Qualcomm Tricorder XPRIZE Competition Guidelines

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1. Overview

One key measure of a nation's development is its health system and ability to care for its people. In many parts of the world, epidemics continue to present grave and costly challenges for governments and health providers. In developing nations there is an outright shortage of health workers: It is estimated that worldwide, 57 countries have an absolute shortage of 2.3 million physicians, nurses, and midwives.

The U.S. has an availability of health workers 75 times greater than that of the 10 lowest-resourced countries in Africa-- 2.3 health workers per 1,000 people vs. 0.03 per 1,000 people.[2] Despite relative prosperity and apparent success, the U.S. faces a different set of health challenges. The ballooning cost of U.S. healthcare is well recognized: over the last 35 years, the nation's overall spending has risen at an average annual rate of 7.2 percent, yet healthcare spending has grown at an average annual rate of 9.8 percent. As a consequence, an increasing proportion of Americans simply cannot afford adequate healthcare.[3]

Unfortunately, the cost of healthcare is not the only problem the U.S. faces. There is strong evidence that despite having access to some of the best modern medicine, the care being delivered is prone to delay and inadequacies in the eyes of the most important party: consumers. Consider these common situations faced by many people seeking medical attention:

- It takes 21 days on average to obtain a doctor's appointment[4]
- Three out of four people have difficulty making appointments or receiving after-hours care without visiting an emergency room[5]
- Only 57 percent of people report that their doctor listened, explained, showed respect, or spent enough time with them[6]

In addition to affordability and access hurdles, when individuals finally do obtain care, *only 55 percent receive the recommended screening, diagnosis, or treatment.*[7] Change is long overdue

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[2] The World Bank, *World Development Indicators 2011*.

[3] Christensen et al., *The Innovator's Prescription*.

[4] Merritt Hawkins & Associates, *2009 Survey of Physician Appointment Wait Times*

[5] The Commonwealth Fund, *A Call for Change: The 2011 Commonwealth Fund Survey the U.S. Health System*

[6] The Commonwealth Fund Commission on a High Performance Health System, *Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008*.

[7] Elizabeth A. McGlynn, Ph.D., et al., "The Quality of Health Care Delivered to Adults in the United States, *The New England Journal of Medicine*, June 26, 2003.

but it needs to be directed at the heart of the problem; peripheral improvement within the system has been unsuccessful. Funding has been poured into this problem; healthcare reform has been a priority for decades across presidential administrations. Yet not only is the system hemorrhaging the increasing resources that we are putting into it, but there are also many signs, some previously noted, that it is fit for change so radical it would be classified as "disruption." Some researchers, stakeholders and others are fighting to change the existing paradigm, but displacing such a swollen, self-serving system is no easy task.

The problems facing U.S. healthcare are not unique. At the outset, products and services offered in the early stages of most industries are so complicated and expensive that only a few, privileged people can afford them, and only those with great expertise can provide or operate them. Initially, only the wealthy had access to telephones, photography, air travel, and automobiles. Quality higher education was initially limited to those born into wealth. And the same access issues are now affecting healthcare, although modern healthcare as we know it today has been around since World War II. It is an industry in regression not progression. Today, it is very expensive to receive care from highly trained medical professionals. Without the largesse of well-heeled employers and governments that are willing to pay for much of the costs, healthcare would be inaccessible to the majority. [8]

Disruption in the healthcare system is the first step in bringing better health to more people. The Qualcomm Tricorder XPRIZE's role in disruption is to incentivize technology breakthroughs that enable problems to be addressed on a smaller scale not at the millions that monolithic health care companies aim their turrets at, but at the one, the individual, one person at a time, with far less human skill and physical presence than traditionally required. Technologies that enable *reliable self-diagnosis or assessment* and, subsequently, predictable and effective treatments, are the ones that have the most potential to transform healthcare through disruption.

Up to now, healthcare consumers have been forced to rely on a physician's expert opinion as the starting point from which care can begin. It has traditionally required experts with years of training to interpret incompletely understood information and to help navigate the healthcare system, but even a doctor's knowledge and abilities are limited. However, as our understanding deepens, the established system is being disrupted by innovations allowing us to more easily make reliable assessments that thus "de-skill" medicine. Teams of highly skilled

[8] Christensen et al., *The Innovator's Prescription*.

engineers operated the first computers, but today's smart phones (which have infinitely more computing power) can be operated by a ten-year old effectively. Why not healthcare?

By using technology to convert speculative, difficult diagnoses based largely on expert judgment into verifiable and reliable assessments based on data and technology that makes heath assessment routine, consumers will finally be able to more competently address their own care. This is the first aspect of our Qualcomm Tricorder XPRIZE Grand Challenge: "de-skilling the 'art' of diagnostic medicine." Embedding this expertise in mobile consumer devices will enable personal healthcare to become more accessible, more affordable, and much easier to obtain, addressing the second aspect of our Qualcomm Tricorder XPRIZE Grand Challenge of "making health a desirable part of consumers' daily lives." Presenting information in the way and form consumers understand and seek, together with incorporating user-friendly and entertaining elements, such as games and social networks, will also begin to address this second facet of the Competition's Grand Challenge.

In addition to technology disruption, the Qualcomm Tricorder XPRIZE can leverage other important areas of disruption to ignite change in healthcare:

- *Regulatory disruption*: Convene industry stakeholders, including regulators, to reassess how standards and regulations can stimulate or stifle innovation and change
- *Business model disruption*: Incent new, innovative business models that can bring healthcare tools directly to consumers
- *Infrastructure disruption*: Provide a forum in which Teams can tackle risk and be rewarded for their efforts through monetary and other means, and encourage partnerships and alliances that would not otherwise be created

It is the expectation of the XPRIZE Foundation that the Qualcomm Tricorder XPRIZE will bring major disruption to global healthcare systems, initially in the U.S. and, later, to the benefit of even poorest nations. In places like Sub-Saharan Africa and Southeast Asia, there is new hope that the explosive growth and widespread use of wireless communications, including smartphones, will improve access to reliable health assessment and higher quality healthcare.

Bold and capitalized terms not defined herein bear the definitions in the **Master Team Agreement**.

Target Requirements

The winner(s) of the $10M Qualcomm Tricorder XPRIZE will be the best-performing solution in its ability to assess a set of 16 distinct conditions and five (5) Vital Signs in a pool of people

within three days, while providing a strong consumer experience in the areas of usability, understandability, engaging and desirable presentation of information, and ability of the solution to willingly invoke action on the part of the user. In addition, the winning solutions must:

- Meet minimum scores for both consumer experience and health condition assessment
- Continuously monitor five Vital Signs over the course of the consumer testing period and log this data to the cloud
- Have a maximum mass of no more than 5 pounds for the entire solution provided by the Team to the consumer

This assessment and monitoring, as well as the interpretation and interaction of the solution must be performed solely in the hands of a consumer, independently of a healthcare worker or facility. Use of telemedicine or simply sending a person's health data directly to a healthcare worker is not acceptable. This requirement is intended to put the means for health awareness, metrics, and initial steps of care first in the hands of the person to whom the health belongs.

Competition Structure

The Qualcomm Tricorder XPRIZE is a 3.5-year, fixed-date Competition with a total prize purse of $10M. The Competition will include a **Qualifying Round** and, for those Teams that advance past this first stage, a **Final Round** followed by **Prize** awards.

The **Qualifying Round** will take place during the first quarter of 2014 and will include:

- A controlled demonstration of system performance
- An evaluation of supporting studies, multimedia, prototypes, and plans
- An evaluation of the user interface, understandability and appeal

From the **Qualifying Round**, 10 Teams will be selected to advance to the **Final Round**, scheduled to occur during the first half of 2015. This **Final Round** will include:

- A health assessment Competition on a group of consumers
- A concurrent, comprehensive consumer experience evaluation
- Continuous monitoring of 5 Vital Signs and proof of adequate high-frequency data logging

It is the intent of XPRIZE Foundation that Teams may elect to acquire one another, 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 **Prize**, subject to

the terms and conditions in the **Master Team Agreement**. Teams cannot withdraw and enter into the **Competition** as new Team.

*The terms and conditions attached hereto as **Schedule A** are hereby incorporated into the Guidelines and the Master Team Agreement of the Qualcomm Tricorder XPRIZE by this reference (collectively, this or the "Extended Final Round Guidelines"). All terms and conditions set forth in the Master Team Agreement or the Competition Guidelines V28 that are not explicitly revised pursuant to this Schedule A shall remain in effect without modification. In the event of any discrepancy or conflict between the terms of: (i) this Schedule A; (ii) the Master Team Agreement; (ii) the Competition Guidelines V 28; and (iii) any other Competition documents, the terms of this Schedule A shall prevail and control.*

NEW SECTION: SCHEDULE A EXTENDED FINAL ROUND

EXTENDED FINAL ROUND	
December 2015	Re-Entry Qualification Period Begins
July 26th 2016	Re-Entry Qualification Period Ends
September 2016	Consumer Testing Begins
Early 2017	Judging and Validation of entries
Early 2017	Awards Ceremony

The **Extended Final Round** is an extension of the Competition. This round is scheduled to begin in the latter half of 2015. The Extended Final Round will include:

1. Re-Entry gate
2. A health assessment Competition on a group of consumers
3. A concurrent, comprehensive consumer experience evaluation
4. Continuous monitoring of five Vital Signs and proof of adequate high-frequency data logging

~~*Leaderboards*~~

~~The XPRIZE Foundation intends to implement Leader Boards that will allow the press and public to follow the progress of the Competition and periodically see the relative progress and "success" of various Teams at different stages of the Competition. The Foundation will encourage Teams to compete in Leader Boards and will provide requirements for participation in this aspect of the Competition.~~

~~*Awards*~~

~~Prizes will be awarded to the top three finishing solutions from the **Final Round**:~~

- ~~1st Place = $7,000,000~~
- ~~2nd Place = $2,000,000~~
- ~~3rd Place = $1,000,000~~

~~The winner of the Qualcomm Tricorder XPRIZE is determined based on a consumer experience evaluation score and an overall health condition assessment score (see section 3.1 for a detailed description).~~

Competition Guidelines

These **Competition Guidelines** summarize the high-level requirements and Rules of the Competition and are binding on Teams as referenced in, and as part of, the **Master Team Agreement**. Additional requirements, testing procedures, and other Competition details will be published as appropriate and will be binding on Teams. During the Competition, there may be unanticipated issues that arise that require modifications to the **Competition Guidelines**. **XPRIZE Foundation** will publish such changes on the Competition website, and such changes will be binding on Teams ten (10) business days following such publication. **XPRIZE Foundation** further reserves the right to make such changes effective immediately in exigent circumstances. Thus, the XPRIZE Foundation reserves the right to revise these **Competition Guidelines** as appropriate. In all cases, the XPRIZE Foundation will endeavor to remain true to the guiding principles summarized in the next section.

2. Guiding Principles

The XPRIZE Foundation has designed the Qualcomm Tricorder XPRIZE so that it adheres to the following principles:

- Achieve our main goals: stimulate innovation and integration of technologies, making reliable health assessment available directly to health consumers in an appealing way that is deemed desirable by consumers
- Stimulate the development of new options for consumer-driven healthcare
- 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

The Qualcomm Tricorder XPRIZE 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.

3. Competition Outline, Terms, and Conditions

~~3.1 Prize Criteria and Prize Payment~~

~~A **$7,000,000 USD first place prize purse** will be awarded to the Team that can demonstrate the highest health assessment Competition score while being one of the five Teams with the highest consumer experience score (both subject to minimum scores), while meeting the requirements for maximum mass, data capture, and logging.~~

~~A **$2,000,000 USD second place prize purse** will be awarded to the Team that can demonstrate the second highest health assessment Competition score while being one of the five Teams with the highest consumer experience score (both subject to minimum scores), while meeting the requirements for maximum mass, data capture, and logging.~~

A **$1,000,000 USD third place prize purse** will be awarded to the Team that can demonstrate the third highest health assessment Competition score while being one of the five Teams with the highest consumer experience score (both subject to minimum scores), while meeting the requirements for maximum mass, data capture, and logging.

The winner of the Qualcomm Tricorder XPRIZE will be determined in the following manner:

1. Teams solutions must be selected for participation in the **Final Round** via the **Qualifying Round**
2. **Final Round** Teams' solutions must have a combined mass, including all components supplied by the Team to the consumer user, of no more than 5 pounds (see section 4.5 for details)
3. **Final Round** Teams' solutions must meet the minimum achievement scores for both the consumer experience and assessment portions of the **Final Round** in order to be eligible for the prize purse
4. **Final Round** Teams' solutions must be able to measure data within the specified frequencies and ranges of reliability for the Vital Sign Set in the **Final Round**, and upload data to the cloud at a minimum every 12 hours in order to be eligible for the prize purse (for details, please see section 5)
5. Of the **Final Round** Teams meeting the mass restrictions, the minimum scores for both the consumer experience and health assessment, and meeting the measurement frequencies and range of reliability for the Vital Sign Set, the five Teams with the highest consumer experience score in the **Final Round** will be eligible to win a prize purse
6. Among the **Final Round** Teams meeting all of the above conditions, the Qualcomm Tricorder XPRIZE winners will be determined by their health assessment Competition scores in the **Final Round**

Teams will only be paid a **Prize** upon winning the **Competition**'s **First**, **Second**, or **Third Place Prizes**. Winning Teams will be paid a **Prize** per the terms of the **Master Team Agreement** and Teams will not receive payment for preparation or participation in the Competition. Teams are solely responsible for their own costs.

If there are ties, **Prizes** will be awarded according to the tie breakers and procedures set forth in the **Master Team Agreement**.

3.1 Extended Final Round Eligibility and Prize Purses

3.1.1 Extended Final Round Eligibility. In order to qualify as a "Finalist Team" and be eligible to participate in the Extended Final Round, a Team must satisfy the Extended Final Round Re-Entry Requirements set forth in Appendix B, Section 7 below. To be eligible to receive any award pursuant to Sections 3.1.2 and 3.1.3 below, a Finalist Team must receive an average Consumer Experience Score of at least seventy percent (70%), pursuant to Section Appendix B, Section 7 below.

3.1.2 Health Assessment Category Prize Purse.

3.1.2.1 A **Best-in-Category Prize** of **Six Million Dollars ($6,000,000.00)** will be awarded to the Finalist Team that: (i) receives an Extended Final Round Health Assessment Score of at least 70% pursuant to Section 4.2 of the Guidelines and Appendix B, Section 7 below; and (ii) receives the highest Extended Final Round Health Assessment Score, pursuant to Section 4.2 of the Guidelines and Appendix B, Section 7 below

3.1.2.2 A **Second-Best-in-Category Prize** of **Two Million Dollars ($2,000,000.00)** will be awarded to the Finalist Team that: (i) receives an Extended Final Round Health Assessment Score of at least 70% pursuant to Section 4.2 of the Guidelines and Appendix B, Section 7 below; and (ii) receives the second highest Extended Final Round Health Assessment Score pursuant to Section 4.2 of the Guidelines and Appendix B, Section 7 below.

3.1.2.3 If only one (1) Finalist Team receives an Extended Final Round Health Assessment Score of at least 70%, then that Team will be awarded a prize equal to the **entire Health Assessment Category Prize Purse** in the amount of Eight Million Dollars ($8,000,000.00).

3.1.2.4 If no Finalist Team receives an Extended Final Round Health Assessment Score of at least 70%, then, the amount of the Health Assessment Category Prize Purse shall be decreased to Four Million Dollars ($4,000,000.00) and shall be awarded, at the discretion of the Judging Panel, to the Finalist Team(s) in recognition of significant category-specific accomplishments by the Team(s) during the Competition

3.1.3 **Vital Signs Category Prize Purse.** A **Best-in-Category Prize** of **One Million Dollars ($1,000,000.00)** will be awarded to the Finalist Team that receives the highest Extended Final Round Vital Signs Score pursuant to Appendix B, Section 7.

3.1.4 In the event that a single Finalist Team wins BOTH the entire Health Assessment Category Prize Purse AND the Vital Signs Category Prize Purse, then that Finalist team will be designated as the **"Grand Prize Winner"** of the Competition.

NEW SECTION: MILESTONE ACHIEVEMENT AWARDS

Qualcomm Tricorder XPRIZE has instituted milestone awards corresponding to some of the re-entry requirements as described below:

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Qualcomm Tricorder XPRIZE has instituted milestone awards corresponding to some of the re-entry requirements as described below:

Lab Test Demonstration Milestone:

1. To attain this milestone, a team must accurately diagnose, as confirmed by XPRIZE, a total of 9 conditions (7 of 10 Core and 2 of 3 elective conditions) to satisfy the Laboratory Test Component Demonstration phase of the re-entry process per Competition Guidelines (Appendix B, Section 7).

2. Upon attainment of such milestone criteria, the Chief Judge shall sign a "Lab Test Demonstration Milestone Achievement Form" validating the results.

3. Upon receipt of the respective Lab Test Demonstration Milestone Achievement Form executed by the Chief Judge, XPRIZE shall process a $50k milestone payment per team that has achieved the milestone.

Tricorder Human Qualification Milestone:

1. Tricorders will be evaluated as an entire system at UCSD (Qualification Test Sessions) dependent on performance on the re-entry criteria per Appendix B, Section 7 of these Competition Guidelines.

2. The QTXP judging panel will review the results and determine if a team successfully met all of the applicable re-entry criteria per Appendix B, Section 7 and will document the results on a "Tricorder Human Qualification Achievement Form."

3. Teams that have successfully met such re-entry criteria will participate in the "Tricorder Human Qualification Milestone Pool." The milestone payment amount to be paid to each qualifying team (“MPA”) will be calculated as follows:

$$\text{MPA} = \frac{(\$1{,}000{,}000 \text{ minus the total Lab Test Demonstration Milestone payment amount})}{\text{Number of Teams in Tricorder Human Qualification Milestone Pool}}$$

4. Upon receipt of the respective Tricorder Human Qualification Achievement Form documenting attainment of the Tricorder Human Qualification Human Milestone for the teams, XPRIZE shall process a milestone payment for each team in an amount equal to MPA in the above formula.

