6. HOW TO REGISTER

To participate in the Competition, teams must complete the **Registration** process using the competition website once Registration has opened (https://nokiasensing.xprize.org/). Teams interested in competing and being eligible for a Purse in the Nokia Sensing XCHALLENGE must have registered by 16 April, 2014. No late registrations will be accepted. Registration involves the following steps:

1. Complete and submit an Intent to Compete Form (https://challenge2.nokiasensingxchallenge.org/competition-details/intent-compete-form). Upon approval of this form by XPRIZE, the team will be invited to activate an account on the Team Portal with instructions sent to the Team Leader by email.

2. Activate Team Portal to add additional Team Information and pay the Registration Fee. Additional Team Information shall include a brief description of the team's proposed sensing technology, or **Entry**. The additional Team Information will be reviewed and approved by XPRIZE.

3. Upon approval, a Master Team Agreement and related documentation will be sent to the team for signature. These documents include the Competition Guidelines, the Media Rights Agreement, Insurance Requirements, the Branding and Style Guide, the Public Relations Guide, the Team Sponsorship Guide, the Team Release and Waiver Document, and the Team Member Release Waiver and Confidentiality Document.

Teams must submit the **Registration Fee** at the time of Registration. The Registration Fee is $1,000 USD, payable in U.S. Dollars only, per Entry. A team may submit the same or a substantially similar **Entry** in successive competitions only if the **Entry** has not won a **Prize**, either the **Grand Prize** or a **Distinguished Prize**. A team that has won a **Prize**, either the **Grand Prize** or a **Distinguished Prize**, may enter in subsequent competitions only if the **Entry** is substantially different from the one that won a **Prize**.

If XPRIZE has not received a signed, unrevised Master Team Agreement from a team by the Registration deadline, XPRIZE will refund any Registration Fee submitted by the team and will disqualify the team from the competition.

Registration must be approved and accepted by XPRIZE in order for a team to compete and be eligible to receive any Prizes. XPRIZE may refuse Registration for any reason, including, but not limited to, XPRIZE's determination that a prospective team: (i) lacks the understanding of the financial or technical means required to present a viable Entry; (ii) is not or will not remain an Eligible Entity; (iii) is not likely to comply with the terms of the Master Team Agreement; or (iv) is likely to disrupt relationships with the other teams, sponsors, or otherwise unreasonably endanger the administration of the competition or related activities. Registration materials will be reviewed by XPRIZE for completeness and for compliance with the principles and rules of the competition using all available information. XPRIZE may pose additional questions or requests for clarification to supplement the Registration materials as part of its evaluation. All rejection or acceptance decisions by XPRIZE will be final and in its sole and absolute discretion.

7. COMPETITION OVERSIGHT

A **Scientific Advisory Board** (SAB) will be formed to assist with the formulation of the scientific aspects of the competition. The Scientific Advisory Board will be independent of XPRIZE and all Teams and Team Members. All members of the Scientific Advisory Board will be required to sign non-disclosure or similar agreements, as well as statements acknowledging that they make no claim to the **Intellectual Property** developed by teams or relevant team sponsors or partners.

The **Judging Panel** will evaluate the Entries and will be responsible for assessing compliance with the Competition Guidelines, Rules and Regulations. The Judging Panel will be comprised of highly qualified and impartial judges. The Judging Panel will be independent of any team participants and will not be involved in any other area of prize operations. All members of the Judging Panel will be required to sign non-disclosure or similar agreements, as well as statements acknowledging that they make no claim to the Intellectual Property developed by teams or relevant team sponsors or partners. XPRIZE shall select all members of the Judging Panel and submit them to the SAB for review and approval. Members of the Judging Panel will have cross-functional and relevant backgrounds in order to ensure that the Judging Panel will be able to address all of the requirements of the competition. The Judging Panel will have the sole and absolute discretion to select the Prize recipients. The decisions of the Judging Panel are final, binding, and are not subject to challenge.

NOKIA SENSING XCHALLENGE®

EXHIBIT A

Competition Guidelines

I. PRIZE PURSES

The Nokia Sensing XCHALLENGE has two separate competitions. The total prize purse is split equally between the competitions. This second Nokia Sensing XCHALLENGE has the following Prize Purses:

A. GRAND PRIZE. A $525,000.00 Grand Prize will be awarded to the team with the best achievement during Final Round Judging as determined by the Judging Panel and the Crowd Panel using the judging criteria herein (see Table 2 below for Final Round scoring details).

B. DISTINGUISHED PRIZES. Up to five (5) Distinguished Prizes, each valued at $120,000.00, will be awarded to up to five (5) teams with the best achievement in Final Round Judging as determined by the Judging Panel using the judging criteria herein.

II. JUDGING CRITERIA

A. QUALIFYING ROUND: SUBMISSIONS AND JUDGING. Teams will submit their Entries initially in a qualifying round ("Qualifying Round") in which the Entries will be judged ("Qualifying Round Judging"). Teams will need to comply with the Rules and Regulations, which are hereby incorporated into and made a part of these Competition Guidelines. Team Qualifying Round submissions will be evaluated based on the following criteria:

Table 1. Qualifying Round Judging Criteria

Qualifying Round Criteria	Weighting /Available Points
Accuracy	20
Technical Innovation	20
Human Factors	15
Originality/Creativity	10
Portability	10
Relevance	10
Integration	5
Multi-Functionality	5
Submission	5
Total Available Points	100

Note: *The minimum score required to advance to the Final Round is fifty (50) points.*

The Judging Panel will select up to twelve (12) "Finalist Teams" (also referred to herein as "Finalists") to enter into the Final Round of the competition. A description of each Finalist Team's Entry, but not any proprietary data, will be published on the XPRIZE Foundation's website, along with the names and biographical information of the Team Members of the Finalist Teams. A public announcement of the teams that advance to the Final Round will take place on the dates per the competition schedule in Section 3, Table 3.

