STARR Site Certification
Clinical research advances our scientific understanding of diseases and works to find cures for the most elusive of indications. Over the last several years, a trusted group of thought-leaders throughout research and advocacy have identified foundational topics clinical research sites can employ to raise the standards of practice. By becoming certified through this program, Sponsors of clinical research trials are able to immediately identify research sites adhering to these standards and best practices set forth in the certification manual.

These modules are intended to be an educational tool for researchers to adapt best practices in the areas of language, advocacy, community integration, suicide prevention, stigma reduction, and empathy training.

This certification is intended to be a living document. As The STARR Coalition recognizes new areas to be addressed, we will distribute materials accordingly. In addition, we welcome any input and suggestions on ways to help improve the clinical research process.

The STARR Coalition is a resource for you. If you have any questions, concerns, or need assistance in any way, please reach out to us.

This manual contains multiple modules targeted towards different operational aspects of your clinical research site. It is the responsibility of each site to designate a point-of-contact for the STARR Site Certification to review each section, understand the information, and distribute content to appropriate staff.
STARR Site Certification

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SITE CERTIFICATION EXPECTATIONS
Language is recognized as one of the greatest barriers in forging partnerships with individuals and organizations across the industry and advocacy. Terminology and formal semantics will impact inference and intent.
Members of the STARR Coalition represent a wide range of fields; pharma, CRO’s, clinical research, treatment, academia, advocacy, as such, many of our areas of expertise require very specific language. In the mental health arena, for example, language is especially important to those receiving services. Many individuals feel that as people living with psychiatric conditions, they have been marginalized by the industry and society in general. Language can be a contributor to those feelings. Over the years, the practice of person-centered or person-first language has emerged.

We recognize that in many cases it is appropriate to use specific language to designate the relationship of the individual to the provider of services. For instance, it is appropriate for a doctor to refer to the person they are serving as a “patient”. This is the norm in society. In the same vein it is important that people are not labeled by their diagnoses. People are not schizophrenics or bipolars. They are people living with schizophrenia or living with bipolar disorder.

Language should not be a barrier to achieving our goals. When appropriate it is acceptable to talk about patients, clients, and subjects as long as it is used in the appropriate environment. The point is that relationships between researchers and individuals participating in a study are better when we can accentuate personhood. In essence people are people first.

There is an expectation all stakeholders within The STARR to simply recognize language as a potential barrier and agree to never let semantics get in the way of meaningful progress. Many times, we must remind those in different areas of work that the language we use is the language given to us.
COMMON TERMINOLOGY

Labels we give people living with different indications evolve over time. Terminology changes; such as mentally retarded, mentally deficient, feeble-minded, mentally handicapped to more recent terms like developmentally delayed, developmentally disabled, cognitively impaired. Many people will dismiss this as “political correctness”, but remember, it matters to the person being spoken to.

We also see the same dynamic in the labels we use for those participating in a trial. For instance:

Within research: Subject, volunteer

Within medical community, Patient

Within treatment: Client, consumer

Within advocacy: Person living with (indication), person with lived experience

Many times, if you use the term “subject” to an advocate, there could be a misunderstanding you only see the person as an experimental subject and not the as an individual. The reality is we use the language given to us in our specific area of expertise. Yet, we must know how our language can be interpreted by others who are not within your field. Instances have occurred where an advocate has heard a research site describe someone as a “subject” and the advocate shut down the conversation. Simply acknowledging to others that you do not wish language to be a barrier is a step in the right direction.
The following are terms used in the treatment realm. Many individuals entering a study will be familiar with these terms.

**Assertive Community Treatment (ACT):** a team approach to providing rehabilitation and support to individuals who require intensive services in order to live in the community.

**Caregiver:** A person who has special training to help people with mental health problems. Examples include social workers, teachers, psychologists, psychiatrists, and mentors.

**Case manager:** An individual who organizes and coordinates services and supports for individuals with mental health problems and their families. *Alternate Terms: service coordinator, advocate, and facilitator.*

**Case management:** A service that helps people arrange for appropriate services and support. A case manager coordinates mental health, social work, educational, health, vocational, transportation, advocacy, respite care, and recreational services, as needed. The case manager makes sure that the changing needs of the individual served are met.