3.2. Competition Schedule

QUALIFYING ROUND: Submissions	
8 Jan 2013	Registration opens
30 Aug 2013, 11:59 a.m. Pacific Time	Registration deadline
15 May 2014, 11:59 a.m. Pacific Time	Submissions deadline
15 May – 8 Aug 2014	**Qualifying Round** for review and selection of **Finalist Teams** (up to 10)
27 Aug 2014	Formal announcement of **Finalist Teams**
FINAL ROUND: Consumer Testing and Health Assessment	
27 Aug 2014 to 1 May 2015	**Finalist Teams** design and build
17 June 2015 to 15 Dec 2015	Consumer testing of up to 10 **Finalist Teams'** Solutions
16 Dec 2015 to 22 Jan 2016	Judging and Validation of **Finalists Teams'** Entries
27 January 2016	Awards Ceremony
EXTENDED FINAL ROUND	
December 2015	Re-Entry Qualification Period Begins
August 1st 2016	Re-Entry Qualification Period Ends
September 2016	Consumer Testing Begins
Early 2017	Judging and Validation of entries

Early 2017	Awards Ceremony

The Competition will occur in two rounds: the **Qualifying Round** (Submissions) and the **Final Round** (Consumer Testing). An overview of the Competition timeline is provided below

NEW SECTION: EXTENDED FINAL ROUND

As of October, 2015 the Qualcomm Tricorder XPRIZE has had an extension of the Final Round of the Competition. *ALL PREVIOUS TEST SESSION RESULTS WILL* NOT *BE USED IN THE EXTENSION.* Teams will be afforded an opportunity to update their Tricorders and then will be required to pass "Re-Entry" criteria in order to return to the Consumer Test Sessions of the Final Round Test program. During the extension, Teams will be responsible for paying for and executing their updates and for the mandated Re-Entry test sessions. The Re-Entry programs are intended to ensure:

1. That Teams activate and modify fully integrated Tricorder systems in their home development locations *ultimately by testing on people who have Competition conditions. Laboratory bench reports will be inadequate for Re-Entry.*
2. That the extension interval will allow sufficient time for updates and modifications both informally and then with formal certification sessions. Where feasible, schedules for completion of all demonstrations will be open up until deadlines.
3. That assistance from XPRIZE will be offered where simple and practical (for example, with guidance on working with IRBs)
4. That the on-board laboratory testing technologies will perform accurately as *built-in components* of the Tricorders
5. That the Diagnostic Logic systems of the Tricorders can accurately perform assessments of people with wide ranges of presentation of Competition conditions
6. That people with Competition conditions can be successfully diagnosed by Tricorders *for each Competition condition*
7. That appropriate Monitoring and Certification of the Re-Entry tests results will be carried out by requiring Re-Entry Test Session data be sent to the Competition cloud for examination by XPRIZE

Summary of Changes in Final Round

1.) Extension of Competition Schedule
    a. The Competition Test Program will re-commence on September 1, 2016 and is anticipated to be complete in early 2017
2.) Human Testing Required (see below)
3.) Conditions for Assessment (Guidelines Section 4.20)
    a. The Core Conditions set will be reduced to 10
    b. In the Elective Conditions, Teams will be afforded the opportunity to change one (1) condition
4.) User Survey Guidelines Section 4.5
    a. User Survey questions about Social Media will be updated
5.) Vital Signs Section 5.3
    a. The Sampling upload requirements will be reduced
6.) Session Duration (Appendix B, Section 5.7.3)
    a. Sessions will now be either 90 minutes or 24 hours in duration
7.) Re-Entry Qualification (Appendix B Section 7)

a. New requirements will be necessary for any Team to re-enter the Test Program:
    1. Laboratory Test Component Demonstrations
    2. Diagnostic Logic Demonstrations
    3. Human Test Sessions

3.3. Who Can Participate?

To be eligible to compete and claim any prize, 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 Qualcomm 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.

One person must be designated as the Team Leader and will be responsible for receiving communications from and communicating with the XPRIZE Foundation.

The Competition is void in those countries where prohibited or restricted by law. The XPRIZE Foundation 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**.

3.4. Scientific Advisory Board

A Scientific Advisory Board (SAB) has been formed to assist with the formulation of the scientific aspects of the Competition. Duties of the SAB are to assist with the establishment of qualifications for prospective judges, approve the **Judging Panel**, assist with development of judging criteria, and provide input toward the development of final **Competition Guidelines**.

3.5. Judging Panel

The official judges of the Competition comprise the **Judging Panel**. The **Judging Panel** will be responsible for evaluating compliance with these guidelines and Rules. The **Judging Panel** will also 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.

The XPRIZE Foundation 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.

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.

All determinations, exercises of discretion, and decisions made by the XPRIZE Foundation or the **Judging Panel** may be made in the XPRIZE Foundation's or the **Judging Panel**'s sole and absolute discretion, including without limitation, the award of **Prizes**. All decisions and opinions made by the **Judging Panel** shall be rendered by a majority of the judges and are binding on both the Teams and the XPRIZE Foundation, and are not subject to review or contest. The **Judging Panel** retains sole and absolute discretion to declare a winner of the Competition and otherwise award all **Prizes**. Any such decisions of the **Judging Panel** are final, binding, and may not be challenged by the Teams.

3.6. Official Language and Currency

The official language of the **Competition** is English. All communications with the XPRIZE Foundation must be in English unless a Team has received prior written permission from the XPRIZE Foundation.

All references to a currency are references to United States Dollars (USD).

All references to a time are references to Pacific Time (PT).

3.7. Registration

To participate in the Competition, Teams must accurately and truthfully complete the **Registration** process online at the designated website form once **Registration** is opened. Teams must complete the **Registration** process by the deadline per section 3.2.

To register, Teams must fill out the **Registration Form**, which will include (but not be limited to), the following:

- Team name
- Team leader's name and basic information
- Team logo
- List of all Team Members, providing each Team Member's full name, e-mail address, phone, mailing address, affiliation, if any, and country
- A quote about the Qualcomm Tricorder XPRIZE (150 word statement expressing your views on the importance of the Qualcomm Tricorder XPRIZE that can be used on the XPRIZE Foundation website, as well as in marketing and promotional materials)
- A brief technical description of the proposed solution (up to 3 pages long)

Teams must sign and complete an unrevised **Master Team Agreement**, and each Team Member (as defined in the **Master Team Agreement**) must sign a complete and unrevised Team Member Release, Waiver, and Confidentiality Agreement. A Team is not eligible to compete or receive **Prizes** unless and until these documents are provided to the XPRIZE Foundation and accepted by the XPRIZE Foundation, as described below and in the **Master Team Agreement**.

Teams must submit the **Registration Fee** at the time of **Registration**. The **Registration Fee** is between $5,000 and $25,000 USD, payable in U.S. Dollars only. The **Registration Fee** that each

Team must pay depends upon when they register for the Competition with the fee being lower for Teams that register early. The following are the **Registration Fee**s and timelines:

- **Registration Fee** to Teams that register between 8 January 2013 and 11:59 a.m. PT 21 June 2013: $5,000
- **Registration Fee** to Teams that register between noon PT 21 June 2013 and 11:59 a.m. PT 1 August 2013: $10,000
- **Registration Fee** for Teams that register between noon PT 1 August 2013 to 11:59 a.m. PT 30 August 2013: $25,000

The **Registration Fee** will not be refundable once the XPRIZE Foundation has accepted and executed the Team's **Master Team Agreement**. If the XPRIZE Foundation has not received a signed, unrevised **Master Team Agreement** from a Team by the **Registration** deadline, the XPRIZE Foundation will refund any **Registration Fee** submitted by the Team and will disqualify the Team from the Competition.

Registration must be approved and accepted by the XPRIZE Foundation in order for a Team to compete and be eligible to receive any **Prizes**. The XPRIZE Foundation may refuse **Registration** for any reason, including, but not limited to, the XPRIZE Foundation'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, including the **Registration Form**, the **Master Team Agreement**, the Team Member Release, Waiver, and Confidentiality Agreement, and the **Registration Fee**, will be reviewed by the XPRIZE Foundation for completeness and for compliance with the principles and Rules of the Competition using all available information. The XPRIZE Foundation may pose additional questions or requests for clarification to supplement the **Registration** materials as part of its evaluation. All rejection or acceptance decisions by the XPRIZE Foundation will be final and in its sole and absolute discretion.

4. Competition Structure

This is a two round incentivized Competition that will allow Teams to demonstrate reliable, mobile assessment technologies, making health assessment findings available directly to consumers in an understandable, appealing way.

The XPRIZE model actively avoids presupposing what the eventual winning design may entail. Solutions submitted by Teams will vary immensely, and are expected to represent a wide range of innovative approaches.

4.1. Qualifying Round: Completion of Competition Submissions

The "test readiness level" reporting has now been incorporated into the template documents of the Qualifying Round Submission.

Once registered, Teams may access the official Competition Submission Form. The Competition Submission Form requires each Team to provide the following information by the deadline date in section 3.2

- Description of the solution's concept. There will also be a description of the Team's development plan including management structure, general description of funding plan, major milestones accomplished, and conformance to the Competition timeline.

- Description of the solution's functionality including any supporting documentation, diagrams, testing, studies, multimedia, video, or other materials necessary to demonstrate and validate the performance of the system. The goal of the submission for this section is to provide evidence of assessment functionality for 13 of the 21 total conditions, of which are a minimum of five (5) Core Set conditions, one (1) Elective Set condition, and continuous monitoring of three (3) Vital Sign conditions.

- Description of solution's appeal to consumers and usability, including any supporting documentation, diagrams, testing, studies, multimedia, video, or other materials necessary to demonstrate desirability of the system.

Technical components of the description must be written at a level appropriate for an individual working in an engineering and medical support capacity to understand and verify. Usability components of the description must be written at a level appropriate for an individual working in a customer support capability to understand and advise users.

There are no limitations for the length of a submission. Prototypes are not permitted. Teams are encouraged to submit all relevant information needed to demonstrate their solution is viable in both assessment capability and usability. However, the **Judging Panel** will take note of concise entries that provide a convincing basis for the total data presented. Judging will be based on the strength and conclusiveness of the Team's submission.

Teams will be responsible for securing or recruiting any consumers they deem necessary to develop or test their systems for the **Qualifying Round** submission. Teams are responsible for determining and obtaining necessary clearance and releases for any consumer/patient testing that they conduct. Teams are expected to ensure protections for consumer testing and safety, informed consent, privacy, and disclosure are held in the highest regard. The Foundation has the right to audit documentation to assure adherence to U.S.-based consumer testing standards.

Upon closing of Submissions, eligible submissions will be judged (see Section 4.3: Qualifying Round: Judging). An eligible submission provided for review must describe a solution that is originally developed or implemented (e.g. must not violate or infringe on any applicable law or regulation or third-party right).

If no qualifying submission can be verified at the completion of the **Qualifying Round**, the Competition may reopen to new Teams, at the sole and absolute discretion of the XPRIZE Foundation, and new Competition Submissions from any Team will be considered according to the protocol described above.

Up to 10 top Teams from the **Qualifying Round** will advance to the **Final Round** of the Competition.

4.2. Conditions for Assessment

There are three broad groups of health conditions that Teams will be expected to detect or monitor. These are classified into the Core Set, Vital Signs Set, and Elective Set:

- The Core Set is composed of conditions that are considered essential to any successful Team solution; many of these are already covered by commercially available standalone diagnostic systems or sensors.

- The Elective Set is also composed of important conditions, but is considered a more ambitious list than the Core Set in light of the current state of technology. These may require entirely new technologies or very significant miniaturization pushes.

- The Vital Signs Set is intended to challenge Teams to rapidly move from today's single point-in-time measurement toward a continuous monitoring and cloud-logging paradigm that enables ongoing pattern and trend recognition.

One of the biggest considerations for the Competition is selecting the optimal set of conditions around which to frame the Competition. The ultimate goals of the Competition are to de-skill

the art of diagnostic medicine and make health a desirable part of consumers' daily lives; conditions chosen are intended to promote both equally. In addition, the conditions must balance a number of different factors to ensure that Teams are motivated to compete, are solving difficult challenges, and are working toward attainable targets. Several factors have been taken under consideration in the initial selection of these conditions including:

- *Consumer acceptance and usefulness*. Advances in medical sensing and health assessment must be helpful and of interest to people in their daily lives. This first generation consumer solution considers this need for practicality, convenience, and the ability to drive consumer adoption.

- *Relevance*. In this context, relevance includes the significance of a condition—in terms of factors such as prevalence, incidence, potential threat, morbidity, and mortality—as well as the effectiveness of treatments available.

- *Definitiveness*. Many conditions recognized today will inevitably turn out to be multiple, different illnesses masquerading as a similar set of symptoms. And many of the tests that health workers currently rely on to assess health conditions will be replaced by more reliable methodologies. Even Criterion Standards that are considered diagnostic "gold standards" today may rapidly prove inferior to newer methods. Thus, the very yardsticks used to define illness may prove to be a moving target. Where possible, it is important to pick conditions that we can identify in absolute terms and establish standards against which Teams can be compared.

- *Advancing Sensing*. Much of the process of de-skilling medicine into the hands of the consumer will come as a result of assessment tests that can be quantified through the use of sensors and sensing, whether in the form of improved traditional laboratory tests, alternative mechanisms such as use of accelerometers in place of medical imaging, non-invasive blood pressure readings, rapid PCR, or other means. By choosing conditions that are likely to result in a diversity of sensing modalities, the Competition rewards successful partnerships and builds expertise across multiple conditions and domains.

The following table outlines the difference between the **Qualifying Round** and **Final Round**.

	Qualifying Round	**Final Round**		Scoring
Core Set	A minimum of 5 of 13 conditions*	All 13 conditions		Points
Elective Set	A minimum of 1 of 3 conditions	Any 3 acceptable conditions		Points
Vital Signs Set	A minimum of 3 of 5 parameters	All 5 parameters		Pass/Fail

	Qualifying Round	Final Round	Scoring
Total	13 of 21 conditions and parameters	21 of 21 conditions and parameters	

*Except “Absence of conditions”

Please note: the numbers of conditions that need to be met during the **Qualifying Round** listed above are minimums for each of the sets. Overall, at least 13 of the 21 conditions and parameters must be demonstrated, except Absence of conditions. Of those 13, at least five (5) conditions are from the Core Set, one (1) condition is from the Elective Set, and three (3) parameters are measured in the Vital Signs Set. Teams are strongly encouraged to submit all that their system is capable of at the time of the **Qualifying Round**, as the **Judging Panel** will consider the strength of the entry based on all capabilities submitted.

The following sections offer an overview of each set and the list of conditions for each.

Core Set

The Core Set is composed of conditions that are considered essential to a successful winning solution. Commercially available standalone diagnostic systems or sensors already serve many of these conditions. There are 13 conditions in the set. One of these is “Absence of conditions” which means the individual is free of any of the remaining conditions in the Core Set as well as the three conditions chosen by the Team from the Elective Set. This is included so that, in the **Final Round**, Teams will need to show that they can correctly make negative assessments.

1. Anemia
2. Urinary Tract Infection
3. Diabetes
4. Atrial Fibrillation
5. Stroke
6. Sleep Apnea
7. Tuberculosis
8. Chronic Obstructive Pulmonary Disease (COPD)
9. Pneumonia
10. Otitis Media
11. Leukocytosis
12. Hepatitis A
13. Absence of Core Conditions

The **Final Round** health assessment results for each of the Core Set conditions for each Consumer Tester must, at a minimum, be uploaded to the cloud at the end of the assessment period. The details of this upload will be found in the Testing Procedures as noted in section 5.

The Core Set includes:

The Criterion Standards for Core and Elective conditions can be found in Appendix A.

Elective Set

The Elective Set is also composed of important conditions. In light of currently available technology, this set is considered a more ambitious list than the Core Set. These may require entirely new technologies or very significant miniaturization pushes.

In the **Final Round**, Teams will be asked to declare the three conditions they intend to include in their solution no later than 60 days after being notified that they are a Finalist Team.

To encourage Teams to pursue innovative, outstanding (but perhaps unconventional) sensing technology, a system is in place to allow Finalist Teams to petition for a condition to be added to the Elective Set. These petitions will be reviewed by the **Judging Panel** to determine if the condition is worthy of being included. The conditions already in this set are a guide to the **Judging Panel** as to what caliber of technology and condition belongs in the Elective Set. The same combination of subjective and objective criteria that guided disease inclusion in each of the sets will be used to decide if the petitioned condition is relevant, challenging, and requires sufficiently advanced sensors and sensing. Each Finalist Team will be allowed to file a petition for one condition at a time, and each Finalist Team will be allowed one successful petition. Once a condition has been added to the Elective Set, it is available to all Teams in the Competition. The Finalist Teams will be given until close of Qualifying Round submissions to submit a petition for Elective conditions.

The **Final Round** health assessment results for each of the Team's chosen Elective Set conditions for each Consumer Tester must, at a minimum, be uploaded to the cloud at the end of the assessment period. The details of this upload will be found in the Testing Procedures as noted in section 5.