B. FINAL ROUND: JUDGING. The Judging Panel's evaluation and scoring during the Final Round will be based on the thirty (30)-minute in-person presentation. The criteria for evaluation and its scoring weight are detailed in Table 2.

Table 2. Final Round Judging Criteria

Final Round Criteria	Weighting/Available Points
Accuracy/Consistency	20
Demonstration Quality	15
Technical Innovation	15
Crowdsourcing	10
Human Factors	10
Market Opportunity	10
Originality/Creativity	10
Packaging/Portability/User Experience	10
Total Available Points	100

Teams that advance to the Final Round for "Final Round Judging" are required to submit a video up to three (3) minutes long describing their sensing technology Entry no later than twenty-one (21) calendar days prior to the Final Round Judging. All three (3)-minute videos will be posted on the Nokia Sensing XCHALLENGE website. The three (3)-minute video will be used during Crowdsourcing.

Customers can and should play a key role in the development of any technology, as they are the primary driver of success or failure of any technology. To recognize this principle, the Nokia Sensing XCHALLENGE will use crowd sourced evaluation to play a role in determining the winners of the competition. The Crowd Panel will consist of potential users of sensing technology. The Crowd Panel will have a period of time to evaluate the final entries. Crowd Panel results will be disclosed to the Judging Panel after the Judging Panel has completed its evaluations of the finalists. The Judging Panel's evaluation will then be combined with the Crowd Panel's evaluation, resulting in the ultimate determination of the winners.

The following scoring method will be used to award points from the Crowd Panel voting. Points from the Crowd Panel score will be added to the totals from the Judging Panel to determine the Grand Prize winner and Distinguished Prize winner(s).

The lowest observed number of votes (minimum) is deducted from the highest number of votes (Maximum). The difference is divided by 10 and steps of $1/10^{th}$ of the difference are created. Thus if the team with the minimum votes achieved is 20 and the team with the maximum votes achieved is 220 then the steps are 20 votes wide. Scoring bands are determined by adding the minimum score

with the band-width (20 in the example). Thus if a team receives 110 ballots they would be in the 4th band (20 + 4*20, 20 +5*20) and receive 4 points from the Crowd Panel as part of their total score. This procedure allows proportional comparison between teams and a range of 0 to 10 points possible from the Crowd Panel voting.

The Judging Panel reserves the right to disregard the results of the Crowd Panel and award any Prize solely based on its judgment in the event of: (i) any suspected technology malfunction or failure; or (ii) circumstances that cause the Judging Panel to suspect the veracity of such results.

Final judging will take place on the dates per the competition calendar found in Section 3, Table 3. Exact dates and times for the in-person Judging Panel presentation will be scheduled with each Finalist Team once the Finalists are announced.

The Final Round Judging will evaluate presentations based on total scores derived from each judging category. Team presentations will be evaluated based on the Judging Panel's scoring of the following weighted criteria:

- **Accuracy and Consistency –** *Accuracy, reliability and effectiveness of data collection and reporting (20 points):* The submission shall demonstrate the methodology employed is accurate, reliable and effective in collecting meaningful data that can be used for identification or diagnosis of a disease state, medical condition or a pattern of health in either individuals or populations of individuals.

- **Demonstration Quality** – *Is the demonstration of functionality and use compelling? (15 points):* The submission will be presented to judges by the teams supported by a variety of means that will demonstrate validity, use, accuracy and effectiveness of the solution and its ability to address relevant health problems. The quality, presentation impact and credibility of the demonstration will be evaluated.

- **Technical Innovation –** *Technology utilized to collect and report physiological data (15 points):* The submission should reflect a quantifiable improvement in the sensor or sensing technology over preexisting methods and/or reflect a novel methodology not previously demonstrated in the commercial marketplace.

- **Crowdsourcing –** *Assessment of final submissions by Crowd Panel (10 points)*: The submission shall be presented, by the XPRIZE Foundation or a third-party organization, in person or online, to participants for their evaluation as part of a "crowdsourcing" evaluation process.

- **Human Factors –** *Considerations for end-user applications (10 points)*: The submission is relatively easy to use or apply for either a clinician or end-user. It does not require extraordinary technical or medical knowledge to deploy the method and obtain the benefits of the sensing or sensor technology.

- **Market Opportunity –** *Likelihood that submission will achieve market acceptance (10 points)*: The submission will be evaluated for its likelihood to succeed in the commercial marketplace based on all of the features categorized in both judging processes.

- **Originality and Creativity –** *How cool is the solution? (10 points):* The submission should ideally be a unique and novel solution that is more than an incremental improvement on a preexisting

technology (incremental example: simply changing from a wire-based to a wireless technology with no change in the underlying sensing method). Furthermore, the submission should reflect a highly creative approach that will excite the imagination of consumers and the healthcare industry.

- **Packaging, Portability & User Experience –** *The final form of the submission and use of same (10 points):* The submission will be evaluated on its finished physical form that is presented by the team that may include features such as device enclosures, methods of body attachment, means of installation and so forth. Alternately, if the sensing method is expressed as a software application it will be evaluated on its graphic user interface and usability.

For a summary of how points will be weighted for each Prize Purse, see Table 2 above.

III. COMPETITION ROUNDS

The Competition will occur in two (2) rounds. Points will be awarded to Teams based upon the Entry Submission in the Qualifying Round and up to 12 teams will be invited to participate in the Final Round Judging.