**Continuum of care:** A term that implies a progression of services that an individual moves through, usually one service at a time. More recently, it has come to mean comprehensive services. Also see *system of care* and *wraparound services.*

**Crisis Intervention Training (CIT):** a specialized law enforcement unit comprised of officers who have received training in how to interact with individuals experiencing a psychiatric crisis.

**Cultural competence:** Help that is sensitive and responsive to cultural differences. Caregivers are aware of the impact of culture and possess skills to help provide services that respond appropriately to a person’s unique cultural differences, including race and ethnicity, national origin, religion, age, gender, sexual orientation, or physical disability. They also adapt their skills to fit a family’s values and customs.

**Day treatment:** Day treatment includes special education, counseling, vocational training, skill building, crisis intervention, and recreational therapy. It lasts at least 4 hours a day. Day treatment programs work in conjunction with mental health, recreation, and education organizations and may even be provided by them.

**Early intervention:** A process used to recognize warning signs for mental health problems and to take early action against factors that put individuals at risk. Early intervention may help individuals get better in less time and can prevent problems from becoming worse.
Family support services: Help designed to keep the family together, while coping with mental health problems that affect them. These services may include consumer information workshops, in-home supports, family therapy, parenting training, crisis services, and respite care.

Individualized services: Services designed to meet the unique needs of each individual and family. Services are individualized when the caregivers pay attention to the needs and strengths, ages, and stages of development of the individual and family members.

Interdisciplinary team (IDT): a team approach to treatment; typically consists of a psychiatrist, a case manager, a nurse and a peer specialist (an individual whose mental illness is stable).

Plan of Care: A treatment plan especially designed for each individual and family, based on the individual’s strengths and needs. The caregiver(s) develop(s) the plan with input from the individual being served. The plan establishes goals and details appropriate treatment and services to meet the special needs of the individual.

Recovery: Recovery is the personal process that people with mental health conditions experience in gaining control, meaning and purpose in their lives.

Residential treatment centers: Facilities that provide treatment 24 hours a day. Individuals with serious mental illness may receive constant supervision and care. Treatment may include individual, group, and family therapy; behavior therapy; special education; recreation therapy; and medical services. Residential treatment is usually more long-term than inpatient hospitalization. Centers are also known as therapeutic group homes.

System of Care: A spectrum of effective, community-based services and supports for individuals with or at risk for mental health or other challenges and their families, that is organized into a coordinated network that builds meaningful partnerships with families and individuals while addressing their cultural and linguistic needs, in order to help them to function better at home, in school, in the community, and throughout life.

*As times change, the words people prefer change. To show respect in conversations with others, be mindful of the impact your word choices have. If you need to use a descriptive term but are unsure of the words to use, ask the person how he or she would like to be addressed or referred to.*
Stigma is a powerful social process of devaluing people or groups based on real or perceived differences – such as gender, age, sexual orientation, behavior, ethnicity and disease state. Stigma is a major barrier in accessing treatment for many indications. Here we explore the roots of stigma, raising our awareness, and practical ways to combat discrimination.
STIGMA REDUCTION

ROOT CAUSE

Stigmatization occurs on multiple levels simultaneously; intrapersonal (self-stigma), interpersonal (relations with others), and structural (policies, laws and systems) impacting both volunteers and researchers. Fortunately, evidence-based solutions exist to improve both volunteer and research interactions and quality of care.

Individuals living with chronic illnesses commonly report feeling devalued, dismissed, and dehumanized by many of the health professionals they come in contact with. This occurs when health professionals “see the illness ahead of the person.” According to SAMSHA, this can contribute to the fact only 2.5 million of the 21.2 million individuals living with mental illness seek treatment. We must confront the lack of awareness causing underlying stigma-related behaviors to ensure we are modelling person-first behaviors instead.
MAKING CHANGE

Here is a list of tools we in clinical research can use to fight stigma and discrimination in the work we do:

1. **Know the facts.** Educational anti-stigma interventions present factual information about the stigmatized condition with the goal of correcting misinformation or contradicting negative attitudes and beliefs. They counter inaccurate stereotypes or myths by replacing them with factual information.