The Elective Set includes:

1. Pertussis
2. Hypertension
3. Mononucleosis
4. Allergens (airborne)
5. Hypothyroidism/hyperthyroidism
6. Food-borne illness

7. Shingles
8. Melanoma
9. Strep throat
10. Cholesterol Screen
11. HIV Screen
12. Osteoporosis

NEW SECTION: COMPETITION CONDITIONS NOVEMBER 2015

Reduced Competition Condition List

Because of evolving medical standards and changing epidemiology, the list of Competition conditions has been reduced. The following principles were followed in selection of this list:

1.) New conditions were not admitted to the Competition list.
2.) Maintaining the list as close as possible to the original was important for both fairness to the Teams and for the validity of the Competition. The legitimacy of the Competition construct is dependent on the understanding that the Rules are fixed and would only be changed in extra-ordinary circumstances.
3.) The point of the Competition is that a broad based, wide variety of conditions was put forward to demonstrate the concept of a multi-purpose consumer usable product. The list of conditions continues to reflect, in terms understandable to the public, the breadth of capabilities to be demonstrated in Competition winners.
4.) Any revision of the conditions list was considered in fairness: Teams that designed their Tricorders around specific conditions could be potentially handicapped in their competitiveness.
5.) Safety of Testers is a primary consideration. Conditions that may have heavy physical or emotional implications in the face of use of an unreliable system were considered
6.) Changing medical management practices since the original list was developed was considered.
7.) Competition conditions that may not be recruitable due to changes in epidemiology were considered. If no cases of a condition were to be available during a recruitment interval, that lack of availability would affect the ability to complete the Competition in a timely manner.

Core Conditions

Stroke, Tuberculosis and Hepatitis A were removed and Core Conditions has been reduced to 10 conditions.

1. Anemia
2. Urinary Tract Infection, Lower
3. Diabetes
4. Atrial Fibrillation
5. Sleep Apnea, Obstructive

6. Chronic Obstructive Pulmonary Disease (COPD)
7. Pneumonia
8. Otitis ("Ear Infection")
9. Leukocytosis
10. Absence of Core Conditions

Elective Conditions

For the Elective Conditions, conditions not selected by the Finalists have been removed: Airborne Allergens and Osteoporosis. Also, in order to improve competitiveness, Teams may elect to change ONE (1) Elective condition. However Food-borne Illness and Pertussis may NOT be a new selection.

The Elective Set includes:

1. Pertussis (Whooping Cough) (not allowed as new selection)
2. Hypertension
3. Mononucleosis
4. Hypothyroidism/Hyperthyroidism
5. Food-borne Illness (not allowed as new selection)
6. Shingles
7. Melanoma
8. Strep Throat
9. Cholesterol Screen
10. HIV Screen

The following section outlines the requirements for the **Extended Final Round**.

	Extended Final Round	
Core Set	litions	
Elective Set	tions	
Vital Signs Set	neters	Points

The overall health assessment score will be the combined point total earned in both the elective and core set of conditions.

Vital Signs Set

The Vital Signs Set is intended to challenge Teams to move toward a continuous monitoring and cloud-logging paradigm which emphasizes regular connectivity over wireless networks to a cloud based platform. This set consists of traditional Vital Signs, all of which can currently be collected using some form of existing hardware, but for purposes of this Competition is not limited to using existing sensor devices.

Teams must be able to measure at the frequencies and ranges of reliability listed in Section 5 at a minimum. In addition, Teams must log this data to a cloud whenever and wherever connectivity is available or minimally at least every 12 hours. The Vital Signs Set will be evaluated on a pass/fail basis. Teams unable to meet the requirements in terms of data sampling and logging will not be considered for advancement in the Competition.

The Vital Signs Set includes:

1. Blood pressure
2. Electrocardiography (heart rate/variability)
3. Body temperature
4. Respiratory rate
5. Oxygen Saturation

The Criterion Standards for the Vital Signs Set can be found in Appendix A.

In addition to the Vital Signs data, results from all other diagnostics, including any diagnosis reached, must also be communicated to a cloud platform, with date, time and location when connectivity is available. The data will be reviewed by the Physician Oversight Committee.

4.3. Criterion Standard

The XPRIZE Foundation recognizes that the Criterion Standard can be defined as a method having established or widely accepted means for determining a diagnosis, providing a reference to which a new screening, assessment or diagnostic test can be compared. The method need not be a single or simple procedure but could include the consensus of an expert panel of clinicians.

Criterion Standards will be used in the Competition to determine whether consumers have the health conditions that Teams are required to assess. The correct assessment will be determined by the Physician Panel, who will use the Criterion Standard testing found in Appendix A as the basis for their determination and create a benchmark against which all Finalist Teams' assessments will be compared. Points will be tallied based on correct or incorrect assessment

per section 5.

Methodologies used in current Criterion Standards are meant only for reference and only for use by the Physician Panel in determining the answer key. These Criterion Standards have no influence on the allowable means by which Teams may arrive at their assessment of consumer conditions.

A full discussion of conditions and Criterion Standards for the Core and Elective Set conditions can be found in Appendix A. Note that standards are subject to change as technology, manufacturing advancements, and even understanding of conditions evolve or improve.

4.4. Qualifying Round: Judging

In order to advance, Teams must prove to the **Judging Panel** that their technology has a feasible, concrete means to be developed into a health assessment tool within the Competition timeline. In the **Qualifying Round**, each entry submitted must be able to demonstrate usability from a consumer's point of view, as well as preliminary assessment capabilities and continuous monitoring capabilities. The **Qualifying Round** of the Competition will judge Teams on the following weighted criteria:

1. Health assessment performance (45%)

   To ensure that Teams are on track technically, they will be required to demonstrate their assessment performance. Teams will have to demonstrate that their solutions are able

to correctly assess at least 13 total conditions or Vital Signs, with a minimum of any five (5) Core Set conditions and one (1) Elective Set condition as part of the 13 total conditions. The list for these specific conditions can be found in section 4.2.

Although the Registered Team will not be required in the **Qualifying Round** to demonstrate their system under true Competition conditions, they must convey proof of performance and adequacy. Examples include submitting videos of their solution being compared to Criterion Standard measurement techniques for the given condition, providing analysis for standard lab samples, demonstrating an algorithm's ability to interpret data for an assessment conclusion, or using the solution in a computerized model or simulation. The current Criterion Standard measurement techniques for each condition can be found in Appendix A. As an example, if one of the conditions the Team chooses for testing is hypertension, the Registered Team may shoot a video showing their solution assessing high blood pressure measuring blood pressure in three individuals and then showing those same consumers immediately having their blood pressure taken via a commercially available sphygmomanometer (the current Criterion Standard). As these aspects may be apt to gaming and video editing, XPRIZE Foundation reserves the right to further investigate claims where necessary.

2. Evaluation of supporting studies and proposed solution development pathways (10%)

   The second criteria of the score in the **Qualifying Round** of the Competition will be a review of the Teams' supporting materials. The **Judging Panel** will review submitted data, papers, studies, trials, and proposed plans that demonstrate the feasibility or means for feasibility of the solution.

   Ten percent of the possible **Qualifying Round** points will come from this evaluation component.

3. User interface, understandability and consumer appeal (45%)

   In order to promote the importance of a solution that users find understandable, appealing and desirable, Teams will be judged on criteria that demonstrate usability of their solution/system/device. This includes but is not limited to:

   - *Physical appearance*. An important part of the Competition will be the consumer experience, a factor very likely to be affected by the system's physical appearance and appeal. As such, physical appearance of the device will be considered, representing user willingness to adopt and use the device.

- *Complexity and number of components*. There is no limit as to how many discrete components constitute a system. Sensors may be attached to a control unit, fastened individually to the consumer, or kept apart and reserved for occasional use or home monitoring. This category will be evaluated on system simplicity and the need for a consumer to carry, attach or operate components, as well as the power or recharge requirements

- *Device interface*. Rapid growth in consumer electronics use has and will continue to push the bar in terms of how users interface with their devices. Teams will be evaluated on means and ease of interface, including presentation and understandability of sensor output.

- *Engagement*. The ability of the solution to invoke action on the part of the user is a reflection of its overall desirability. Actions can include customizing the appearance of the device, pursuing further information from multiple sources, communicating with others and maintaining a dialogue deemed worthwhile by the user, taking proactive or responsive actions, and re-checking health status over a period of time.

4. Measurement and logging of Vital Signs Set conditions (Pass/Fail)

   In order to meet the requirement for measuring at a minimum three states from the Vital Signs Set, Teams will have to show that they can achieve the sampling frequency outlined in Section 5 and be able to send this data to the cloud at a minimum of every 12 hours, measured for a distinct individual. The data captured by Teams' solutions must be accessible remotely via the Internet but, beyond this, the XPRIZE Foundation does not require a specific online interface, security convention, or particular credentialing system. However, the XPRIZE Foundation will require that Teams provide this data in a format this is accessible and reviewable by the **Judging Panel**. Teams must show acceptable performance levels to be considered for the **Final Round**.

Criteria	Weighting
Health Assessment Performance	45%
Evaluation of supporting studies and proposed solution development pathways	10%
User interface, understandability and consumer appeal	45%
Safety	Pass or Fail (Pass required as a condition to advance)
Measurement and logging of Vital Signs Set conditions	Pass or Fail (Pass required as a condition to advance)
Total	100%

The total possible number of points is 100. Note that a minimum Qualifying Round score of 70% of total possible points, or 70, plus a review of Pass on Vital Signs monitoring and on Safety is required to qualify for the Consumer Testing portion of the Competition. Of those Teams that meet these criteria, it will be the 10 highest scoring Teams that will be invited to move on in the Competition as a **Finalist Team**.

Teams shall reasonably cooperate with the **Judging Panel** in any verification activities. Application of the judging criteria to eligible Competition entries will be at the **Judging Panel**'s reasonable discretion and, as to elements of the judging criteria involving matters of subjectivity, at the **Judging Panel**'s sole and absolute discretion.

The **Judging Panel** may select up to 10 **Finalist Teams** 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 website, along with the names and biographical information of the Team Members of the **Finalist Teams**.

A summary public announcement regarding the **Finalist Teams** will take place on or about the date specified in section 3.2

4.5. Final Round: Consumer Testing

Once selected, **Finalist Teams** will prepare for consumer testing and evaluation of their technology.

Finalist Teams are required to submit their testing methodologies for all Core and their chosen Elective conditions by 31 March 2015 so that alternative test methodologies can be adequately accommodated. The evaluations will be conducted at no more than two U.S.-based, major metropolitan areas to be determined by the XPRIZE Foundation. The XPRIZE Foundation will select and work with a Consumer Testing Partner and/or a Clinical Testing Partner Organization (Testing Partner) to conduct consumer testing for **Finalist Teams**. The Testing Partner will be responsible for recruiting all participants on the Consumer Testing Panel.

Each consumer will test more than one Team's solution. The XPRIZE Foundation will ensure the testing order of solutions does not create a bias in the Competition. The testing order will be equalized so that each Team's solution is used similarly to others in being the first, middle, or last to be tested by consumers.

Finalist Teams' initial prototypes must be delivered to the XPRIZE Foundation Testing Partner according to the master schedule provided. The number of solutions required to be submitted by **Finalist Teams** for the Consumer Testing will be detailed in the full Testing Procedures, but will be no less than 30 identical solutions. **Finalist Teams**' solutions will each be weighed to determine if each solution conforms to the maximum mass of 5 pounds. All items supplied by the **Finalist Team** to the Consumer Tester are considered to be part of the solution and part of the total weight restriction. One AC adapter and adapter cord is allowed that is not included in the weight limit. Additional chargers and extra batteries are *part of* the 5 pound limit. Equipment supplied by the Competition, for example Wi-Fi hubs, is *not* part of the weight limit. If any one solution of any one Team exceeds the mass limits, that **Finalist Team** will be disqualified from the Competition. Additionally, **Finalist Teams** must provide to the XPRIZE Foundation a detailed list of instructions as to how to operate each solution at the time of delivery.

The Testing Partner's personnel will be responsible for reviewing the detailed instructions and providing any questions to the XPRIZE Foundation who will, in turn, forward to the Team for clarification, no later than 35 days before consumer panel training.

Each Team will be responsible for performing a brief training of the Testing Partner personnel as specified in the master schedule provided. This Train-the-Trainer activity will be conducted in person and will be consist of instructional training as well as a first-line troubleshooting training.

The Testing Partner will perform no more than 60 minutes of training for each consumer on the use of a Teams' solution, including instruction time and a question and answer period. Training

will take place immediately prior to the start of consumer testing. Training will be held in the same metropolitan area where testing will be conducted. The Testing Partner will obtain all signed consent forms from the Consumer Testers with respect to testing. **Finalist Teams** will not be present when the Consumers are being instructed on the use of their solution and will not have contact with any of the Consumer Testers for the duration of the Competition.

The XPRIZE Foundation, in conjunction with the Testing Partner, will finalize and oversee the administration of a comprehensive consumer experience evaluation as indicated in Section 5. This evaluation will be completed by each Consumer Tester based on their time with each device. The preliminary categories for evaluation are:

A. Appeal ("Do I like the way it looks and feels?")

Characteristic	**Weighting**	**Judging Criteria description**
1. Form factor - Mobile device	1.5	The device's shape, volume and dimensions (L vs W vs H) is appealing to me
2. Form factor - health attachment(s)	1.5	The device accessory's shape, volume and dimensions is appealing to me
3. Screen Appearance	1.5	The screen layout and appearance is appealing to me
4. Wearable & Portable	1.5	I did not mind carrying the device, and wearing the accessory is comfortable and not bothersome
5. Device "personality"	2	The character, personality, and interaction style of the overall device is appealing to me
6. Appeal and desirability overall	2	My overall rating on the way this device looks and feels
	10	

B. Understandability ("Can I understand the information and is it provided in a way I like?")

Characteristic	**Weighting**	**Judging Criteria description**
1. Understanding of test	3	I understood what the test was measuring and what effect it could have on me
2. Info on health condition	3	Information on the health condition tested was provided and was complete, but not too much
3. Next steps	3	The device gave me an idea of possible next steps, and did not simply default to "call your doctor"
4. Free of techno-speak	3	There were no acronyms, medical/technical jargon, or other terms that I did not know
5. Graphical display	4	Color, graphics, video, etc. helped me understand my results or condition

Characteristic	Weighting	Judging Criteria description
6. Interactive nature	4	The device gave me appealing games, crowd sourced interaction, or social media links to my information
7. Desirability of information	4	The device gives me a more desirable way to know about my health than going to a medical facility
8. Geared for consumers	4	I feel special care was taken to have the device be used by a person like me
9. Overall understandability	5	My overall rating on the understandability of information and way it's given to me
	33	

C. Functionality ("Do I like the way it works?")

Characteristic	Weighting	Judging Criteria description
1. Start-up	3	I was able to easily figure out how the device starts up (connections, calibration, total effort)
2. Input required	3	I feel the device asks for a reasonable amount of effort from me to use it
3. Ease of measuring health	3	I like the way the sample is collected using the accessory(s) and how the test is run
4. Ease of navigation	3	It was easy to navigate and find/do something specific or return to the home screen
5. Power requirements	3	I like the way the device is powered and the ease of charging or powering it up
6. Sharing	3	There is a way for me to download and/or send my information to another person
7. Confidence in the device	3	I feel confident about using this device to assess my health
8. Fun factor	3	I would describe the way this device works as enjoyable, appealing or fun
9. Seamless Integration	4	I feel all the parts of the device connect easily and work together as one
10. Overall functionality	5	My overall rating on how this device works
	33	

D. Action ("Does having the information make me want to do something")

Characteristic	Weighting	Judging Criteria description
1. Desirability of device use	4	I would like to get other tests and health information from this device
2. Further interest	4	Using the device led me to think about for look for information related to my health
3. Communication with others	4	After using the device I am more likely to speak

Characteristic	Weighting	Judging Criteria description
		or communicate with another person about my health
4. Action related to state of mind	4	Using the device made me change my views or state of mind about health or wellness (more positive)
5. Action related to state of health	4	Using and interacting with the device led me to take some kind of action for my health or wellness
6. Future impact	4	Using this device in the future, I would likely give more attention to my health
	24	

Criteria	Weighting
Appeal	10
Understandability	33
Functionality	33
Action	24
TOTAL	100

The total possible number of points is 100. Note that a minimum Final Round score of 70% of the total possible points, or 70, is required to qualify for a prize purse.

At the end of the Consumer Tester's testing period the Testing Partner will receive the solution back from each consumer participant. At that time, the Testing Partner will ensure that all parts of the consumer experience evaluation have been completed.

Finalist Teams are responsible for paying all costs, travel, and miscellaneous expenses including transportation and customs for getting their equipment and Team Members to the identified testing site in order to participate in the train-the-trainer activity. **Finalist Teams** will not be allowed to be present during the Consumer Training, the testing period nor the administration of the consumer experience evaluation for the testing period.

The **Finalist Teams** will make available an email/telephone troubleshooting/help line for the XPRIZE Foundation that will be in operation during the entire testing window, 24 hours a day, 7 days a week. Any issue, question, or circumstance that warrants contacting the Team will first be validated by the **Judging Panel**. Once the **Judging Panel** approves the interaction, the XPRIZE Foundation will contact the **Finalist Team** with the issue, question, or circumstance that needs to be addressed for resolution. The response will be conveyed to the Testing Partner who will then take the appropriate action.

The XPRIZE Foundation will be responsible for all costs associated with the facility, facility personnel, **Judging Panel**, as well as any costs associated with the Consumer Testing, including the recruitment of the Consumer Testing Panel.

NEW SECTION: EXTENDED FINAL ROUND CONSUMER EXPERIENCE EVALUATION NOVEMBER 2015

Questions regarding interaction with Social Media will be removed and each Team will be awarded the four (4) points for interaction and all sections will remain weighed as shown in Section 4.5.

Pending logistics and availability, each consumer may test up to 3 different devices.

4.6. Final Round: Judging

The winners of the First, Second, and Third Place Prizes will be determined in accordance with the criteria found under Section 3.1 using the testing procedure summarized in Section 5 and the additional testing procedures and test standards detailed in the Appendices and the judging and tie-breaking processes specified in the **Master Team Agreement**.