Table 3. Competition Calendar

25 Jun 2013	Registration Formally Opens
16 Apr 2014	Registration Deadline (11:59 a.m. Pacific Time)
1 May 2014	MTA Execution Deadline (11:59 a.m. Pacific Time)
24 Jun 2014	Entry Submission Form Deadline (11:59 a.m. Pacific Time)
Jun 2014	Virtual Team Summit
Jun/Jul/Aug 2014	Qualifying Round Judging; Finalist Teams Determined
Jun/Jul/Aug 2014	Virtual Finalist Team Summit
Sep/Oct/Nov 2014	Final Round Judging and Awards Ceremony; Winners Determined and Awards Presented

Note: *The above dates and locations are subject to change pursuant to the terms and conditions of the Master Team Agreement.*

A. REGISTRATION AND ENTRY SUBMISSIONS

1. **Registration**. Team's participation in the competition may begin upon Team's submission of the Intent to Compete Form and will be open to all prospective and registered Teams. For details concerning the Intent to Compete and Registration, visit www.nokiasensingxchallenge.org.

2. **Entry Submission Form**. By the submissions deadline, all registered Teams must complete and submit an "Entry Submission Form." The Entry Submission Form and procedures for its submission will be available on the Team Portal. The Entry Submission Form will provide detailed information to the Judging Panel regarding Team's Entry. The deadline for submission of Entry Submission Forms ("Entry Submission Form Deadline") is listed in the Competition Guidelines.

3. Criteria for Evaluation of Entry Submission Forms. The burden rests entirely on the Team to present a compelling case for its Entry to the Judging Panel within the parameters of the Entry Submission Form. Teams are encouraged to consider the following principles when completing their Entry Submission Form(s); submissions should be:

- **Clear**: Documentation will be needed to prove and validate the feasibility of the Entry. Relevance rather than volume of information will be rewarded;
- **Concise**: Presentation of all information submitted creates a logical, succinct case for the Entry; and
- **Convincing**: The Entry derives a solid, convincing conclusion for its significance in advancing the field of ocean health sensing.

The Judging Panel strongly recommends succinct, brief materials that directly address the technology proposed for the competition. If any additional documentation is included as an attachment, the sections relevant to the submission should be clearly indicated (for example, by saying on page 10, paragraph 3 the following information can be found…). Lengthy documents with no directions to relevant sections will result in low scores by the Judging Panel.

NOTE: Teams will not be providing the actual physical form of their entry (i.e., a device with the sensing technology attached or embedded) *for the Qualifying Round.*

4. Entry Submission Form Details. Each completed Entry Submission Form must be submitted through, and in the form provided on, the Team Portal and should include accurate and detailed information regarding the Entry. A complete submission will include each of the following sections:

- **Accuracy –** *Accuracy, reliability and effectiveness of data collection and reporting (20 points)*: The submission shall demonstrate the methodology employed is accurate, reliable and effective in collecting meaningful data that can be used for identification or diagnosis of a disease state, medical condition or a pattern of health in either individuals or populations of individuals. It must also demonstrate consistency in results.
- **Technical innovation –** *Technology utilized to collect and report data (20 points)*: The submission should reflect a quantifiable improvement in the sensor or sensing technology over preexisting methods and/or reflect a novel methodology not previously demonstrated in the commercial marketplace. Some examples of enhancements of existing technologies may include miniaturization, wireless implementation, or conversion to a non-invasive method. Other examples of innovation include (but are not limited to) novel ways of determining physiological or biological markers and significant increases in accuracy/reliability over previously known methods.
- **Human factors –** *Considerations for end-user applications (15 points)*: The submission is relatively easy to use or apply for either a clinician or end-user. It does not require extraordinary technical or medical knowledge to deploy the method and obtain the benefits of the sensing or sensor technology.
- **Originality and creativity –** *How cool is the solution? (10 points)*: The submission should ideally be unique and novel solution that is more than an incremental improvement on a preexisting technology (incremental example: simply changing from a wire-based to a wireless technology with no change in the underlying sensing method). Furthermore, the submission should reflect a highly creative approach that will excite the imagination of consumers and the healthcare industry.

- **Portability –** *Portability and form factor (10 points)*: The submission is portable, meaning that it meets the need for personal mobility and does not restrain a user from their ordinary activities. It is also beneficial that the submission is as small and light as possible so that it is not physically intrusive and employs low power requirements and power efficiencies for operations over significant time periods between charges.

- **Relevance –** *Relevance to prevalent public health needs (10 points)*: The submission should have relevance to statistically significant and specific public health needs that are well documented and have a known clinical basis so that the submission can be evaluated for accuracy and reliability.

- **Integration –** *Integration capability (5 points)*: Can the submission easily integrate, using hardware and/or software, with other sensing devices and/or handheld interpretive devices to enable a complete "solution"?

- **Multi-functionality –** *Multi-functionality (5 points)*: Is the submission multifunctional? Can the submitted solution discern an array of diagnostic data about an individual or situation with one device or process? Does the submission reduce the accuracy and/or consistency of any one of its functions to achieve this goal? The intent of this measure is that individual functions are as good as or better than comparable stand-alone sensors.

- **Submission –** *The quality and clarity of the submission presentation (5 points)*: The submission shall contain all the required information elements needed for initial round judging to proceed including the stated goal of the sensor/sensing system, physiological and clinical basis of the device or solution, its methodology and an engineering plan for practical implementation and testing. **Please note that the demonstration and testing/validation plan is a critical part of the finalist selection process.** Teams can expect a penalty in their submission review if any part of their submission does not meet the criteria of *Clear*, *Concise*, and *Convincing*.

- **Team Biographies:** Provide a short (one paragraph) biographical description of each Team Member and a listing of funding partners or sponsors.

The description of the solution provided by each team in the Competition Submission Form must include any diagrams or supporting material as necessary. The description must be written at a level appropriate for a practitioner in engineering to understand and verify. A score of at least fifty (50) points out of a total of one hundred (100) must be achieved in order for a Team to be eligible to become a Finalist Team.