2. **Be aware of your attitudes and behavior.** We are a sum of our experiences. Many have grown up with specific prejudices and judgmental thinking.

3. **Language.** Be aware of possible derogatory or hurtful language. See more information in our language session.

4. **Focus on the Positive.** Health problems are just a piece of who we are. When speaking about clinical research, be sure to show volunteers in a positive light. We all have value in our society.

5. **Educate yourself and others.** Challenge myths and stereotypes. Find opportunities to pass on facts and positive attitudes about people in clinical research studies.

These strategies are aimed at reducing stigma on a person-to-person basis and have also been shown to benefit “self-stigma” by creating a sense of empowerment and boosting self-esteem.
Advocacy in all its forms seeks to ensure that people, particularly those who are most vulnerable in society, are able to have their voice heard on issues that are important to them, defend and safeguard their rights, and have their views and wishes genuinely considered when decisions are being made about their lives.
ADVOCACY

PURPOSE

Advocacy organizations use various forms of advocacy in order to influence public opinion and/or policy. They have played and continue to play an important part in the development of political and social systems. Advocacy groups fulfill their mission in different ways through national, state and local affiliates.

Clinical research’s partnerships are as varied as the indications themselves. Many advocacy organizations for disease states such as cancer, heart disease, diabetes and others work closely with research, often raising money for new cutting-edge therapies. Yet other indications such as brain disorders, do not receive the same support from advocacy and sadly, our society.

It is vital that clinical research, especially the sites at the local level, become involved in advocacy. This can take many forms, but always with the intent to better serve the volunteers entering a clinical trial. Research must educate themselves on local advocacy organizations, their mission, and how advocacy can become a support network for those entering a trial.

EXAMPLES OF ADVOCACY ORGANIZATIONS

The following are examples of top advocacy organizations for mental health in the US. Most of them have advocacy organizations at the state and local level. You can see through the descriptions how they each have a unique mission and serve a different purpose in the system of care.

Mental Health America (MHA) — Founded in 1909, MHA has an established record of effective national and grassroots advocacy and achievement. With over 200 affiliates in 41
states, 6,500 affiliate staff and over 10,000 volunteers, they are a powerful voice for healthy communities throughout the nation. Much of their current work is guided by the Before Stage 4 (#B4Stage4) philosophy – that mental health conditions should be treated long before they reach the most critical points in the disease process.

For more information visit www.mentalhealthamerica.net

**Depression Bipolar Support Alliance (DBSA)** — DBSA envisions wellness for people who live with depression and bipolar disorder. Because DBSA was created for and is led by individuals living with mood disorders, their vision, mission, and programming are always informed by the personal, lived experience of peers. Through more than 700 support groups and nearly 300 chapters, DBSA reaches millions of people each year with in-person and online peer support; current, readily understandable information about depression and bipolar disorder; and empowering tools focused on an integrated approach to wellness.

For more information visit www.dbsalliance.org

**National Alliance on Mental Illness (NAMI)** — NAMI is the nation’s largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness. NAMI is the foundation for hundreds of NAMI State Organizations, NAMI Affiliates and volunteer leaders who work in local communities across the country to raise awareness and provide essential and free education, advocacy and support group programs.

For more information visit www.nami.org

**Active Minds** — Active Minds empowers students to change the perception about mental health on college campuses. Active Minds supports a network of campus-based chapters across the United States and Canada that are made up of students passionate about mental health advocacy and education. Chapters provide their campuses with a wide range of programming that educates their peers about mental health, connects students to resources, and aims to change negative perceptions about mental health disorders. Active Minds chapters are changing the way students address mental health and giving a voice to this important issue.

Learn more at www.activeminds.org
Schizophrenia and Related Disorders Alliance of America (SARDAA) – SARDAA improves lives affected by schizophrenia-related brain illnesses (mental illnesses involving psychosis). SARDAA promotes hope and recovery through support programs, education, collaboration, and advocacy. Our vision is that every person living with a schizophrenia-related brain disorder receives respect, appropriate treatment, and an opportunity to live a meaningful and satisfying life in a compassionate community free of discrimination. Learn more at www.sardaa.org.