The **Final Round** Competition is intended to highlight the two key components of the solutions created by Teams: health assessment capability and consumer acceptance. Teams are incentivized to achieve innovations in assessment technologies through the means of their choosing. However, consumer desire to own and use these solutions will be the definitive disruptive element that revolutionizes healthcare as we know it today. The **Final Round** scoring system reflects this and as an example of such, it is possible that a **Finalist Team** can achieve the highest health assessment score but would not be eligible for a prize purse if it also did not finish in the top five Teams based on its consumer evaluation score.

To ensure an adequate level of performance worthy of an XPRIZE, a minimum score of 70% of total possible points for both the health assessment and consumer experience portions of the Competition is required. Teams must meet these hurdle levels in order to be eligible for a prize purse.

If no **Finalist Team** meets the Competition minimums, the **Judging Panel** will evaluate how close the **Finalist Teams** were to meeting the criteria found under section 3.1. The **Judging Panel**

retains sole and absolute discretion to declare a winner of the Competition and otherwise award all prizes. Any such decision may not be challenged by the Teams. If no Team in the Competition fulfills all such requirements, but the **Judging Panel** determines, in its sole and absolute discretion, that a Team or Teams has or have substantially fulfilled such requirements, it may award prizes to one or more such Teams.

5. Testing Procedure

A summary of the Testing Procedure is included below. A draft of the full Testing Procedure will be available in the Consumer Testing Procedures and will be made available to Teams by 9 August 2014.

The highlight of the Qualcomm Tricorder XPRIZE Competition will be the consumer usability and health assessment Competition portion of the **Final Round**. Up to 10 Teams who have successfully qualified will face off to prove the superiority of their solutions. This **Final Round**, scheduled to occur approximately in the third and fourth quarters of 2015, will be used to arrive at the following:

1. Assessment score: Resulting from a health assessment Competition on a group of consumers (per Team).

   Teams will provide their solution to a group of consumers. The number of consumers testing each **Finalist Team**'s solution will be detailed in the full Testing Procedures. Each of the consumer pools will be composed of either consumers with real conditions from the Core Set and the Finalist Team's chosen Elective Set or samples of consumers who had the conditions. Teams will be tasked with assessing the correct conditions in each consumer. For example, one of the consumers may have silent hypertension but be otherwise free of the other conditions.

   It is possible that a Consumer Tester may have more than one condition, especially as there is the possibility of co-morbidity among the conditions being assessed. A portion of the consumers will have only one of the 15 conditions being tested for that Team in the **Final Round**, 12 from the Core Set or three from the Elective Set. Furthermore, some consumers in the test pool will be free of any of the conditions under examination ("absence of Core Condition", the 13th condition from the Core Set). A panel of physicians will verify all consumer health states and this verification will be reviewed by the **Judging Panel**, as detailed in section 4.3.

   Teams will earn Assessment points according to their performance in correctly

concluding positive or negative status of health conditions. This scoring scheme is designed to reward correct responses, penalize incorrect responses, and avoid incentives for guessing or gaming the system:

Finding	Points
Correct Positive Assessment	5
Correct Negative Assessment	0
Incorrect Assessment	-1

The **Final Round** health assessment results for each of the Finalist Team's Core Set and chosen Elective Set conditions for each Consumer Tester must, at a minimum, be uploaded to the cloud at the end of the assessment period. The details of this upload will be found in the draft Testing Procedures which will be made available to Teams no later than August 9 2014, as noted above.

All points from each Consumer Tester will be totaled by the Testing Partner to become the Finalist Team's Assessment Score.

2. Consumer experience score: Resulting from the comprehensive consumer experience evaluation during the assessment Competition

   Consumers are central to the Qualcomm Tricorder XPRIZE's objectives. It is important that Teams not only be tested on the technical sensing and assessment merits of their solutions, but also on the user experience they offer, as this is paramount in the ultimate success of any consumer device. This will be tested in the **Final Round** of the Competition via a consumer experience evaluation at the end of each testing period, resulting in a Consumer Experience Score. This evaluation will be conducted by the Testing Partner.

   By intertwining these critical, consumer-based metrics for success with the assessment Competition, the consumer experience will encompass all aspects of Teams' systems, including the consumer interface, as well as the invasiveness of sensors, portability, seamlessness of integration, understandability, physical appeal of the solution, and the ability of the solution to evoke willing action and usage.

   All points from each Consumer Tester will be totaled by the Testing Partner to become the Finalist Team's Consumer Experience Score.

3. Vital Signs conditions measurement and data logging requirement: Teams must demonstrate continuous data capture on three principal axes in order to advance and be considered for prize awards:
   a. Ability to obtain data at the required sampling frequency

b. Ability to store data centrally, quickly, and in a form that is easily accessible and understandable by the **Judging Panel** via the internet (format to be specified by XPRIZE) at a minimum of every 12 hours during the 72 hr consumer testing period
c. Data is within a reasonable reliability as measured by the Criterion Standard during spot checks. This Criterion Standard defines a range of error for accuracy and performance consistency over a specific number of reports.

The judging requirements for Vital Signs monitoring include (a) the user interface reporting requirement, (b) the device sampling requirement, and (c) the reliability index of the submission. The table below defines the properties that will be evaluated:

Condition	**U/X Reporting Requirements**	**Device Sampling Requirements**	**Reliability (Notes)**
1. Blood pressure	At least 1x screen refresh per measurement	Continuously available on 30 seconds demand; otherwise at least once per hour	Range error: Systolic and Diastolic +/- 10% (1)
2. Electrocardiography (heart rate/variability)	Continuous Charting Strip	Continuous; Sampling 240 Hz	range error: 5% STD DEV of R-R variability (2)
3. Body Temperature	At least 1x screen refresh per minute	Continuous; once per minute	range error: +/- 0.5 Deg C (3)
4. Respiratory rate	At least 1x screen refresh per 5 seconds	Continuous; at least 1x per second	range error: plus/minus 5% (4)
5. Oxygen Saturation	At least 1x screen refresh per second	Continuous; at least 10x per second	range error: +/- 2% P02 (5)

Notes:

1. 8 out of 10 tests demonstrate consistency on systolic and diastolic measures in this range
2. Will benchmark strip from clinical ECG device to examine accuracy and variability
3. Referenced to oral thermometer standard
4. Referenced to observed respiratory rate
5. Referenced to industry standard pulse/ox device

To verify the validity of the collected data, the consumers using each Team's solution may undergo a number of "spot checks" throughout their testing period. Random checks may be conducted for 2-minute windows each day during testing. These will be conducted by personnel trained in administering the applicable Criterion Standard

method of measurement. For instance, if blood pressure is required, a qualified health professional will take the measurement with an industry standard sphygmomanometer for comparison.

All conditions on the Vital Signs Set will be required for each Finalist Team. If the Finalist Team fails to demonstrate that they can meet the three criteria above, the Team is disqualified from the Competition, regardless of assessment scores or consumer experience scores.

NEW SECTION: VITAL SIGNS NOVEMBER 2015

The Vital Signs component of the Competition will remain largely unchanged in the Competition format. However the sampling rate for data upload will be drastically reduced for the ECG and PO2 reporting requirement.

Vital Signs will be judged via the Competition Judging Portal and the award in the Vital Signs category will be selected based on an equally weighted score of audited Vital Signs and an average of the percentage of continuous Vital Sign data.

Each team will also be required to provide the following information:

1. Method used to calculate Standard Deviation (S.D.) of the ECG r-r interval (RR)
2. Integration of time and computation method used for each of the vital signs reported

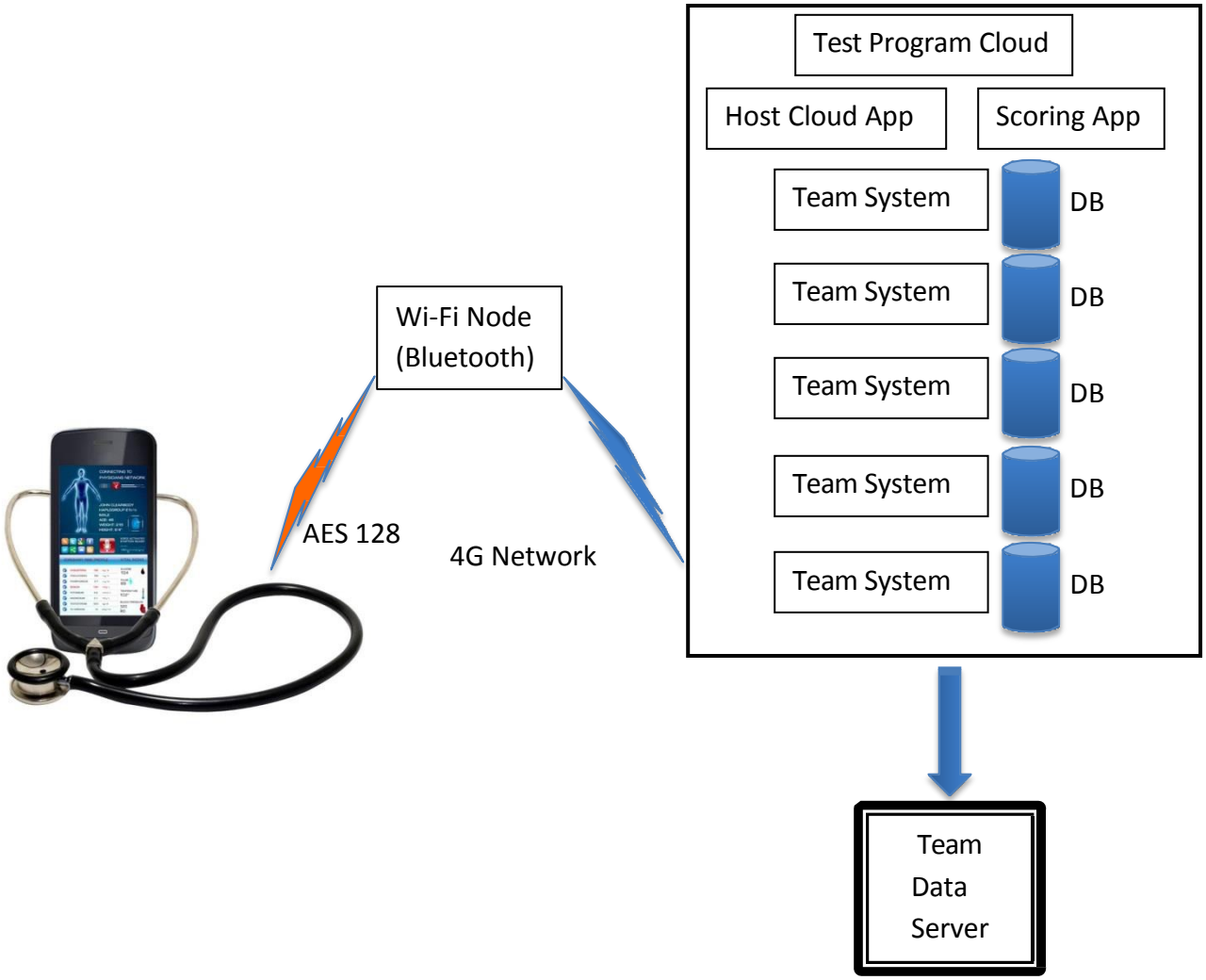
The judging requirements for Vital Signs monitoring include (a) the user interface reporting requirement, (b) the device sampling requirement, and (c) the reliability index of the submission. The table below defines the properties that will be evaluated:

	ing Requirements	**pling Requirements**	**Notes)**
essure	creen refresh per measurement	y available on 30 seconds demand; otherwise at least once per hour	Range error: Systolic and Diastolic +/- 10% (1)
rdiography (heart rate/variability)	Charting Strip	Sampling 240 Hz, **UPLOAD REPORTING 5 HZ**	range error: 5% STD DEV of R-R variability (2)
3. Body Temperature	creen refresh per minute	s; once per minute	range error: +/- 0.5 Deg C (3)

ry rate	creen refresh per 5 seconds	s; at least 1x per second	range error: plus/minus 5% (4)
aturation	creen refresh per second	s; **REPORTING 1 per Second**	range error: +/- 2% P02 (5)

~~All 10 Finalist Teams will participate in the assessment Competition. After determining that each Finalist Team has passed all requirements for the Vital Signs set as well as meeting or exceeding the minimums established for both the assessment and consumer experience portions of the Competition, the top five Teams, as determined by their Consumer Experience Score, are eligible for the prize purses. These remaining five Teams are then ranked according to their Assessment Score, and awarded the 1st, 2nd, and 3rd Place Prize Purses according to that rank.~~

4. Data Infrastructure Requirement:
   The Competition will have a Test Program infrastructure with the general configuration as in the diagram below. Teams will be offered the ability to host their Cloud applications on a Cloud server, which will communicate via a cellular based Wi-Fi node to the Tricorders. The Test Program will also include a host app which will accept the required data logging information from the Tricorder systems (including Vital Signs and user interaction logs). There will be a Scoring Application, where the Tricorders' assessments of the Core and Elective Conditions will be loaded and scored. It may be possible to offer Teams a one-way feed of the data uploading from their systems so they can monitor availability and performance. Complete features of the transmission system, Cloud processing server capabilities offered and APIs for host and scoring Apps will be made in Q1 of 2015.


Test Program Cloud
Host Cloud App
Scoring App
Team System
DB
Team System
DB
Team System
DB
Team System
DB
Team System
DB
Wi-Fi Node
(Bluetooth)
AES 128
4G Network
Team
Data
Server

Appendix A

Criteria for Diagnosis of Core and Elective Conditions

Principles behind Diagnostic Criteria used by Partner Organizations for Core and Elective Conditions:

The primary objective in the health assessment test component of the Qualcomm Tricorder XPRIZE Competition is determination of capability to reliably assess the health of the individual in a consumer level context. Unlike physicians and hospitals, assessment by Qualcomm Tricorder XPRIZE **Finalist Teams**' solutions must be accomplished by people with no expert medical knowledge and be without substantial risk of injury or harm to either the device user or any participants being tested with the device.

The conditions listed below are general disease states that are important to the health of people in North America. They may have only one cause or they may have a variety of etiologies. The point of the Competition is for the Finalist Teams' solutions to demonstrate the identification of a disease state without requiring technologies involve an expensive, invasive, or time consuming test in combination with a diagnostic medical professional.

It is understood that modern medical diagnosis is a knowledge set in evolution. Conditions that are recognized as one "disease" today will be better understood in the future as variants or even different diseases. Future knowledge may include genetic sub-categories of disease and understanding of how various environmental conditions, infections or other variants may lead to what is now categorized as one disease or disease state. Competitors may well be able to determine genetic, environmental, or sub-variants of a variety of the conditions in the list. We highly encourage the advancement of medical knowledge and technology. However, our Competition surrounds the conditions listed below, *defined by the Criterion Standards listed.* Scoring in the Competition will be solely based on comparing the **Finalist Team**'s assessment of people with the identified conditions to the Partner Organizations' Criterion Standard diagnosis. Thus detection of only a sub-variant of a condition may be insufficient for optimal scoring in the Competition. Further, detection of a "risk factor" may be an interesting strategy, but risk factors are NOT scored in the Competition, only actual presence of the Criterion Standard identified conditions.

Importantly, the Competition *does not require replication* of the Criterion Standard techniques. In fact, attempts to replicate these standards may well result in failure because of the Competition requirements for safety during the consumer's use. New techniques are highly

encouraged. Government approval for clinical use of any technique *is not required* and participation of a Team's test in the Competition has no implication of government endorsement or any kind of regulatory assessment of the system. Competition health assessment scoring will solely be on the basis of accuracy of detection of the listed conditions and the clarity of communication to the end-user so that action can be taken.

Below are the Core and Elective Set conditions for the Competition. Each of the conditions has listed the Criterion Standard testing that the Partner Organizations will use in the evaluation of the consumer Testers and determination as to whether or not each individual has a particular condition. The Criterion Standard diagnostic criteria are presented and representative literature citations are given.

Special issues regarding the condition are also included. It is possible that in some conditions, the effective treatment of the condition would return the Criterion Standard Values to normal: thus the certification window (i.e. the time between the establishment of the Criterion Standard and the beginning of the Testing interval is described for some conditions). Thus it is anticipated that the presence of the Criterion Standard values will be present in the Testers *despite the onset of treatment in some conditions.* On the other hand, people who have been effectively treated for their condition (diabetes or hypertension for example), i.e. whose Criterion Standard values are normal, *will not be admitted as Testers.* Thus an *uncontrolled diabetic meeting the Criterion Standard <u>while on medications</u> may be used as a Tester.* It is not a practical possibility for some conditions to have sufficient numbers of Testers available for the Competition who are not being treated, for example, tuberculosis. However, where treatment might well interfere with Team's attempting novel technological approaches to conditions, Testers will be identified and enrolled before treatment. For example, oral glucocorticoids might interfere with some serological investigations and thus Testers on these medications would be excluded for conditions such as Shingles.

Post Hoc Certification and False Starts Some conditions may have pathological verification after the initial clinical identification, such as Melanoma or infectious disease conditions. *Where such verification is available, it will be made use of.* For example, pathological verification of Melanoma will be made by microscopic examination of the excised sample by a certified pathologist. Another example of such post hoc certification would be growth of bacterial cultures of a urine specimen in a Tester with a positive test in clinic. If the post hoc certification DOES NOT verify the presence of the condition using the Criterion Standard, all of the results from that test event will be erased and the individual test event will be repeated (False Start). No penalty or bonus will be applied to the Team for a repeat test under these conditions.

The Core Set

1. **Anemia: Microcytic Iron Deficiency Anemia**
   Criterion Standard: Serum Hb level ([hemoglobin (Hb) <11.0 g/dl]) and Low Ferritin level (30ng/mL (=µg/L) for males, and 15 ng/mL (=µg/L) for females.