XPRIZE Foundation may provide additional details to assist teams in answering the Competition Submission Form questions as deemed necessary in the sole and absolute discretion of the XPRIZE Foundation. Teams shall reasonably cooperate with the Judging Panel in any verification activities. Application of the judging criteria to eligible Entries entails some subjectivity and, as such, will be at the Judging Panel's sole and absolute discretion. Qualifying Round Judging will take place on the dates per the competition schedule in Section 2, Table 3. At the end of this period, eligible submissions will be judged. An eligible submission provided for review must describe a technology that is originally developed or implemented (i.e., must not violate or infringe on any applicable Law or third-party right).

B. FINAL ROUND. The Final Round will take place at a location and venue in the United States to be announced upon determination of the Teams that qualify to participate in the Final Round. Teams that qualify to participate in the Final Round will be allowed up to three (3) Team Members to present or demonstrate their submitted Entry to the Judging Panel. Each Team will have an approximately thirty (30)-minute, face-to-face session with the Judging Panel to present the merits of their Entry and to respond to questions from the Judges. No Team Members from other Teams may be present in the room during the Final Round judging session for another Team. Teams are not required to provide the actual physical form of their Entry (i.e. a device with the sensing technology attached or embedded), but may elect to do so.

Modifications and/or improvements to original Entries are discouraged. However, XPRIZE recognizes the importance of continual improvement in this rapidly evolving field. Upon prior authorization from XPRIZE and the Judging Panel (which may be given or withheld in XPRIZE's or the Judging Panel's sole and absolute discretion), Finalist Teams may submit a revised Entry for Final Round Judging. The revised Entry will include (only) a maximum two (2)-page executive summary of the original technology and the improvement, which will be made available to the Judging Panel at least twenty-one (21) calendar days prior to the commencement of Final Round judging. No Final Round requirements will change for a revised Entry.

The maximum three (3)-minute video is required by twenty-one (21) days prior to the commencement of Final Round Judging. The video should show the device performing sensing activities in a way that demonstrates as many of the judging criteria as is possible.

1. Final Round Judging: The Judging Panel will assign points for each Entry based on the criteria listed in section and the weights described in Section 2 Table 2, above. The Judging Panel will then combine their score with the Crowd Panel score as outlined in Section 2B above.

2. Awards Ceremony: The Grand Prize winner and Distinguished Prize winner(s) will be determined after the total score is derived from combining the Judging Panel score and the Crowd Panel score. Following the conclusion of the Competition, an awards ceremony will take place at an appropriate time and venue to be determined and announced by XPRIZE, at which the winning Team(s) will be announced. Actual awarding of the Prize Purses will take place as soon after the awards ceremony as possible.

These Competition Guidelines summarize the high-level requirements and rules of the Competition. The requirements herein are binding on Teams as provided in Section 15 of the Master Team Agreement.

IV. LEADERBOARDS

XPRIZE may, at its sole and absolute discretion, choose to implement interim status reports and/or other information postings describing the progress of the Teams involved in the Competition ("Leaderboards") to help engage key audiences in the Competition and promote Teams by providing public and industry visibility. Rules and Regulations pertaining to Leaderboard programs will be periodically published and Teams will be encouraged to participate. Please note that Leaderboard participation will be optional and will not influence the decisions of Judges in the actual Competition.

V. SCIENTIFIC ADVISORY BOARD

A. SELECTION OF ADVISORS. The "Scientific Advisory Board" (as defined in Section 5.1 of the MTA) will be comprised of independent scientific advisors and will remain in place throughout the Competition to advise XPRIZE regarding the scientific elements of the Competition. Each member of the Scientific Advisory Board ("Advisor") will enter into an agreement with XPRIZE that will: (i) outline Advisor's duties and obligations; (ii) require Advisor to maintain confidentiality of XPRIZE's and Team's Confidential Information, in accordance with Section 9 of the MTA; and (iii) require Advisor to acknowledge that he or she shall make no claim to Team's Intellectual Property.

B. INDEPENDENT SCIENTIFIC ADVISORY BOARD. The Scientific Advisory Board and each Advisor will be independent of XPRIZE and all Teams and Team Members. No Advisor, nor any member of Advisor's immediate family, shall participate, nor have any financial or other material interest, in any Team or Team Member. All members of the Scientific Advisory Board shall promptly disclose to XPRIZE any such current, former, or expected future conflict of interest with XPRIZE and/or any Team or Team Member.

C. ROLE OF SCIENTIFIC ADVISORY BOARD. The duties and responsibilities of the Scientific Advisory Board may include, but not be limited to: (i) assisting with the establishment of qualifications for prospective Judges; (ii) approving each member of the Judging Panel; (iii) assisting with development of testing protocols and judging criteria; (iv) and providing input toward the development of these Competition Guidelines.

VI. JUDGING PANEL

A. SELECTION OF JUDGES. "Judging Panel" (as defined in Section 5.2 of the MTA) will be comprised of highly qualified and impartial Judges. XPRIZE, in its sole and absolute discretion, will recommend Judging Panel candidates to the Scientific Advisory Board for its review and consideration. The Scientific Advisory Board will select the candidates it believes are best suited to serve on the Judging Panel, Each Judge will enter into a Judging Agreement with XPRIZE that will: (i) outline the Judge's duties and obligations; (ii) require each Judge to maintain confidentiality of XPRIZE's and Team's Confidential Information in accordance with Section 9 of the MTA; and (iii) require each Judge to acknowledge that he or she shall make no claim to Team's Intellectual Property.

B. INDEPENDENT JUDGING PANEL. The Judging Panel will be independent of XPRIZE, the Title Sponsor, and all Teams and Team Members. No Judge, nor any member of Judge's immediate family, shall participate, nor have any financial or other material interest, in any Team or Team Member. All members of the Judging Panel shall promptly disclose to XPRIZE any such current, former, or expected future conflict of interest with XPRIZE, the Title Sponsor, and/or any Team or Team Member.

C. ROLE OF JUDGING PANEL. The duties and responsibilities of the Judging Panel will include, but not be limited to: (i) evaluating Teams' compliance with the MTA, these Guidelines, and the Rules and Regulations for the purposes of the Competition; and (ii) the awarding of points and selection of Teams and Entries that will proceed to each subsequent phase of the Competition.

D. ROLE OF CROWD PANEL. For the Qualifying Round, the Judging Panel will be the only panel to evaluate Entries to determine the Finalist Teams. For the Final Round, both the Judging Panel and the Crowd Panel will evaluate the Finalist Teams' Entries to determine the winners, as detailed in Section 2B.

E. GROUNDS FOR JUDGING PANEL DECISIONS. Official decisions made by the Judging Panel will be approved by a majority of the Judges that vote on each such decision after careful consideration of the testing protocols, procedures, guidelines, rules, regulations, criteria, results and scores set forth in the MTA, these Competition Guidelines (including the Rules and Regulations to be attached hereto), and all other applicable Exhibits to the MTA. If any vote of the Judges results in a tie, then the Judging Panel shall determine, in its sole and absolute discretion, the mechanism to settle the tie. Similarly, if one or more Teams or Entries are tied at any stage during the competition, the Judging Panel shall have the sole and absolute discretion to settle the tie. If no Entry meets the criteria for any Award, then the Judging Panel will retain sole and absolute discretion to declare or not declare a winner of the Competition and/or otherwise allocate or choose not to allocate one or more of the Awards and/or any other Award associated with the Competition.

F. DECISIONS OF JUDGING PANEL ARE FINAL. Judging Panel shall have sole and absolute discretion: (i) to allocate duties among the Judges; (ii) to determine the degree of accuracy and error rate that is acceptable to the Judging Panel for all Competition calculations, measurements, and results, where not specified in the Rules and Regulations; (iii) to determine the methodology used by the Judging Panel to render its decisions; (iv) to declare the winners of the Competition; and (v) to award the Prize Purses and other Awards. Decisions of the Judging Panel shall be binding on XPRIZE, Team and each Team Member. XPRIZE and Team agree not dispute any decision or ruling of the Judging Panel, including decisions regarding the degree of accuracy or error rate of any Competition calculations, measurements, and results. Team shall have no right to observe other Teams' testing or evaluation, or to be informed of other Teams' calculations, measurements and results, unless such information is made publicly available by XPRIZE.

Attachment One – Rules and Regulations

to

EXHIBIT A – Competition Guidelines

These "Rules and Regulations" are an attachment to the "Competition Guidelines" for the Nokia Sensing XCHALLENGE ("Competition") and are incorporated into the Master Team Agreement for the Competition. All Teams that submit documentation in order to qualify to move to the Final Round must adhere to these submission procedures in order to qualify to move to the Final Round. All Teams that the Judging Panel selects for participation in the In-Person Demonstration and Testing round ("Finalist Teams") must adhere to these demonstration and testing procedures in order to qualify for selection as a winner of the competition. Failure to adhere to these Procedures, either for submission or for demonstration, may result in the suspension or disqualification of the Team by the Judging Panel, in its sole and absolute discretion.

I. INTRODUCTION

Teams must submit valid documentation of their simulations, test designs, and results. Further, Teams are expected to understand and follow not only the rules of the competition but also any local rules and regulations (i.e., Laws in the country in which the Team is located and/or operating) applying to their efforts. Complete documentation of both the legal compliance *and* the Team's activities related to the adherence of rules and regulations is required with Team submissions. XPRIZE personnel and the independent Judging Panel for the Nokia Sensing XCHALLENGE *will not* research regulations nor will XPRIZE personnel or the Judging Panel determine legal compliance with regulations. Teams are expected to provide regulation information and compliance information, including evidence of compliance, if appropriate, as part of their competition submission. Incomplete documentation or failure to submit documentation will affect the score the Team receives. Failure to do so may result in disqualification from the competition or revocation of Prizes.

The overarching principle for submission in this competition is concise, clear, and complete documentation by Team of its efforts and results. A balance will need to be struck between the volume of data that is submitted and the amount of time it will take the Judging Panel to review each submission. If the Team feels it necessary to submit all test data, government paperwork such as patents or reviews, it is highly recommended that summaries be provided to aid the Judging Panel in their review process.

II. COMPETITION PRINCIPLES

A. SAFETY AND PRIVACY. Sensing systems may have physical or chemical effects on the human body. Sensing systems may also affect private human medical data, including diseases and social information. All Team personnel should be aware of the risks related to the technologies they are describing and the information they are collecting. All reasonable efforts should be made to maximize safety and minimize invasion of privacy for test subjects, Team Members or anyone who might come in physical contact with equipment or specimens.

B. EVOLVING SPECIFICATIONS. These Procedures are subject to change. In addition, during the competition, there may also be unanticipated issues that arise and require modifications to these Procedures. Thus, XPRIZE reserves the right to revise these Procedures as appropriate. XPRIZE will publish such changes on the competition website and such changes will be binding on Teams ten (10) business days after such publication. XPRIZE further reserves the right to make such changes effective immediately in exigent circumstances. In all cases, XPRIZE will endeavor to remain true to the guiding principles in the Competition Guidelines.

III. SCIENTIFIC AND TESTING PRINCIPLES

Good scientific principles must be followed by the Teams entering the Nokia Sensing XCHALLENGE. Ethical and legal management of human and animal research for technology for any Nokia Sensing XCHALLENGE submission is expected. Documentation of good scientific practices and sound ethical supervision is required in the Nokia Sensing XCHALLENGE.