   Clin J Am Soc Nephrol. 2006 Sep;1 Suppl 1:S4-8.
   Assessing iron status: beyond serum ferritin and transferrin saturation.
   Wish JB.

2. **Urinary tract infection**
   Criterion Standard: Urinalysis: test strip positive, followed by Urine Microscopy, showing positive presence of pathogenic bacteria including: e.coli. Post hoc certification will be made by urine culture.

   Am Fam Physician. 2011 Oct 1;84(7):771-6.
   Diagnosis and treatment of acute uncomplicated cystitis.
   Colgan R, Williams M.

3. **Diabetes**
   Criterion Standard: glycated hemoglobin (HbA_{1C}) of greater than 6.5%. Serum glucose level greater than 200 mg/dL. Tester may be on oral hypoglycemic, but not insulin.

   Diabetes Care. 2010 Jan;33 Suppl 1:S62-9. doi: 10.2337/dc10-S062.
   Diagnosis and classification of diabetes mellitus.
   American Diabetes Association.

4. **Atrial fibrillation**
   Criterion Standard: Atrial Fibrillation identified on 12 lead ECG with physician confirmation.

   Circulation. 2006 Aug 15;114(7):e257-354.
   ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society.

Fuster V, Rydén LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Le Heuzey JY, Kay GN, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann S, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Antman EM, Halperin JL, Hunt SA, Nishimura R, Ornato JP, Page RL, Riegel B, Priori SG, Blanc JJ, Budaj A, Camm AJ, Dean V, Deckers JW, Despres C, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Tamargo JL, Zamorano JL; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; European Society of Cardiology Committee for Practice Guidelines; European Heart Rhythm Association; Heart Rhythm Society.

5. **Stroke, Acute Hemorrhagic Stroke.**
   Criterion Standard: Neurologist verified acute hemorrhagic stroke on Brain MRI and/or CT Scan (no anti-coagulant treatment).

   Lancet. 2007 Jan 27;369(9558):293-8.
   Magnetic resonance imaging and computed tomography in emergency assessment of patients with suspected acute stroke: a prospective comparison.
   Chalela JA, Kidwell CS, Nentwich LM, Luby M, Butman JA, Demchuk AM, Hill MD, Patronas N, Latour L, Warach S.

6. **Sleep apnea, Severe Obstructive**
   Criterion Standard: Home sleep testing with PO2, Respiratory drive and Breath expiration monitoring with Apnea-Hyponea Index (AHI) >15/hour.

   American Academy of Sleep Medicine, 2007
   The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications
   Conrad Iber

   Sleep. 2009 Feb;32(2):150-7.
   The new AASM criteria for scoring hypopneas: impact on the apnea hypopnea index.
   Ruehland WR, Rochford PD, O'Donoghue FJ, Pierce RJ, Singh P, Thornton AT.

7. **Tuberculosis, Positive Lung Disease**
   Criterion Standard: Positive Acid-fast bacillus in sputum sample by a reference laboratory

   Early detection of tuberculosis: an overview of approaches, guidelines and tools
   World Health Organization

8. **Chronic obstructive pulmonary disease (COPD)**
   Criterion Standard: FEV_1/FVC ratio is <70% and GOLD criteria (Global Initiative for Chronic Obstructive Lung Disease) showing values still the same after bronchodilators.

   Respir Res. 2007 Dec 4;8:89.
   COPD diagnosis related to different guidelines and spirometry techniques.
   Nathell L, Nathell M, Malmberg P, Larsson K.

9. **Pneumonia, Acute Pneumonia.**
   Criterion Standard: Acute pneumonia, verified on Chest X Ray

   Curr Opin Pulm Med. 2007 May; 13(3):159-69. **Radiological imaging in pneumonia: recent innovations.** Sharma S, Maycher B, Eschun G.

10. **Otitis Media ("ear infection")**
    Criterion Standard: Direct visualization of otitis media by Otolaryngologist, video/photographic verification.

    Pediatr Infect Dis J. 1998 Jun;17(6):540-3; discussion 580.
    Otoscopy for the diagnosis of otitis media.
    Pelton SI.

11. **Leukocytosis, Acute**
    Criterion Standard: Serum leukocytosis, with no concomitant white blood cell disease, such as lymphoma or leukemia. White blood cell count greater than 11,000 per mm^3 (11×10^9 per L)

    Ann Intern Med. 1987 Jan;106(1):65-74.
    The complete blood count and leukocyte differential count. An approach to their rational application.
    Shapiro MF, Greenfield S.

12. **Hepatitis A**
    Criterion Standard: Serum measurement of Hepatitis A, Positive RIA IGM test for Hepatitis A Antibody.
    No concomitant white blood cell disease, no previous vaccination against Hepatitis A

J Clin Microbiol. 1977 May;5(5):521-30.
Serodiagnosis of viral hepatitis A: detection of acute-phase immunoglobulin M anti-hepatitis A virus by radioimmunoassay.
Bradley DW, Maynard JE, Hindman SH, Hornbeck CL, Fields HA, McCaustland KA, Cook EH Jr. J Infect Dis. 1995 Mar;171 Suppl 1:S9-14. **Host immune response to hepatitis A virus.** Stapleton JT.

13. Absence of Core Conditions

Criterion Standard: Consumer Testers to have serum blood work, ECG, chest X Ray, lung function tests, sleep apnea tests and brain MRI. All must be negative within 30 days of testing, with no acute symptoms that are defined in the Core and Elective sets chosen by a Team or Vital Signs disorders in 24 hours before testing.

The Elective Set

1. **Pertussis (Whooping Cough)**

Criterion Standard: B Pertussis culture positive +/- PCR Positive for b pertussis DNA. Tester not to be on Glucocorticoid Treatment.

Curr Infect Dis Rep. 2003 Jun;5(3):213-219.
Progress in the Diagnosis, Prevention, and Treatment of Pertussis.
Munoz FM, Keitel WA.

2. **Hypertension**

Criterion Standard: Serial sphygmomanometer tests. Hypertension: Systolic > 140 mm Hg (18.7 kPa) and Diastolic > 90 mm Hg (12.0 kPa). Tester may be on anti-hypertensive medications. Post hoc certification of the condition of hypertension will be made by review of the data log values from the tricorder's Vital Signs monitoring system. The average of the home based blood pressure measurements must exceed 135/85. (Pickering, 1996, Verdecchia, 2001)

Hypertension. 2003 Dec;42(6):1206-52. Epub 2003 Dec 1.
Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, Jones DW, Materson BJ, Oparil S, Wright JT Jr, Roccella EJ; Joint National Committee on Prevention, Detection, **Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute**; National High Blood Pressure Education Program Coordinating Committee.

Am J Hypertens. 1996 Jan;9(1):1-11.
Recommendations for the use of home (self) and ambulatory blood pressure monitoring. American Society of Hypertension Ad Hoc Panel.
Pickering T.

Blood Press Monit. 2001 Dec;6(6):323-7.
Reference values for ambulatory blood pressure and self-measured blood pressure based on prospective outcome data
Verdecchia P.

3. **Mononucleosis**
   Criterion Standard: Positive Monospot test. Subject to post-test verification with Epstein Barr Virus IGM serological verification. Tester will not be Glucocorticoid Therapy.

   J Clin Pathol. 1969 May;22(3):324-5.
   Monospot: a differential slide test for infectious mononucleosis.
   Basson V, Sharp AA.

4. **Allergens (airborne)**
   Criterion Standard: Aerosolized test samples of windborne pollens

   J Immunol Methods. 2012 Sep 28;383(1-2):47-53. doi: 10.1016/j.jim.2012.01.012. Epub 2012 Feb 3.
   Immunologic, spectrophotometric and nucleic acid based methods for the detection and quantification of airborne pollen.
   Rittenour WR, Hamilton RG, Beezhold DH, Green BJ.

5. **Hypothyroidism OR hyperthyroidism**
   Criterion Standard: Hypothyroidism: TSH > 4.0 mU/ml; Hyperthyroidism: TSH <0.4 mU/mL; Tester may be on l-Thyroxine.

   https://www.aace.com/files/hypo-hyper.pdf

6. **Food-borne illness**

Setting: Laboratory, testing with verified contaminated food products Criterion Standard: Positive tests for E Coli in test samples

Appl Environ Microbiol. 2012 Dec;78(23):8403-11. doi: 10.1128/AEM.02272-12. Epub 2012 Sep 21.
Detection and Identification of Salmonella enterica, Escherichia coli, and Shigella spp. via PCR-electrospray ionization mass spectrometry: isolate testing and analysis of food samples.
Pierce SE, Bell RL, Hellberg RS, Cheng CM, Chen KS, Williams-Hill DM, Martin WB, Allard MW.

Special Conditions: No human Consumer Testers required.

7. **Shingles**

Criterion Standard: Dermatologist observation. Verified with PCR or intravenous IGM levels. Subject to Post-Hoc verification with Varicella Zoster Virus PCR test when available.

Clin Microbiol Rev. 1996 Jul;9(3):361-81.
Varicella-zoster virus.
Arvin AM. J Clin Virol. 2004 May;30(1):39-44.
Routine use of a highly automated and internally controlled real-time PCR assay for the diagnosis of herpes simplex and varicella-zoster virus infections.
Stránská R, Schuurman R, de Vos M, van Loon AM.

8. **Melanoma**

Criterion Standard: Biopsy positive for melanoma. Stage 0 or higher. May or may not have metastases. Note: initial identification of Melanoma will be by visual inspection by a Dermatologist specializing in pigmented lesion identification and removal. Because of the absence of a non-biopsy method of positive identification of melanoma, there may be Testers with lesions found not to be melanoma on biopsy. In such cases where the post hoc verification is negative, then replacement sessions will be carried out.

Surg Clin North Am. 2003 Feb;83(1):77-95, vi. **Dermatological perspectives of malignant melanoma.** Swetter SM.

9. Streptococcal Pharyngitis

Criterion Standard: Positive Rapid Antigen detection test. Subject to possible post-hoc verification by culture of strep pharyngitis. Testers will not be treated with glucocorticoids.

J Am Board Fam Pract. 2002 Jul-Aug;15(4):261-5.
Accuracy of rapid strep testing in patients who have had recent streptococcal pharyngitis.

10. Cholesterol Screen

Criterion Standard: Fasting LDL > 130 mg/dL. Testers may be on oral treatment for hyperlipidemia.

Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Executive Summary". National Heart, Lung, and Blood Institute (NHLBI). National Institutes of Health. May 2001.

11. HIV Screen

Criterion Standard: HIV antibody ELISA test (repeat positive)

MMWR Recomm Rep. 2001 Nov 9;50(RR-19):1-57; quiz CE1-19a1-CE6-19a1.
Revised guidelines for HIV counseling, testing, and referral.
Centers for Disease Control and Prevention.

12. Osteoporosis

Criterion Standard: Dual-energy X-ray absorptiometry (DXA), T-score -2.5 or below

WHO Scientific Group on the Prevention and Management of Osteoporosis (2000: Geneva, Switzerland) (2003). **"Prevention and management of osteoporosis: report of a WHO scientific group"**

http://whqlibdoc.who.int/trs/WHO_TRS_921.pdf

Appendix B

Qualcomm Tricorder XPRIZE

SUBMISSION AND CONSUMER TESTING PROCEDURES

These **Procedures** are an addendum to the **Competition Guidelines** of the Qualcomm Tricorder XPRIZE. The Competition is organized in two stages: the Qualifying Round, where Teams electronically submit documentation about their entry and a Consumer Testing Round, where the Finalist Teams entries will be tested by Consumer Testers. All Teams submitting documentation in pursuit of qualifying for the Consumer Testing round must adhere to the submission procedures outlined in Sections 1 to 4 in these Procedures. All Teams that the **Judging Panel** selects for participation in the Consumer Testing round ("**Finalist Teams**") must adhere to the Consumer Testing procedures outlined in Section 5, in order to qualify for selection as a winner of the Competition. Failure to adhere to these **Procedures**, either for Qualifying Round submission or for Consumer Testing, may result in the suspension or disqualification of Team by the **Judging Panel**, in its sole and absolute discretion. Any bold, capitalized words not defined in these **Procedures** bear the definitions in the **Competition Guidelines** or **Master Team Agreement**.

1. Introduction

For participation in the Competition, Teams must submit valid documentation of their technologies, their plans, simulations, and test results. Teams are expected to understand and follow not only the Rules of the Competition but also all regulations in their local jurisdiction regarding development and testing of medical devices. As stated above, participation in the Competition does not imply any regulatory assessment by the United States FDA . Further, participation in the Competition will not have any bearing on any subsequent regulatory assessments of the FDA of any Competition systems or components. For the Qualcomm Tricorder XPRIZE is an international Competition. Competition events with human Testers will take place in the United States. Thus competitors must follow US regulations for medical technologies. The United States Food and Drug Administration (FDA) regulates medical technologies. Importantly, the FDA and the XPRIZE Competition embrace data and information from outside the United States. All competitors must comply with approved research and development procedures. Compliance must fit with the laws and regulations of the country in

which the research was conducted, or by United States regulations, whichever provides greater protection of the human subjects. 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 Foundation personnel and the independent **Judging Panel** for the Qualcomm Tricorder XPRIZE *will not* research regulations nor will XPRIZE Foundation personnel or the **Judging Panel** determine legal compliance with regulations. For Competition purposes, Teams are expected to provide regulation information and compliance information, including evidence of compliance by independent certifying authorities, 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 complete disqualification from the Competition or revocation of a **Prize Purse**.

The overarching principle for submission in this Competition is concise, clear, and complete documentation by the 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 concise summaries be provided to aid the **Judging Panel** in their review process. The Competition on-line submission site will provide clear guidance on the expected organization and format of documentation.

2. Competition Principles

2.1. Safety and Privacy

Medical technologies may have physical, chemical, or mental effects on the human body. They may also affect the privacy of human medical data, including diseases and social information. All Team personnel should be aware of the risks related to the technologies they are building and the information they are collecting. Documentation of safety evaluations will be required to participate in the Competition. All reasonable efforts should be made to maximize safety and minimize invasion of privacy for Consumer Testers, Team members or anyone who might come in physical contact with equipment or specimens or have access to private medical information.

2.2. 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, the XPRIZE Foundation reserves the right to revise these **Procedures** as appropriate. The XPRIZE Foundation will publish such changes on the Competition website and such changes will be

binding on Teams ten (10) business days after such publication. XPRIZE Foundation further reserves the right to make such changes effective immediately in exigent circumstances. In all cases, the XPRIZE Foundation will endeavor to remain true to the guiding principles in the **Competition Guidelines**.

3. Scientific and Engineering Test Principles

Good scientific and engineering principles must be followed by the Teams entering the Qualcomm Tricorder XPRIZE. Ethical and legal management of human and animal research for technology for any Qualcomm Tricorder XPRIZE submission is expected. Documentation of good scientific practices, formal engineering design procedures, and sound ethical supervision is required in the Qualcomm Tricorder XPRIZE.

3.1. Competition Participation is Not a Clinical Trial

It is important to understand that participation in the Qualcomm Tricorder XPRIZE Competition is *NOT* participation in a clinical trial. A clinical trial is a formal process where technologies are assessed for their safety and for how well they work, with the ultimate objective of determining whether a technology is fit for sale. The Qualcomm Tricorder XPRIZE has similarities to and differences from clinical trials. Equipment physical safety and information security requirements for the Competition will be similar to those for clinical trials: documentation of the safety plans, tests and certificates will be required for Competition. However, *unlike* a clinical trial, the Competition will not involve formal evaluation of efficacy. Circumstances preclude a formal clinical trial for the numerous individual functions of a competitor's technology (see section 3.2 below). Instead a head-to-head Competition where points are accumulated or lost has been established. Statistical certainty will *not* be established in the Competition, unlike what is required in a clinical trial. Further, the XPRIZE Foundation encourages inclusion of novel technologies that have been determined to be physically safe, but may not have passed through formal clinical efficacy research procedures for regulatory approval. It is understood that technologies may have been evaluated for safety, but not have complete information from performance testing.

Because of these differences, results of the Competition will *not* serve as data for evaluation purposes for regulatory approval in the United States or other countries. While the detailed testing results will remain the property of the XPRIZE Foundation, the data will be provided to the Finalist Teams after being scrubbed of any identifying information of the Consumer Testers. Feedback will be provided to all Finalist Teams, but data collected on individual Consumer Testers will not. Further, the documentation procedures for the Competition do *not* conform to

normal clinical trial testing procedures for medical devices. The required documentation of safety and efficacy for prototype medical devices for the Competition may not necessarily be the formal requirements for regulatory approval in the United States or other countries.

However, many of the procedures of the Competition will involve common elements with procedures for legal certification for approval. In fact, documentation for medical device approval in the United States or other jurisdictions will be the highest level of quality of documentation of safety and efficacy for the Competition. If a component technology of a Team's solution has already achieved legal approval for sale, then documentation of that approval will be taken as the primary documentation of safety and efficacy for the Competition. It is anticipated that most of the component technologies in the Competition will have prior legal approval. Newer technologies that have not received approval are also anticipated and expected to be part of Team systems. Teams will have to have appropriate documentation for the Competition for their new technologies. Importantly, the level of documentation for admission to Competition on performance (also known as efficacy) will not have to be completed to the level required for regulatory approval, in order to be considered for Competition.

3.2. Competition of Multi-Function Systems

In the Qualcomm Tricorder XPRIZE Competition, systems must carry out a large variety of functions: monitoring Vital Signs, carrying out health assessments and providing interactive information to users. Such complex integration has never been required before, thus there have been no testing standards established or approval standards for sale of such devices. As stated above, the Competition is not a clinical trial and there will not be a comprehensive statistical assessment of the integrated packages. The Competition test plan has been established where Vital Signs monitoring will be audited, health assessments will be tested against patients and the user experience rated by users. Documentation of preparedness will be described below. Documentation will be required for each individual technology in the integrated system as well as for the use of the complete system. For example, a photon based sensor for measurement of heart rate will have to have documentation of its safety, of its anticipated performance and of the use of its information in the overall user experience. On-line submission of documentation will thus be divided into technology components, largely by component use, such as measurement of heart rate, blood hemoglobin level or disease presence. The on-line submission will also require a description of the user interface, its functionality and results of tests on individual users. Guidance will be provided about the on-line submission procedure.

3.2.1. Failure of Individual Technology Components

It is anticipated that Teams will have many different technologies at different levels of preparedness in their complete systems. Components with regulatory approval will be reviewed highly favorably by the **Judging Panel** for consideration for progression to the finalist testing. However, some technologies may have limited documentation of safety and/or performance. The **Judging Panel** will have sole discretion, as detailed in the **Master Team Agreement**, in their review of all technologies. A critical part of the judging process will be determining whether the complete system should be rejected from the Competition if an individual component of the system is inadequately documented, If the component that fails review is both removable and its removal will not prevent successful completion of the Competition, then the **Judging Panel** may allow further Competition with the failed component removed.

3.3. Safety and Performance Data Standards

Respect for human and animal safety is paramount in the Qualcomm Tricorder XPRIZE. 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 Foundation requires that all Teams competing for the Qualcomm Tricorder XPRIZE ensure that they pay close attention to risks to Consumer Testers from their technologies. Technologies with chemicals or radiation have obvious hazards. Inaccurate or inappropriate health assessments not only have medical consequences, but emotional implications for Testers (see section 3.3.2 below). Sometimes the risk may not be completely apparent. 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. It is to be recognized that user identity may not always be protected even when personal information is subjected to “de-identification” procedures. Even though a given technology may not appear to create an imminent human risk, XPRIZE Foundation 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 (FDA)
- 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

International Teams may submit certification from their local review bodies as long as those bodies follow the international standards on human research safety (see FDA document "Guidance for Industry. Acceptance of Foreign Clinical Studies": http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm124939.pdf

However, not-withstanding the certification of a non-United States regulatory authority on research risk, the **Judging Panel** completely reserves the right to reject participation in Competition procedures for any actual or perceived safety violation by a Team.

Any Team that is found to be avoiding government regulations either by an external authority or by the **Judging Panel** may be denied participation in the Competition as a Finalist Team.

3.3.1. Documentation of Safe Design, Safety Testing, and Safety Certification

Personal safety for all people involved in testing each Finalist Team's system is paramount. This includes the Consumer Testers, Testing Partner personnel, care-givers, the **Judging Panel**, and Qualcomm Tricorder XPRIZE Team personnel. Medical devices have a variety of potential illness or injury causing characteristics which include, but are not limited to:

- Physical injury: trauma through weight, sharp surfaces, or forces
- Radiation: High level Rf, radiation, light, or sound
- Electricity: AC or high voltage DC power
- Chemical: direct chemical exposure, volatile chemicals, internal (such as reagents), or external (such as disinfectants)
- Biological: contaminated surfaces, sample carriers, or other pieces of equipment
- Psychological: Presentation of disturbing or stressing information, such as illness state, stress levels, and presentation of inappropriate materials for the general public, such as medical images. As addressed in section 3.3.2 below, there are medical and psychological consequences for both false positive and false negative health assessments.
- Social: Invasion of privacy or public revelation of confidential medical or other personal information

All of these characteristics will be considered not only in Competition events, but also in the development and testing of the Team's medical devices, in the laboratories and during research by Qualcomm Tricorder XPRIZE Teams. Documentation of independent safety evaluation is mandatory for acceptance of submissions or equipment from any Team. Careful review of documentation and formal safety review of equipment will be carried out by the Qualcomm Tricorder XPRIZE **Judging Panel**.

3.3.2. Safety Regarding Information Accuracy

A critical component of safety for medical devices for public use is the accuracy of information presented and the implications of that information. What if a technology erroneously provides information about the presence of a potentially fatal disease? If the technology falsely reports a disease, a person might become erroneously despondent. In contrast, a person might not carry out appropriate action to avoid illness if a diagnosis is missed. Even correct information can be distressing. Further, *false negative* information, i.e. the Tricorder failing to identify a Competition condition that the Tester knows to be present is also a risk: how will they reconcile the new technology's evaluation against their physician's diagnosis.

Despite these risks, in the Qualcomm Tricorder XPRIZE Competition, statistically certain determination of diagnostic accuracy is not a prior condition for entrance. Government reviews for approval for sale of medical technologies do require reporting of accuracy and a plan for statistical review of data. Such a review of accuracy and performance will be prior condition for clinical trials that a Team conducts in pursuit of device approval. Volunteer test Consumer Testers in the Competition will be informed in the consent documents for Competition procedures that the accuracy of individual test components may not be completely known. Of course, existing reports of accuracy of equipment will required for Competition.

3.3.3. Documentation Procedures for System Safety Review

Documentation of safety of Competition systems will be required to be submitted in the on-line submission system. The **Judging Panel** will review the documentation provided by Teams and will only allow further consideration for Competition if safety documentation is complete for each component of a Team's system that is put forth. Components of the system are in three categories:

- Technologies for Vital Signs measurements or health assessments
- The physical chassis of the system including the enclosure and the electronics for power, controls and displays
- The user software interface

All components of a system must have documentation of safety review. It is incumbent upon Teams to determine both the level of risk associated with a component technology and the regulatory review associated with the PHYSICAL safety of the use of the component. For example, technologies that emit energy that enters the body are subject to FDA regulations in the United States:
http://www.fda.gov/Radiation-EmittingProducts/FDARadiologicalHealthProgram/default.htm

These regulations outline the procedures for design, testing, and documentation of energy emissions. Importantly, most technologies anticipated for the Competition will fall into categories that have well established safety standards, such as radiation limits, chemical controls, biological contamination etc. These standards are to be sought out, referred to, compared to the proposed technology, and submitted to the appropriate review for the location of the Team. Competition test procedures will be carried out in the United States. Thus United States regulatory standards on physical safety of technologies will be applicable. Information can be found at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

In these standards, it is noted that work carried out outside the United States may be appropriate for documentation. Teams must consult the appropriate United States and international regulations in order to determine if such work will obtain acceptance in the United States.

Teams are responsible for determining both what regulations they should be following for safety review in their own location and that such reviews will be acceptable for safety review in the United States. It is recognized that such regulations are highly complex and time consuming. Estimates of weeks or months are common for completion and approval of medical device safety documents. Teams must plan accordingly for approvals or certifications. Documentation will be reviewed by the **Judging Panel** and, if incomplete, may result in rejection from Competition or be reflected in submission scores. If Teams are uncertain of the requirements, they are highly encouraged to seek out and engage with experts on United States and international regulatory requirements to assist in preparation of documentation.

Submission of documentation of safety will be described in Section 4 below. Documentation of safety will be of different qualities for different technologies, even within a given Team's system. In order from highest to lowest acceptable quality, such documentation includes:

- FDA Approval/Clearance for sale in the United States
- Approval/Clearance (or equivalent terms) for sale outside the United States

- Investigational Device Exemption (IDE) approval for testing in the United States (See: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm)
- Approval for testing outside the United States under a formal human experimentation protocol

For each technology in a Team's system, certified documentation of one of the above categories will be required. Not-withstanding such certifications, the **Judging Panel** reserves the right to reject any system for testing for safety reasons from its own review. It should be noted that participation in the Competition is not a guarantee that any regulatory requirements are being met or that participating technologies are in compliance with any regulatory authority.

Many Teams will not have submitted all of their technologies for formal human testing. For example, in the United States, some work is done under "Research Grade" standards. Such work is carried out with little or no human subjects' protection oversight. XPRIZE Foundation strongly recommends 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 work done in "Research Grade" conditions or their country's or region's equivalent conditions will document their review process and document the reasons they should be exempt from formal human research supervision by an Institutional Research Board or similar organization. Teams should 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). As described above, a plan for formal government approval should be included. It is highly unlikely that technology that is tested without appropriate research supervision will be accepted for Competition.

3.3.4. Determination of Performance: Human Test Data

Presentation of evidence of effective performance of a system's component technologies and the overall system itself will be a critical element cornerstone of a Team's submission. Systems selected for finalist testing will have documentation showing performance across all required test conditions, all Vital Signs measurements and all user interactions. The documentation will be from existing device approvals (or approvals for equivalent technologies) or from research that has not been submitted for regulatory review. Note that as above, all human research submitted in documentation must be completed under appropriate review for subject safety. Theoretical descriptions and animal research may be taken into consideration of a performance review, but will be viewed with very low confidence in the absence of testing with humans.

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 the **Judging Panel** in its submission that it used a human subject and provided medical ethics and a safety plan to do so.

3.3.5. Documentation of Experimental Performance Data

It is expected that novel sensing technologies will be presented for review by the **Judging Panel**. 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 and the corresponding approval documents must be included in the system documentation.
- 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**

Regulatory Frameworks for Human and Animal Research

The Qualcomm Tricorder XPRIZE 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 they 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 presenting evidence of the reasons the Team believes that there is an absence of such guidelines, evidence must be presented 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 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 or access to medical records without permission.

Description of the documentation procedures about human performance data based on experimentation is described in Section 4.

3.4. Scientific Validity

Scientific validity is also vital in the evaluation of the technology. In order to determine if a technology is eligible to move on as a finalist entry, 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 **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 in order 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 must 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.

3.5. Privacy and Data Security

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 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 Foundation and the **Judging Panel**.

Please refer to the **Master Team Agreement** with respect to the Team's obligation to obtain consents for their development work on their proposed solutions.

3.6. Submission to Regulatory Agencies

The ability for a device to obtain approval from regulatory agencies for commercialization is NOT an immediate 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: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

These documents provide 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 that are not in the United States or that are intending to submit their technologies to other country's or region's regulatory agencies will need to review those 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. Such information will improve the scoring and likelihood of selection of a Team's submission for finalist Competition.

4. Qualifying Round Submissions

Please use the following in conjunction with the **Competition Guidelines**, Section 4.1, for submissions.

There is no limit on the overall length of the submission; however, some sections will have specified lengths. 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, character limits are provided. 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 (such as a government regulation website) 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 **Competition Guidelines**, Section 4, 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 English translation.

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

- Evaluation of Supporting Studies and Proposed Solution Development Pathways

- Health Assessment Performance
- User Interface, Understandability and Consumer Appeal
- Vital Signs Monitoring

The total possible number of points is 100. Note that a minimum Qualifying Round score of 70% of total possible points, or 70, plus a review of Pass on Vital Signs monitoring is required to qualify for the Consumer Testing portion of the Competition. Of those Teams that meet these criteria, it will be the 10 highest scoring Teams that will be invited to move on in the Competition as a **Finalist Team**.

1. Evaluation of supporting studies and proposed solution development pathways (10%)

   The first criteria of the score in the Qualifying Round of the Competition will be a review of the description of the concept and its development plan and a review of the overall quality of the Teams' supporting materials including documentation of testing and safety. The **Judging Panel** will review submitted data, papers, studies, trials, and proposed plans that demonstrate the safety and feasibility or means for feasibility of the proposed system.
   Required documentation:
   - Summary description of System Concept and Development Plan. This description should include a review of regulatory review considerations. (5000 Character maximum)
   - Supporting documentation of concept and development plan including: figures, papers, web-based simulations or videos and other on-line materials

2. Health assessment performance (45%)

   To ensure that Teams are on track technically, they will be required to demonstrate their assessment performance for each health condition they intend to test in Competition. As described in the Guidelines, Competition requires testing of 12 Core conditions, 3 Elective Conditions and Absence of Conditions. Thus a total of 15 Conditions (plus "Absence of Conditions") are expected to be tested in the Consumer Testing portion of the Competition. In the Qualifying Round, documentation of performance is not required for a complete set of Core and Elective conditions. Documentation of at least 13 health status conditions is required, which includes Vital Signs. A minimum of 5 Core conditions, 1 Elective condition and 3 Vital Signs parameters is required. For example, it is possible to submit documentation a minimum of only 8 health assessment conditions, if documentation of all 5 Vital Signs are included. It is understood that the individual

technologies used in the health assessment portion of the Competition may be at different levels of completeness, some with regulatory approval to go to market, others with only preliminary clinical trial evidence or even only laboratory testing data. It is recommended that Teams submit whatever data they have on performance of every one of their technologies. Physical safety review of all components for human use must be documented. Scoring will be aggregated (Not averaged) over all of the conditions that are submitted: the more conditions that are presented means a higher potential score can be achieved.

For each Health Assessment condition the Required Documentation includes:

1. Summary of performance of technology component (2000 Characters maximum)
2. Supplementary Data Reports on performance, as attachments
   Supporting Data Reports for each health assessment component may include: Papers of clinical testing, Patents, or other reports with certificates of authenticity (if available) will be submitted. The strength of scientific validity will be ranked as described in Section 3.4 above.
3. Summary of Safety of Testing Technology for each health assessment condition. (2000 Characters maximum)
4. Supplementary Safety reports for the technology, as attachments. Reports may include the Team's Design review process, independent consultant reports and/or regulatory review documents, such as clearance for market.
5. If Human testing has been carried out, documentation of appropriate approvals must be included. Such documents may include:
   - Human Research Regulatory Reviews
   - Local Regulations for research in the Submission
     - Laws, Rules, or guidance sources
   - Certificates of Review
     - Documentation of Approval for Human Research such as a letter or Certificate from Ethics review board (s) or similar committee

3. User interface: Understandability and Consumer Appeal (45%)

The user interface is a critically important component of a Team's system. The guidelines for the user interface review are described in Section 4.4.3 of the Guidelines document. Teams should be incorporating design of the interface from the outset of their system design process. Note that documentation of the Design review process will NOT be required for the Team submission, but this information is needed for review for regulatory purposes in many jurisdictions, including the United States. For the

Competition, a design summary and documentation of any human testing of the interface will be required in the submissions for the Qualifying round. The submission documents will include:

1. Summary of the design philosophy, concepts and objectives (5000 Characters maximum)
2. A software prototype may be presented via secure web-link
3. Summary of User Interface User Testing (5000 Characters maximum)
4. Supplementary Data Reports on user interface testing, as attachments
5. Supporting Data Reports for the user interface testing component may include: Papers of testing, Patents, or other reports with certificates of authenticity (if available) will be submitted. The strength of scientific validity will be ranked as described in Section 3.4 above.
6. If human testing has been carried out, documentation of appropriate approvals must be included. Such documents may include:
    - Human Research Regulatory Reviews
    - Local Regulations for research in the Submission
        - Laws, Rules, or guidance sources
    - Certificates of Review
        - Documentation of Approval for Human Research such as a letter or Certificate from Ethics review board (s) or similar committee

4. Measurement and logging of Vital Signs Set conditions (Pass/Fail)

As with the health assessment and user interface components of the Qualifying round submission, documentation of capability of Vital Signs assessment will required. The criteria for Vital Signs monitoring are described in the Guidelines document, section 5.3. The documentation requirements include:

1. Summary of performance of all Vital Signs components (1000 Characters maximum for each Vital Sign)
2. Supplementary Data Reports on performance, as attachments
    - Supporting Data Reports for each health assessment component may include: Papers of clinical testing, Patents, or other reports with certificates of authenticity (if available) will be submitted. The strength of scientific validity will be ranked as described in Section 3.4 above.
3. Summary of Safety of Testing Technology for each Vital Sign. (1000 Characters maximum for each Vital Sign)

4. Supplementary Safety reports for the technology, as attachments. Reports may include the Team's Design review process, independent consultant reports and/or regulatory review documents, such as clearance for market.
5. If human testing has been carried out, documentation of appropriate approvals must be included. Such documents may include:
    - Human Research Regulatory Reviews
    - Local Regulations for research in the Submission
        - Laws, Rules, or guidance sources
    - Certificates of Review
        - Documentation of Approval for Human Research such as a letter or Certificate from Ethics review board (s) or similar committee

5. Consumer Testing: Finalist Teams

5.1 Safety

As has been described above, safety is paramount in the Competition. Because consumer testing portion of the Competition will involve a variety of people including consumers, technicians and Competition personnel, documentation of safety and physical testing of safety of systems will be complete prior to testing with any consumer Tester. Furthermore, the Testing Partner reserves the right to discontinue testing at any time for any actual or possible hazard under the guidance from the **Judging Panel** and the XPRIZE Foundation.

5.2. General Consumer Use

Devices are intended for general consumer use. Thus technologies that are non-invasive or minimally invasive as well as non-intrusive are desired. Devices that require specific medical knowledge, training or certification are not allowed. Demonstrating (by humans) how a device works for the use of devices is acceptable, however Teams will not be allowed train or demonstrate usage to any Testers directly. Testing Partner personnel will be trained by Teams on instruction methods for Testers (see section 5.4 below). Remote sensing, with safe levels of light, sound or other non-injurious methods will be allowed. Surface of the body testing, including with adherent devices or body-worn devices will be allowed. No special handling, such as for volatile chemicals or materials biologically contaminated with body fluids will be allowed. However, sealed containers of consumables, battery packs or other devices will be allowed. Also, appropriate collection and sampling of saliva, sputum, breathe, urine and feces will be allowed, however, no special handling requirements of bodily fluids will be allowed, such

as mixture with chemicals. Test strips will be allowed. Blood sampling which would require the skills of a phlebotomist will not be allowed, whereas testing similar to finger-sticking done by people monitoring their blood sugar will be allowed. Subcutaneous microdevices may be considered, as long as they:

1. Can be applied by a consumer
2. Can be disposed of safely
3. Are acceptable to a consumer.

Note that *all* test conditions will be carried out by the Testers independently without any technical or other assistance after their instruction by the test supervisor. As per the agreement that the Testers will sign, they will be able to freely refuse any proposed test and may discontinue any test they find unacceptable for any reason. Testers selected must be able to understand the proposed procedures, and be willing to complete them. Testers will be provided compensation for volunteering to be a Consumer Tester and for completion of test procedures.