A. HUMAN AND ANIMAL SAFETY AND PRIVACY. Respect for human and animal safety is paramount in the Nokia Sensing XCHALLENGE. Safety includes not only reduction of risk of physical injury but also considerations for items such as protection of privacy of personal and medical information.

XPRIZE requires that all Teams competing for the Nokia Sensing XCHALLENGE ensure that they pay close attention to risks to test subjects from their technologies. Testing technologies with chemicals or radiation have obvious hazards. Sometimes the risk may not be completely obvious. For example, an internet social media sensing system has the potential to affect and compromise privacy. Thus social media information may have to be appropriately secured and protected which may not always be (but is most frequently) solved when the personal information is "de-identified". Even though a given technology may not appear to create an imminent human physical risk, XPRIZE strongly recommends that innovators understand the implications of their technology. If in doubt, please consult the institutions or regulatory bodies that are charged with administrating such standards. Examples of such organizations include:

- United States Food and Drug Administration
- an Institutional Ethics Committee (IEC) in the United States or a Research Ethics Board (REB) in Canada are examples of the appropriate sources for testing of technology on humans or for the collection of medical or social information in their countries
- an Institutional Animal Care and Use Committee (IACUC) is the appropriate source of information for testing of technology on animals

1. Human Research Principles. Human safety has been carefully considered in the development of scientific research. Guidelines for human research have been formally enunciated in the research community and in the United States are derived from the Belmont Report:

(http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

Three basic principles are relevant to the research involving human subjects: respect for persons, beneficence, and justice. All specific regulations are derived from these principles. Thus, ethical guidance of human research not only involves physical safety from such things as radiation or chemicals, but also requires that humans who volunteer as subjects be treated with respect. For example, their privacy must be scrupulously maintained in accordance with applicable Law, and they must provide explicit informed consent for procedures in which they will participate. Team shall

declare to XPRIZE that it will use a human subject in advance and provide medical ethics and a safety plan to do so for approval by XPRIZE and the Judging Panel. Such approval will not limit Team's obligations.

Data produced during the competition may be subject to HIPAA in the United States and other medical privacy laws in other jurisdictions.

2. **Animal Research Principle.** It is anticipated that many novel sensing technologies cannot be evaluated for safety or efficacy on humans. Computer simulation may serve for some technologies, but it is likely that animal research may be needed to evaluate some items. Pain and distress to animals must be eliminated or minimized to the greatest extent possible. For research involving animals, Russell and Burch (The Principles of Humane Experimental Technique, 1959) developed three guiding principles called the Three "Rs": Reduction, Replacement, and Refinement. The ethical guidelines for research on animals all derive from these principles. Again, respect for animals is the primary guiding principle for research involving them. It is incumbent upon the Team to ensure it is following the appropriate and most up-to-date Laws and to provide that information to XPRIZE and the Judging Panel.

3. Privacy. Many information data points about people are private and may not be publicly exposed without consent. Such items include:

- Personal identifiers (name, address, age, government ID numbers, etc.)
- Medical Insurance Information
- Medical History
- Laboratory Test results
- Family and Social information
- Life information, including:
    - financial information (such as credit scores or tax information)
    - educational history
    - social media
    - job information

Maintenance of protected and reasonable expectations for privacy is a difficult problem where regulations are not yet well defined in the large majority of legal (or in the case of Privacy Boards, even administrative) jurisdictions. Teams using private medical data will be required to submit descriptions of their information security, including database summaries, encryption procedures, and controls on access to information including personnel allowed access and the security procedures for those personnel. Again, local experts should be engaged to assist in conforming to both existing legal regulations as well as prudent and practical information control. It is incumbent upon the Team to ensure it is following the appropriate and most up-to-date Laws and to provide that information to XPRIZE and the Judging Panel. Please refer to the Master Team Agreement with respect to the Team's obligation to obtain consents.

B. DOCUMENTATION OF HUMAN AND ANIMAL RESEARCH. In the Nokia Sensing XCHALLENGE, novel sensing technologies will be presented for review by the Judging Panel. Submission guidance is described in Section 4 below. The requirements of the competition include presentation of information that indicates that the novel technology works or has the potential to work. It is therefore anticipated that most submissions will include designs of results from experiments on humans, animals or both. Any submission that includes any results that have been obtained from human or animal research *must* include:

- descriptions of the appropriate governmental "competent authority" regulatory guidelines that were observed during the experiments
- certified documentation that those guidelines were followed by the experimenters
- declarations by the Team that its representations to the Judging Panel are consistent and truthful with their actual testing and documentation procedures
- sample consents from human subjects in accordance with the Master Team Agreement

1. Regulatory Frameworks for Human and Animal Research. The Nokia Sensing XCHALLENGE is an international competition. Each country or region (such as the European Union) has different regulations for supervision of human and animal research. Because the regulatory environments will be dependent upon the country or region of the Team, it is the responsibility of each Team to demonstrate having searched for as well as complied with its local regulatory environment. A resource for finding details of local regulations for human and animal research can be found on the website: International Compilation of Human Research Standards http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html].

It is incumbent upon the Team to ensure that the guidelines which are followed are the most recent, even if different than what is found on the website provided by the above link. If no guidelines exist in a given location, then in addition to evidence of the reasons the Team believes that there is an absence of such guidelines must be presented together with evidence that oversight supervision from an external location was or will have to be sought. Any such oversight compliance and related evidence of exemption or supervision will be the responsibility of the Team.