5.3. Data Security

Because some of the Consumer Testing Round of the Competition will take place in medical facilities, Teams should be aware that data gathered may be subject to the provisions of the Health Insurance Portability and Accessibility Act (HIPAA) in the United States. This law provides strict guidelines for the protection of confidentiality of medical information. Data security procedures such as password protection, removal of un-necessary identifiers such as government identification numbers and other provisions are required for information security. Information technology infrastructure for the Competition, such as wireless transmission and cloud storage will have appropriate security and limitations of content for privacy. Good security practices must be followed for any medical information and should be built into systems, including those for Competition. Data security re provisions will be made available by XPRIZE.

5.4. Finalist Team's Instructions for Users

Teams will demonstrate their entries in person to Testing Partner personnel and provide written instructions on the use, safety considerations and any other relevant information about their systems. The Testing Partner, with oversight from Prize personnel, will be trained on the instruction of consumers. Teams must understand that instructions to consumers must be complete within 60 minutes, and shorter intervals are preferred. All system procedures and processes will be tested in-house by the Testing Partner with oversight by Prize personnel and the **Judging Panel** for safety review and for test procedures.

Teams must provide a one-sheet set of written instructions on the basics of use of the device, (such as how to turn it on, turn it off, force a restart, etc.) Teams are highly encouraged to provide any consumer self-guided instructions and interactions within their device including device prompts and video clips that assist with usage. Teams are responsible for the functioning and connectivity of these features.

5.5. Pre-testing Devices (Bioengineering Inspection)

All system procedures and processes will be tested in-house by the Testing Partner personnel and **Judging Panel** for Bioengineering Inspection and for test procedures in advance of any consumer testing and will include all proposed test technologies. The **Judging Panel** will be responsible for removing Team from the Competition whose submissions/devices fail to meet safety performance criteria. Teams will be given one opportunity to make corrections in 30 days. Any determination of safety failing during the Consumer Testing made by the **Judging Panel** will result in immediate removal of a Team's submissions and/or equipment from Competition and the Team will be deemed ineligible to receive a prize purse.

The pre-test is also intended to review the user interactions carried out by devices and will review all sensor user actions, physical manipulations and data inputs required by the Finalist Team's solution for safety and usability Formal assessment of system accuracy will not be reviewed in the Pre-test.

5.6. Consumer Tester Contract

Qualcomm Tricorder XPRIZE testing with Consumer Testers will be conducted under appropriate contract procedures. This will be the responsibility of the Testing Partners, under the guidance and management of the XPRIZE Foundation. Teams will be responsible for providing all documentation necessary for provision of information appropriate for a contract on participation in a Competition comparing consumer medical devices. This information will include documentation of:

- Safety
- Instructions for test procedures
- Privacy information management

The **Judging Panel** will be responsible for certifying that safety of equipment has been appropriately documented to allow Consumer Testing to go ahead. Testing Partner personnel will instruct the Consumer Testers on use of equipment and monitor safe use. If a Team

submission fails to include required documentation then finalist Competition will not be allowed.

5.7. Competition Test Parameters

Finalist Teams' entries are intended for the general public in their home environment over intervals of up to 72 hours. Competition testing will reflect this primary objective, where practically possible.

5.7.1. Consumer Testers

All consumer Testers will be adults *able* to legally sign a contract. These consumers will be fully informed as to the types of activities that they will be asked to perform, such as interacting with a computerized device, applying and removing items from their skin, pressing devices to their body, testing their breath, skin, urine or feces. They will be informed as to the duration and number of the tests they will carry out. Note that consumer Testers will be informed about ALL test techniques encompassing all technologies in the Competition. Thus even though a given test solution for an individual test may not incorporate a finger lancet for a blood sample or a feces sampling, the contract document will describe all possible actions. Testers will be selected for their stated willingness to complete all required test procedures. However, they will be informed that they are absolutely allowed to refuse any test procedure at any time. Consumer Testers will be assured of personal, medical, social and financial confidentiality. They will be informed of all actual and potential risks and benefits of participation.

Testers will be given an appropriate fee for volunteering for the test and for completing test procedures. They may not have a conflict of interest that would result in unfair bias for or against any Team. Testers may not be employed or experienced as a medical or health professional in any capacity. Testers must be available to complete the whole series of usage tests. Testers must be available for periodic usage spot check and must also be complete the consumers evaluations used in the Competition.

Among the Consumer Tester populations used for testing each Team's system, there will be a generally equal distribution of education level, economic status, age, gender, race, and technology sophistication, given the available people in the region from which Consumer Testers will be drawn. Consumer Testers will have the legal capacity to enter into a contract. Consumer Testers may vary some in cognitive ability, education and experience. Body type may vary. However, in order that no variations in medical systems other than for gender are necessary, Consumer Testers with the following conditions will be excluded from Competition:

Age less than 18 or over 70 ~~21 or over 65~~
Deviations of greater than two standard deviations in weight or height Physical disabilities affecting:
Vision (eyeglasses or contact lenses will be allowed)
Audition (hearing aids will not be allowed)
Manual manipulation
Ambulation (use of assistive devices such as a cane or walker will not be allowed)
Dressing, eating, writing
Use of a computer or mobile device
Other relevant abilities

5.7.2. Settings for testing

Some testing will be done in the home environment. However, some testing of device diagnostic capabilities will be done in medical environments. This reflects the Competition objective of determining diagnostic ability of devices. Test conditions for each diagnosis are described below (section 5.6.13). Controlled access to patients with various diagnoses can only be done in medical conditions. However, *no medical or technical support personnel* will interact with test devices in any fashion (see section 5.6.13 below). Observation of the test devices will be strictly limited and controlled for confidentiality of patients and protection of Teams and the XPRIZE Foundation. Team personnel will not be allowed physical nor electronic access to any testing. Consumer Home or test environments will include the following:

- Privacy behind closed doors
- A desk and chair
- A comfortable platform (such as a bed or couch), where the consumer can lie down
- AC power
- Lighting control
- Access to sink and toilet
- Standard Wi-Fi with secure connection (Supplied by XPRIZE)
- Disposal of hazardous materials

5.7.3. Duration of testing

For some conditions, a window of 72 consecutive hours will be available for testing. However, it is not feasible to test all conditions against multiple Consumer Testers for that amount of time. Thus a number of tests will be carried out in brief intervals, with a maximum of 60 minutes for

the Consumer Tester to use the solution. At the start of each test session, the time limit for that individual test session will be available to the device.

NEW SECTION: SESSION DURATION NOVEMBER 2015

In order to ensure that sessions will provide enough time for a Tricorder to complete the diagnostic process, the minimum session duration will now be NINETY (90) minutes. Most sessions will be of this duration. Note that the 80% continuous data upload requirement for Vital Signs will still stand and that the session timing will start at the time the Competition coordinator starts the tablet as the Tester starts their formal interaction with the Tricorder. NO ADDITIONAL TIME will be provided outside the timing limits for the Tester to don Vital Sign technologies or carry out any other session initiation procedures. The new maximum session duration will be TWENTY FOUR (24) hours.

Some sessions will only be 24 hours in duration. See chart below:

Core Condition	**Extended Final Round: Test Session Duration**
Anemia	90 minutes or 24 hours
Urinary Tract Infection	90 minutes or 24 hours
Diabetes	24 hours
Atrial Fibrillation	90 minutes or 24 hours
Sleep Apnea	24 hours
COPD	90 minutes or 24 hours
Pneumonia	90 minutes or 24 hours
Otitis Media	90 minutes or 24 hours
Leukocytosis, Acute	90 minutes or 24 hours
Absence of Core Conditions	24 hours

Elective Condition	**Extended Final Round: Test Session Duration**
Pertussis	90 minutes or 24 hours
Hypertension	24 hours
Mononucleosis	90 minutes or 24 hours

Hyper/ Hypothyroidism	90 minutes or 24 hours
Food-borne Illness	90 minutes or 24 hours
Shingles	90 minutes or 24 hours
Melanoma	90 minutes or 24 hours
Strep throat	90 minutes or 24 hours
Cholesterol	90 minutes or 24 hours
HIV	90 minutes or 24 hours

5.7.4. Non-interference with device action

All tests of devices will be carried out with the devices in the hands of consumer Testers without any prior professional medical or healthcare experience. No test supervisors will activate, modify or interact with devices at any time before, during or after consumer evaluation. This includes powering devices, changing consumables, assistance on device function, or other interactions, such as obtaining urine samples, breathing tests or other actions. All device activations and other actions will be carried out by non-medical professional consumer Testers. Consumer Testers will be given the devices and will have device activation procedures based on the techniques described by the Teams. In addition, consumers will be required to operate the devices without any assistance from friends, family, or other more technically knowledgeable third parties.

5.7.5. Body Fluid Samples

Humans may not be able to provide sputum, urine or feces samples on demand during a 60 minute test interval. Therefore, for all conditions requiring such samples (established prior to Consumer Testing by Teams), such samples will be provided and stored appropriately for testing during the designated time interval. Samples will be made no more than 6 hours prior to the test interval. Consumer Testers will carry out any required actions with the samples and the solutions they are testing. Storage devices and other handling equipment such as gloves and disinfectants to be used for the samples taken before the Consumer Tester is set to use the solution will be provided by the Testing Partner. Any item needed by the Consumer Tester during the course of their time with the device, including clean containers, handling equipment such as gloves, and disinfectants will be provided by the Finalist Teams.

5.7.6. Consumer Testers and Criterion Standard information

For all Core and Elective test conditions, Consumer Testers may or *may not* be blinded to results

of their Criterion Standard Tests which will be the basis of the assessment score. Testing Partner personnel and any other people interacting with the Consumer Testers will be blinded to the *Criterion Standard test results.* Of course, Consumer Testers and medical personnel involved in their care will know their medical history and the results of some of their medical testing.

5.7.7. Artificial Intelligence and Interaction with Consumer Testers

Artificial intelligence (AI) systems will be an integral component of solutions for the Qualcomm Tricorder XPRIZE. For Qualcomm Tricorder XPRIZE Finalist Teams, AIs will be allowed to make queries of the Consumer Testers, *but no human interactions will be allowed locally or through remote access to systems*. Responses to queries by AIs will be freely given or withheld by the Consumer Testers. However, all Consumer Testers will be asked to respond truthfully, *to the best of their ability.* No interference by or interaction with Testing Partner personnel such as attending health professionals or technicians or others, such as family members will be allowed during test interactions. Misunderstandings or other failures of communication are purely the responsibility of the Teams and their solutions.

AI queries are intended to provide a description of any symptoms or medical history. Queries regarding current diagnoses, possible diagnoses, or current laboratory findings *WILL NOT BE ALLOWED.* Any attempt to query a Consumer Tester regarding current diagnoses or laboratory tests will result in a negative score on that test, *without opportunity for correction .*Any attempts to query Consumer Testers about diagnoses or laboratory tests will result in *expulsion from Competition* in the sole and absolute discretion of the **Judging Panel***.*

Systems may interact in a variety of ways, including, but not limited to, screen, tablet surface, keyboard, microphone, speaker, or any combination thereof. All interactions between the system and the Consumer Testers must be logged and time-stamped. The Team's solution must also log all up-loaded and downloaded information from devices, including time stamps. Logs must also include timing and results of any sensor activity in the system.

During Consumer Testing the following interrogatories are allowed:

- Current symptoms, quality, duration, timing etc.
- History of symptoms
- History of previous diagnoses of non-Competition diseases.
- Family History
- Social History
- Standardized Review of Systems

Note that consumer Testers may or may not have concomitant symptoms of the diagnostic condition for which they are being tested.

During test sessions the following interrogatories ARE NOT ALLOWED:

- Queries about any QTXP diseases listed in section 5.3.13, including conditions that the given system is NOT designed for.
- Queries about current diagnoses (example: Have you had a positive diagnosis in the past week)
- Queries about current laboratory tests (example: Have you had any recent blood work? If yes, what was the condition for which you were being tested?)

Teams are encouraged to submit any queries or sets of queries to Qualcomm Tricorder XPRIZE Competition organizers prior to Competition for review for appropriateness. The **Judging Panel** will review and Competition organizers will provide their response in writing in a timely manner. If a Team is unsure as to whether or not any of their queries of the Consumer Tester would be considered unallowable, they are highly encouraged to submit the question set to the organizers as early in their process as possible for assessment.

5.7.8. Data Infrastructure and Remote Information Provision and Interaction with Consumer Testers

XPRIZE and the Testing Partners will provide an information network and cloud computing platform to Testers. The details of this network will be outlined in the document "Wireless Transmission and Cloud Computing for Qualcomm Tricorder XPRIZE (Appendix A in the Document "Final Round Test Procedures and Rules ".

Competition devices will be live and uploading information to the cloud during test intervals. Downloading to the device will be allowed. Direct human to human interaction with the Consumer Tester and their data via telecommunication links will *not* be allowed. Embedded AI processes in the device or remote AI systems may interact with the Consumer Tester. All interactions between the entry and the Consumer Tester will be logged by the Team, monitored, and subject to audit by the **Judging Panel**. Consumer Testers will be instructed to respond to device commands to the best of their ability.

5.7.9. Consumer Tester Medical Records

Competition devices will not have access to any printed or electronic medical records of Consumer Testers during the diagnostic evaluation testing. Consumer Tester's identification number, age and gender will be available for input into the Tricorder start-up procedure for a test session.

5.7.10. Contingencies

Back-up devices and restarts of testing will be available for unforeseen contingencies such as dropping devices or other circumstances due to the Consumer Tester's handling of the entry. Teams will not be penalized for situations beyond their control. Damage to the system due to causes other than *reasonable* use by the consumer, or by normal handling of Competition personnel, will be penalized. These decisions will be at the **Judging Panel**'s sole and absolute discretion. Their findings are not subject to contest.

5.7.11. Recording

No Finalist Team video or other recording of test procedures during Competition events will be allowed. This includes native recording in devices. Any recording by Teams will be reviewed by the **Judging Panel** and may result in removal from Competition.

5.7.12. Test Observation

The **Judging Panel** or XPRIZE Foundation personnel may observe any or all Consumer Tester interactions with the solutions for tests under 60 minutes. Random audits of test interactions will be made for all Consumer Testing. Audits will be intended to detect safety problems, human-to-human interaction via Teams with their devices or other Competition components. Remote interaction with devices will be allowed for system diagnostic purposes, outside of Consumer Test intervals, under supervision.

5.7.13. Core and Elective Set Health Assessment Testing

Competition testing for diagnostic capabilities will be done in a variety of settings. Each diagnostic condition will be tested for individually. Consumer Testers will have had a Criterion Standard diagnosis of their condition by a clinical laboratory. Scoring for diagnosis will only be for the verified diagnostic condition of a given individual. Possible incidental detection of disease by a given device will not be scored or revealed to the Consumer Tester. Scoring will only be for present, absent or not-tested test result of the test medical condition. The scoring system is outlined in the Guidelines document Section 5. 1. No partial scores will be given. Performance for scoring purposes will be assessed on a given device, for a given Consumer Tester condition at the time of completion of the test session and before the device is used again.

The testing will occur as described as in Appendix A. Testing for each condition will be started by a member of Testing Partner instructing the consumer Tester on how to operate the device and then handing the test device to the consumer Tester and timing will commence by a timing instrument. Devices will have to ascertain which condition is being tested for *without input from any test officials, only by interaction with the Consumer Tester.* However, data input by the consumer Tester is not mandatory. There will be up to 60 minutes of set-up and instruction time carried out in person with the Consumer Tester by the member of the Testing Partner. Each test will last at least 60 minutes and may last up to 72 hours. Once the test interval is up the consumer Tester will bring the device to the location determined by the Testing Partner. At that time, the Testing Partner personnel will retrieve the device and all associated materials.

Each consumer Tester will be expected to test up to three devices and each Team's device will be assigned to up to three different Consumer Testers such that each Team's device is tested equally by each type of consumer. With three tests, Consumer Testers will not be unduly burdened with procedures that may be complicated, unpleasant or uncomfortable and thus they can be expected to complete all procedures with diligence and attention. The Test Partner will also ensure a fair overlap of all test devices across Consumer Testers, minimizing to all reasonable extent any unfair exposure to variation in Consumer Testers. The order of presentation will also give each device equivalent of first, second or third order of testing.

Scoring Procedure:
As outlined in Guidelines Section 5. 1 point will be awarded for the assessment of the condition:

Finding	**Points**
Correct Positive Assessment	5
Correct Negative Assessment	0
Incorrect Assessment	-1

- Correct Positive Assessment is the correct identification of a condition that is present as determined by the Criterion Standard
- Correct Negative Assessment is the correct identification of a condition that is not present as determined by the Criterion Standard
- Incorrect Positive Assessment ("False Positive") is the false identification of a condition which is not present as determined by the Criterion Standard
- Incorrect Negative assessment ("False Negative") is the failure to identify a condition that is present as determined by the Criterion Standard.

The total point range on the low end, if every answer given is incorrect, is -48 with the top possible score by a Finalist Team, if every answer given is correct, is 225. Given that the total range is -48 to 225, the 70% score required by Finalist Teams to qualify for a Prize Purse is 143.

A review of the cloud stored data from a system will be completed. Correct and Incorrect condition assessments will be determined and appropriate values will be added to the score from each Team. The **Judging Panel** will review and certify the scores.

The Core Set

Please note: for all conditions in both the Core and Elective sets, each Consumer Tester is expected to test up to 3 entries.

1. Anemia: Microcytic Iron Deficiency Anemia
Setting: beginning at a medical clinic, testing immediately after serum Hb determination
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

2. Urinary tract infection
Setting: beginning at a medical clinic, testing immediately after positive Urine R and M
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

3. Diabetes
Setting: Home based
Duration: up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

4. Atrial Fibrillation
Setting: beginning at a medical clinic, immediately after 12 lead ECG
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours.