The Judging Panel reserves the right to review any submission derived from human and animal research and determine if appropriate general ethical guidelines were followed. If such a review reveals *any* breech of ethical conduct *or* reveals research to be ethically suspect in any way, *regardless of assertion of supervision under published local guidelines*, the Judging Panel will exclude that complete submission from the competition. Examples of violations include human research without proper consent, animal research without ethical oversight or access to medical records without permission.

Description of the documentation about human and animal experimentation, its supervision, and reporting is described in Section 4.

C. SCIENTIFIC VALIDITY. Scientific validity is one of the cornerstones of evaluating technology. In order to determine if a technology is eligible for a Nokia Sensing XCHALLENGE Prize, the validity of the capabilities of the technology asserted by the Team must be verified. The Judging Panel will not do any testing of technologies as part of the judging process. Further, the Judging Panel will not be subject matter experts in all of the specific scientific and engineering areas of each of the sensing technologies submitted. For example, a judge may be a nano-engineering expert, but may not have specific expertise in nano-engineering of blood

protein sensors. Thus the strength of scientific validity of claims regarding technology will be largely determined by how clearly the Team's submitted materials describes their technology for a scientific and engineering review. The Nokia Sensing XCHALLENGE Judging Panel will have full range of authority to seek opinions as to the veracity of any claim made in a submission. Such unpaid opinions will be sought and provided only under non-disclosure agreements. The more powerful a case that can be made by the Team's scientific validity documentation, the higher the score the Team's technology will likely receive from the Judging Panel. For example, if a Team is proposing a completely novel sensing technology, it is incumbent upon the Team to document, as completely as possible, the scientific basis for the innovation, the design of tests of the technology and the results of the testing of the innovation. The Team should provide reports that are as authoritative as possible about the science and the results. Presentation of laboratory data from the Team without evidence of review (such as a peer-review publication) will result in lower scores. Results of peer-review publication or independent testing, such as testing in independent laboratories, will be given higher scores where appropriate and available. Poor documentation, specifically as it relates to scientific validity, will result in low scoring. The best possible scores will result from complete documentation with independent testing and a concise presentation that the Judging Panel can readily grasp.

Evaluation of validity of assertions will be accomplished by review of documents of a variety of types. Credibility of evidence for scientific and technology review is of varying quality. The list below is ranked generally from most credible (#1) to least credible (#6):

1. Publications in peer-review press
2. Reports by independent authorities of tests of the technology
3. Issuance of Patents directly about the technology by patent authorities
4. Published scientific data: analyzed and raw data
5. Conference papers or abstracts
6. Reports from the Team of their own experiments and data

Documents submitted will have to have demonstrations of authenticity, including official copies of publications, patents, or other reports. Reports by independent authorities will have to have notarized certificates of authenticity including statements of independence from the Teams and verifiable descriptions of the authority. Any expense incurred in the development of these documents, including legal expenses for notarization or other review will be solely the responsibility of the Team. XPRIZE will not pay for any legal, technical or scientific review or opinion in order to validate Team claims.

D. SUBMISSION TO REGULATORY AGENCIES. The ability for a device to obtain approval from regulatory agencies for commercialization is NOT an objective of the competition. However, the testing and validation of a submitted technology so that it can secure regulatory approval and move forward to commercialization is highly desirable. The regulatory framework for development of medical devices for the United States is documented in:

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

This document provides links to information about:

- medical device safety
- medical device engineering development
- documentation requirements for medical devices
- regulations for human and animal testing of medical devices
- quality control (ISO Standards, etc.)

Teams not in the United States or intending to submit their technologies to other country's or region's regulatory agencies will need to review their local regulations for medical device approvals. Identification of the appropriate regulations and the progress or plan for completion of the approval process should be included in the submission summary.

XPRIZE requires that human subject oversight be complete for all technology submitted for competition. Lack of oversight or documentation of oversight will result in low scores or exclusion from competition. Teams submitting data from research done in "Research Grade" conditions or their country's or region's equivalent conditions will document their review process and document the reasons they are exempt from formal human research supervision by an Institutional Research Board or similar organization. Teams must determine if data gathered without supervision is eligible to be submitted for government approval of their technology (for example, in the United States, it typically is not); a plan for formal government approval must be included.

IV. QUALIFYING ROUND SUBMISSIONS

Please use the following in conjunction with the Competition Guidelines, Section 4, for submissions. There is no limit on the length of the submission, unless specified. However, the burden rests entirely on the Team to present a compelling case for their Entry to the judges within these parameters:

- ***Clear*****:** Documentation will be needed to prove and validate the feasibility of the Entry. Relevance and clarity, rather than volume of information, will be rewarded. Teams are encouraged to present their information in a complete, yet clear and concise, manner.
- ***Concise*****:** Presentation of all information submitted creates a logical, succinct case for the Entry.
- ***Convincing*****:** The Entry derives a solid, convincing conclusion for its significance in advancing the field of health sensing.

If documentation provided in the submission is incomplete, absent, or difficult to find or interpret, this will affect the scores given by the Judging Panel. In the sections below where a summary is suggested, no more than one page is recommended. Footnotes or supporting documents can be attached to summaries. It is suggested that if a Team provides a link to an online document in their submission that they periodically check to ensure that the link is still valid. If any of the links change during the time after submission has closed, the Team will need to notify, by email to the Team Relations Manager, of the change to the link. This change will be passed to the Judging Panel.

As noted in the MTA, the language of the competition is English. Any Team concerned about their ability to present information in English is strongly advised to seek assistance in preparation of their written materials. Translation will not be provided. Note that official documents for certification, for example human experimentation oversight, should be presented in both their original signed version and in a certified translation.

Any Team that is found to be avoiding government regulations either by an external authority or by the Judging Panel will not be considered as a Finalist Team. An example of such documentation is located on XPRIZE's Nokia Sensing XCHALLENGE website.

A complete submission will include a response for each of the following sections:

1. **Accuracy –** *Accuracy, Reliability and Effectiveness of Data Collection and Reporting (20 points)*. The documentation of testing will be included in this section. As described in Section 3 above, regulations and certified documents about compliance with regulations will be included in this section. The Team will submit:
   - Summary of Technology Capability
   - Supporting Data Reports, Papers, Patents, or other reports with certificates of authenticity if available
   - Human, Animal or Privacy Research Regulation (all that applicable)
     - Local Regulations for research in the Submission

       What are the laws, rules, or guidance sources that you followed?
       - Human
       - Animal
       - Privacy
     - Certificates of Review
       - Documentation of Human Research; Certificate from Ethics review board or similar
       - Documentation of Animal Research; Certificate from Animal research ethics review or similar
       - Documentation of Private Medical data use review; Certificate from Ethics review or similar

2. **Technical Innovation –** *Technology Utilized to Collect and Report Data (20 points)*. The Team will submit:
   - A written summary of the technology
   - A review of available literature including papers, patents or reports of technologies preceding the innovation. The review should include sources that were examined for the review, such as websites, patent databases etc.

3. **Human Factors –** *Considerations for End-User Applications (15 points)*. The Team will submit:
   - Summary of Human Factors "features"
   - Diagrams or other media demonstrating ease of use.

4. **Originality and creativity –** *How Cool is the Solution? (10 points)*. Why is your technology cool? Can you describe why you think your solution is cool? Cool is an American term that includes such characteristics as innovation, exciting possibilities, provocative concepts and newness. We think that smart phones are cool, that some modern art, design and music is cool, but not all things that are just new are cool. A description of coolness can come in the form of a picture, a compelling graph or a very brief description. Very long written descriptions are not a good way to describe cool. If you

are not sure about how to describe how your technology is cool, we recommend describing your personal excitement about it. How did you feel when you discovered your idea? Did it give excitement to your colleagues? Do you have hopes that it will be an important idea? Is it Transformative of the healthcare industry?

5. **Portability –** *Portability and Form Factor (10 points)***.** Team will submit a description of the technology both in its current state and the potential for miniaturization. Note that physical items will not be accepted with submissions, so specifications or pictures are best. Video is not supported in the initial submission.

6. **Relevance –** *Relevance to Prevalent Public Health Needs (10 points)*. Team will submit a summary of the public health issue being addressed, such as number of people affected, cost of illness, cost of treatment or other parameters.

7. **Integration –** *Integration Capability (5 points)*. Team will submit a summary, preferably with diagrams of how the technology will be combined with mobile technologies. Conformance with known standard interfaces should be described. Again, no physical items will be accepted for submission.

8. **Multi-Functionality –** *Multi-Functionality (5 points)*. Team will submit a summary of the current and planned multifunctional-capabilities such as a product road-map. "Multi-Functionality" includes use in different settings (home, office, health care facility) and for different disease or health evaluation conditions.

9. **Submission –** *The Quality and Clarity of the Submission Presentation (5 points)*. The submission form will have a front page that will include the following items:

    - Team Name
    - One-Page Summary of the Sensing Innovation
    - Applicable Key-Words
    - Description of Experiments
        - Human Research *{Yes or No}*
        - Animal Research *{Yes or No}*
        - Private medical Data included *{Yes or No}*

    Any Team that indicates human, animal or private medical data is included will be required to attach documents about the ethical supervision of their work.

10. **Team Biographies.** Provide a short (one paragraph) biographical description of each Team Member and a listing of funding partners or sponsors

V. IN PERSON EVALUATION

A. CROWD PANEL VIDEO. Finalist Teams are required to send their video at least twenty-one (21) days before competition. This video will be used by the Crowd Panel to perform their assessment of the technology. The Crowd Panel may be administered by a third-party organization in conjunction with the competition. Teams, their Team Members, and members of their organizations are not allowed to vote in the Crowd Panel.

B. COMPETITION

1. <u>In-Person Demonstration Requirements</u>. If an In-person physical demonstration of a sensor technology will be performed, Teams will have to carry them out in accordance to United States laws and regulations for medical devices. Safety review and technology demonstration approvals will be the responsibility of the Team and will be reported to XPRIZE personnel before competition.

2. <u>In-Person Evaluation Procedures</u>. Teams will be given a thirty (30)-minute presentation window along with five (5) minutes both before and after their allotted time for setup and breakdown of any equipment they bring along for their presentation. XPRIZE will provide audio and video equipment, including microphones, a projector, computer, and a screen. Any other equipment that a Team needs will be provided by each Team for their presentation. The Team's presentation to the Judging Panel will be captured on video by XPRIZE. Teams will have access to this video no sooner than thirty (30) days after the competition upon written request made to XPRIZE.

Teams must arrive in the green room between thirty (30) minutes and one (1) hour before their presentation window begins. There may be multiple Teams in the green room waiting their appointed presentation time. It is expected that Teams will respect all other Teams' preparation time. Upon arrival, Teams must give electronic copy of their presentation on a thumb drive to the Team Relations Manager. The document must be in PDF format. Teams are not allowed to be present during any other Teams' presentations to the Judging Panel.

Teams will be escorted into the presentation room for their 5-minute setup. After the five (5)-minute window for setup for the presentation has passed, the clock will start for the Team's presentation and Judging Question and Answer session. Teams will have no more than thirty (30) minutes in front of the Judging Panel to present the merits of their solution. It will be up to the Team to determine how much time they wish to allow for a question and answer session with the Judging Panel.

G. After all Teams have presented their technologies, the Judging Panel may have developed additional questions for each of the Teams. All Teams will be expected to be present at (time) and to be prepared for an additional five (5) minutes for questions. Teams will be brought back in the order that they were first seen, as determined by XPRIZE.