Special Conditions: None

5. Stroke, Acute Hemorrhagic Stroke
Setting: Hospital stroke unit
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: 60 minutes.
Special Conditions: Access to patient within 0-48 hours of stroke symptom onset. Note that Consumer Testers will not have any deficits that will inhibit their ability to cognitively or physically complete testing

6. Sleep Apnea, Severe Obstructive
Setting: Home testing, within 7 days of sleep apnea test positive for severe sleep apnea
Duration: 72 Hours and up to 60 minutes of instruction for the Consumer User
Special Conditions: No concomitant central sleep apnea. No concomitant sleep apnea treatment during solution testing, including splints, CPAP machines or other medications. Patients may be on sleep altering medications, which will be noted in their record

7. Tuberculosis, Positive Lung Disease.
Setting: Medical isolation clinic or community based
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: May be in medical isolation

8. Chronic Obstructive Pulmonary Disease (COPD)
Setting: beginning at a medical clinic, immediately after positive respiratory testing
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

9. Pneumonia, Acute Pneumonia
Setting: beginning at a medical clinic: immediately post Chest X-ray
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours

Special Conditions: No bacteremia, septicemia or other systemic infections. May have history of cough, increased respiratory rate and/or reduced pulse oxygenation

10. Otitis Media ("ear infection")

Setting: beginning at a medical clinic, immediately after physician detection. Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours

Special Conditions: Consumer Tester will not have had any invasive procedures of the affected ear, but may have been previously treated for Otitis media with oral antibiotics. Etiology of otitis media will be various infective agents that will not be verified on culture

11. Leukocytosis, Acute

Setting: beginning at a medical clinic, immediately after serum test

Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours

Special Conditions: No concomitant white blood cell disease, such as lymphoma or leukemia. Etiology of the acute leukocytosis will not be verified clinically.

12. Hepatitis A

Setting: beginning at a medical clinic, immediately after serum test

Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours

Special Conditions: not chronic Carrier; no concomitant white blood cell disease, no previous vaccination against hepatitis

13. Absence of Core Conditions

Setting: Home testing Duration: 72 Hours

Special Conditions: None

The Elective Set

1. Pertussis (Whooping Cough)
Setting: beginning at a medical clinic: immediately after positive test.
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: May be in medical isolation

2. Hypertension
Setting: Home testing Duration: 72 Hours
Special Conditions: None

3. Mononucleosis
Setting: beginning at a medical clinic, immediately after serum test
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: Positive Monospot test in the last 24 hours

4. Allergens (Airborne)
Setting: Laboratory testing with air samples with verified airborne contaminants: vs. control air samples.
Duration: 60 Minutes Special Conditions: None

5. Hypothyroidism OR Hyperthyroidism
Setting: beginning at a medical clinic, immediately after blood test.
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

6. Food-borne illness
Setting: Laboratory, testing with verified contaminated food products vs. verified non-contaminated controls.

Duration: Up to 30 minutes of set-up time; assessment time: minimum of 60 minutes, maximum of 72 hours
Special Conditions: Laboratory testing;

7. Shingles
Setting: beginning at a medical clinic, immediately after Dermatologist observation
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: No concomitant topical or oral medication for Shingles; no previous Shingles vaccination

8. Melanoma
Setting: beginning at a medical clinic, *before* verifying Biopsy
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: solutions will be tested BEFORE biopsy; if biopsy negative, retest will be carried out and all scoring associated with that test will be excluded from the scoring. Each test in this condition will only be for 60 minutes; however the Consumer User may continue to use the device after the biopsy.

9. Streptococcal Pharyngitis
Setting: beginning at a medical clinic, immediately after strep test.
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: No concomitant antibiotic treatment, steroids or vaccinations. Patient may have symptomatic treatment including acetaminophen or NSAID medications

10. Cholesterol Screen
Setting: beginning at a medical clinic, immediately after laboratory test
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: None

11. HIV Screen
Setting: beginning at a medical clinic, immediately after laboratory test
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: No concomitant antiviral therapy

12. Osteoporosis
Setting: beginning at a medical clinic, immediately post bone scan
Duration: Up to 30 minutes of set-up time and up to 60 minutes of instruction for the Consumer User; time with Consumer User: minimum of 60 minutes, maximum of 72 hours
Special Conditions: No concomitant Osteoporosis therapy

5.7.14. Consumer Experience

Based on the features described in the guidelines, Section 4.5 and 5.2 an in-person survey will be carried out by the Testing Partner.

Consumer Testers will be asked to complete a User Experience survey for evaluation at the end of the usage period for each device used. While Testers may decline to use the device for any assessment or monitoring purposes, they will be required to complete all corresponding surveys on their user experience. Consumers will be recruited according to criteria noted in section 5.7.1 above. Teams will be assigned an equalized pool of consumer Testers that accounts for differences demographics and technology adoption. Consumers may not invoke technical/ medical usage ("how to") assistance from other people, however, they will be allowed to share their results, insights, and related information from the device usage with others.

Scoring Procedure:
Each Tester will be asked to complete a survey with score ranges of 1 – 7 on each the aspects of each of the categories below that are outlined in greater detail in the Guidelines section 4.6. For each of the categories the score will be added to the total score. In collaboration with the Testing Partner, the **Judging Panel** will review and certify the scores.

Finalist Teams will need a minimum score of 70% of the total possible points for the consumer experience portion of the Competition to be eligible for a **Prize Purse**.

5.7.15. Vital Signs testing

As described in the Guidelines, section 5.3 Vital Signs auditing will be carried out randomly during any of the intervals where Testers are using the systems. Clinical grade Physical devices will be used to measure the Vital Signs of the Testers. The audits will not interfere with the operations of a system's hardware or software.

10 Audits will be made of each Team's systems. Within 12 hours of the audit measurements, the Testing Partner will compare values in the cloud vs. the values achieved during the audit interval. A passing score based on the criteria in Section 5.3 of the guidelines will be required for each of the audit sessions.

6. Importation of Test Devices for Competition

In the Competition, importation procedures for Team systems from outside the United States will be established in collaboration with United States Federal Government authorities. The systems will be imported to the United States under appropriate legal procedures. Systems will be imported ONLY for Competition purposes. No other use, including clinical trial participation will be allowed. Devices will be marked "For Research Use Only. Not for use in diagnostic procedures". It is the responsibility of each Team to obtain appropriate legal approval for importation in time for the Competition.

7. Tricorder Re-Entry Criteria

Tricorder Re-Entry Criteria for Designated Health Assessments (DHA)

The "Re-Entry" Criteria for the Qualcomm Tricorder XPRIZE are intended to conform as much as possible to the actual wording and the spirit of the Guidelines up to the current V.28. However, since the voluntary recommendation in the existing guidelines of human testing of Competition conditions was not followed, the Re-Entry criteria now mandates testing of: the laboratory technologies of the Tricorder *in-situ,* the Diagnostic Logic Systems and a demonstration of diagnosis on people with the Competition conditions.

Overall Goals:

I.) Fairness to all Competitors
II.) Ensure Performance of Complete Tricorder Systems
    a. To ensure Human Safety for Test Program participants

i. Diagnostic Accuracy
ii. Free from injury potential

b. Demonstration of sufficient performance that it is reasonable to expect a Team allowed to re-enter will be capable of meeting the Competition Guidelines to qualify to win.

III.) Teams must demonstrate performance, at their expense

Description of Testing Involving Humans

December 2015-, July 26, 2016: Engineering Update by Teams

Entry into Test Program for the Qualcomm Tricorder XPRIZE will require successful demonstration of a Tricorder's ability to be successfully operated by people with Competition conditions. Working with people with various diseases for biomedical engineering development purposes is a complex, expensive process that requires documentation. An IRB Task-Force chairman at UCSD will support the IRB process for Teams to work with their local authority. Throughout the redevelopment process there will be human test sessions carried out by Teams and then human test sessions carried out on behalf of XPRIZE in the Competition Test Program. The various human test sessions will have different names and features, described next.

XPRIZE strongly recommends that informal *Development* Human Test Sessions be carried out by competitors intending to be entered into the Competition Test Program. These sessions do not need to be recorded and will not be scored as part of any Competition proceeding. It is expected that Finalist Teams will work with institutions in their local areas to access people with the various Competition conditions. *On a very limited basis,* some Development Human Tests Sessions may be made available through UCSD CTRI. These will be made available on a schedule determined by CTRI with a fair and equitable distribution across all Teams.

Laboratory Test Component Demonstrations

One Re-Entry criterion will be demonstrations of laboratory systems on Tricorders. Many of these demonstrations will be on laboratory samples, but some will require demonstration on humans in instances where an appropriate sample cannot be simulated (such as pneumonia). Teams will be expected to access samples or people with appropriate conditions.

Re-Entry Test Sessions

For EACH COMPETITION CONDITION, a successful Tricorder test session will be demonstrated on a human with the condition in *sessions managed by the Teams*. These sessions will be done with secure data links to the cloud and video recording at a Team's location of choice (See Appendix A, Section 7). Limited slots for *Re-Entry Test Sessions for some Competition conditions* may be available through the UCSD CTRI.

August 2nd-August 31st 2016 Initiation Period

Qualification Test Sessions
For Teams that successfully demonstrate operation of their Tricorders in the Re-Entry Test sessions, there then will be 4 Qualification Test Sessions held at CTRI (conditions TBD) in August, 2016.

September, 2016 Consumer Testing Period

Consumer Test Sessions will resume at UCSD CTRI.

Overall Re-Entry Criteria

The following criteria must be met to be considered for Re-Entry:

- Team selected as a Finalist
- Tricorders must meet minimum scores for both consumer experience and health condition assessment
- Tricorders must continuously monitor five Vital Signs over the course of the consumer testing period and log this data to the cloud
- Tricorders must have a maximum mass of no more than 5 pounds for the entire solution provided by the Team to the consumer

In addition, the Tricorders must also pass the below Re-Entry criteria:

Criteria 1) Laboratory Test Component Demonstrations
(Requirement: 70% Success for each Laboratory Component)

Teams must demonstrate the laboratory test functions of their Tricorders, *as part of their integrated Tricorder system.* Demonstrations of the laboratory functions will include all components of the Tricorder. Thus a blood test will have to include any reagents, blood carrying components, devices and mobile computing platforms. Where indicated, the demonstration will be carried out on an appropriately blinded laboratory sample set, *obtained and documented by the Team (XPRIZE will not provide samples).* The sample test sessions will have to be recorded on a time-stamped video and results communicated to the XPRIZE data-cloud in sessions labeled as Laboratory Test Sessions. Videos must include a time/date stamp and show the entire assay/test run on the system.

The tests below are based on conventional methodologies of providing laboratory verification of a clinical condition. Teams can propose an alternative to the methodology listed below *and demonstrate the alternative on video with data up-load*. There must be scientific validation of alternative method, which the judges will review. In addition, if a Team's technology mandates a fresh sample, (for example, a fresh finger stick for blood), then Teams are free to provide samples obtained in that manner and demonstrate appropriate supervision for the blinding procedure. If a Team is concerned that test samples may not be appropriately processed by their system, XPRIZE strongly advises that the Team do their own laboratory validation of test results.

Note that for some Competition conditions, the demonstration is mandated to be on a person with the clinical condition. Appropriate alternatives may be proposed by a Team, but will have to be approved by the Judging Panel.

Note: Methods of identification of clinical conditions purely by patient input (i.e. symptom description) are inadequate. Further, *Technology described as being present in previous and updated development plans, such as advanced biosampling technologies, need to be present in systems used for the Re-Entry process. If necessary, updates of tricorder technologies will be required to be described in Engineering Change Order (ECO) in a process used in the Finalist program.*

Also, where practical, Teams are encouraged to partner with other Teams or external partners to bring new engineering, laboratory, financial or management resources to their programs. Extra resources may make a Team's submission more competitive.

XPRIZE will provide recommendations on the sourcing of biosamples.

Core Conditions (7 out of 10)

Anemia: Run 10 blinded samples of blood; 5 samples will be anemic and 5 samples will be normal. (7 out of 10 correct)

Urinary Tract Infection: Run 10 blinded samples of urine; 5 samples demonstrating bacterial urinary tract infection and 5 samples will be normal (7 out of 10 correct).

Diabetes Type 2: Run 10 blinded urine or 10 blinded blood samples; 5 samples demonstrating hyperglycemia and 5 samples will be normal (7 out of 10 correct).

Atrial Fibrillation: Demonstrate 1 live patients on video + monitor strip on video and 2 normal controls. (2 out of 3 correct)

Sleep Apnea, Obstructive: Demonstrate recording of reduced PO2 levels conforming to Vital Signs Audit Procedures.

Chronic Obstructive Pulmonary Disease: Show spirometry on video. Compare with laboratory grade spirometer.

Pneumonia: Demonstration with a live patient with a positive diagnosis. Appropriate documentation of condition must accompany the test (e.g. physician's signed statement is sufficient).

If the Team so chooses, the same patient tester may also be used in a distinct Human Re-entry Test Session (Criteria 3).

Otitis Media: Demonstration with a live patient with a positive diagnosis. Appropriate documentation of condition must accompany the test (e.g. physician's signed statement is sufficient).

If the Team so chooses, the same patient tester may also be used in a distinct Human Re-entry Test Session (Criteria 3).

Leukocytosis: Run 10 blinded samples; 5 samples showing elevated white blood cell count and 5 samples will be normal (7 out of 10 correct).

Absence of Conditions: no test necessary.

Electives: (Teams must demonstrate at least 2 out of 3)

Pertussis: Run 10 blinded biosamples; 5 samples positive for pertussis and 5 samples will be normal (7 out of 10 correct).

Hypertension: Demonstration of Blood Pressure accuracy according to Vital Signs Audit criteria.

Mononucleosis: Run 10 blinded biosamples; 5 samples positive for mononucleosis and 5 samples will be normal (7 out of 10 correct).

Hypo/Hyperthyroid: Run 10 blinded blood samples; 5 samples will be abnormal and 5 samples will be normal (7 out of 10 correct)

Shingles: Demonstration with a live patient with a positive diagnosis. Appropriate documentation of condition must accompany the test (e.g. physician's signed statement is sufficient).

If the Team so chooses, the same patient tester may also be used in a distinct Human Re-entry Test Session (Criteria 3).

Melanoma: Demonstration with a live patient with a positive diagnosis. Appropriate documentation of condition must accompany the test (e.g. physician's signed statement is sufficient).

If the Team so chooses, the same patient tester may also be used in a distinct Human Re-entry Test Session (Criteria 3).

Strep Throat: Run 10 blinded biosamples. 5 samples positive for strep throat and 5 samples will be normal (7 out of 10 correct).

Cholesterol Screen: Run 10 blinded blood samples; 5 samples with LDL > 130 mg/dL and 5 samples with LDL < 130 mg/dL. (7 out of 10 correct).

HIV: Run 10 blinded samples. 5 samples positive for HIV and 5 samples will be normal (7 out of 10 correct).
If appropriate samples cannot be sent to the Team (because of biohazards of infective materials restrictions), the Team may send Tricorder to an outside Lab. (Lab provides video)

Criteria 2) Diagnostic Logic
(Recommended: Demonstration on sample data)

Teams will be recommended to test their systems against a blinded data set of 1000 versions of patient demographic information, basic Vital Signs and symptom presentation complexes. Teams are to indicate the probability matrix of presence of Competition conditions based on these data. Teams will be free to present a report on an alternative demonstration of their AI's diagnostic ability to manage variable human disease presentations, subject to judges' acceptance.

Teams should score 70% correct on the blinded data sets for their AI engines. Pending results of the Diagnostic Logic performance review, Teams will be free to upgrade their logic systems at their discretion. MedStar Institute for Innovation in Washington D.C. will provide blinded patient data sets for use for testing. There will be a training set and a test set. While this criteria is only recommended, Teams are reminded that acceptance into the Competition Test Program is subject to Competition Judges' review and that all efforts to improve technologies will be assessed for that acceptance.

Criteria 3) Human Test Sessions
(Requirement: Successful Diagnosis of 70% of Competition Conditions)

Re-Entry Test Sessions

For EACH COMPETITION CONDITION, a Tricorder test session will be carried out on a human with the condition. These sessions will be done with secure data links to the cloud and video recording at a Team's location of choice. These sessions will be formally designated as Re-Entry Test Sessions in the Competition data cloud. The correct DHA for the condition must be demonstrated in order for the Team to pass a given session. Note that if the correct DHA is NOT achieved in a designated session, repeat sessions will be allowed, presuming corrections in the operation of the Tricorder are completed. Successful DHA must occur in a designated Re-Entry Test Session that is video recorded and uploaded to the cloud. Videos must include time/date stamps, and show the tester using the tricorder (the first five minutes of the test

session is sufficient). The intent of these videos is to verify that human testers are performing the test sessions, and tester privacy requests should be respected (e.g. not filming the tester while placing device components under their clothes, etc). Please remember to obtain tester consent before filming.

Limited slots for *Re-Entry Test Sessions* may be available through the UCSD CTRI, subject to schedule and time limitations.

Qualification Test Sessions

Once a Team has completed the Laboratory Test Component Demonstrations, the Diagnostic Logic Demonstrations and the Human Test Sessions, subject to Competition Judges' review, for each successful Team, there will be four (4) Qualification Test Sessions held at UCSD CTRI (conditions TBD). Teams will be able to monitor Qualification Test Sessions via video conference and approve that the session was correctly implemented, BEFORE test scores are reviewed. If Teams are 50% correct in the DHA, have a 70% average in UX and meet the Vital Signs upload and audit scores, then, subject to Competition Judges' review, they may pass into the Competition Test Program. If a Team enters the Test Program, Qualification Test Session scores will be incorporated into the Total Score for Competition Prize qualification.