The STARR Coalition will assist your site in beginning the process of building a partnership with local and/or state advocacy. It has been our experience that some local advocacy groups are reluctant to partner with clinical research for various reasons; mistrust of clinical research, past history when working with sites, or simply no desire to associate with research. No matter the barriers, clinical research sites must become a part of the care continuum and individuals living with conditions must have clinical research as an option as they would any other option for care. We will call upon national partners if needed to open the conversation at the local level.
HOW TO GET INVOLVED

There are many ways research sites can support local advocacy. Here are a few examples:

- Sponsor an event such as a walk or fundraiser.
- Allow staff to volunteer in events or operational pieces needed by advocacy groups.
- Offer your resources to assist in disease education.
- Actively participate in community events.
- Share staff to assist in programs held by advocacy, i.e. having a nurse lead a family education group about medications.
- Hold a community health fair and invite other organizations involved in a specific indication.
- Assess the needs of advocacy in your community and fill those needs.
- Open your doors to advocacy leaders to educate them on the work you are doing. Hold an Open House, invite their staff/board in for lunch, allow them to use your space for meetings. Be creative. You are only limited by your imagination.
- Serve on a Board. Many groups appreciate and desire active participation.
- Reach out to other STARR Certified Sites and learn ways they are engaging advocacy and the community.
POTENTIAL PITFALLS

Important things to remember that can create barriers:

- Advocacy is NOT A RECRUITING TOOL FOR SITES. It is not the mission or obligation of advocacy to find volunteers for your trial. It is perfectly fine to share study information, but do not expect referrals. If you approach the partnership with this expectation, it will fail.

- Building a rapport should be viewed as altruistic. Supporting advocacy helps the entire community. It should be a part of your operations because it is simply the right thing to do.

The process of establishing a trust-based partnership with advocacy can take time. Be patient, but be persistent. It will benefit both the volunteers and your site. Remember, we are here as a resource as needed in this area.
The STARR Coalition relies on its stakeholders to identify needs within clinical research and advocacy, collaborate with fellow thought-leaders, and find innovative solutions to complex issues. Join a workgroup and be a part of meaningful change.
WORKGROUP PARTICIPATION

PURPOSE

One of the core tenets of The STARR Coalition is active participation from stakeholders. Stakeholders are encouraged to bring potential or existing challenges facing research and advocacy to the Coalition. Workgroups are formed around topics of relevance and interest to the stakeholders. With The STARR Coalition being a unbiased, neutral entity, a safe space is created for multiple sponsors, sites, advocates, etc. to work as a collective entity with open dialogue and shared solutions.

Coalition members have worked to discuss the following topics:

- Diversity and Cultural Competency
- Language
- Clinical Site Community Engagement
- Community Education
- Research in Higher Education
- Research Parity
- Media Relations
- Suicide Prevention
- Stigma Reduction

HOW TO GET INVOLVED

If any staff members are interested in joining an existing workgroup, or if you identify a golden thread running throughout research, treatment or advocacy which needs to be addressed, contact The STARR Coalition for assistance. Discussing best practices and progressive ideas can potentially result in industry changing solutions.
Empathy-based training is a powerful tool to allow individuals to step into the shoes of someone who is living with a specific indication. The STARR Coalition has created an Auditory Hallucination Simulation in which participants can experience one symptom associated with brain disorders, auditory hallucinations. This exercise has transformed perceptions of brain disorders for individuals who have participated in this exercise.
**AUDITORY HALLUCINATION SIMULATION**

**CONCEPT**

Many individuals living with brain disorders experience a litany of sensory perceptions. This causes a tremendous amount of difficulty performing day-to-day tasks. This computer-based simulation was created to give people a small glimpse into the mind of someone living with auditory hallucinations, most commonly associated with schizophrenia.

This type of empathy training gives providers of mental health services, family members, friends, peers, and our communities a greater understanding of the complexities of living with schizophrenia. We hope this exercise gives you new insight and awareness.

It must be noted not everyone is willing or able to do this exercise. DO NOT perform this exercise if you have ever been treated for symptoms of auditory hallucinations. Also, not everyone is comfortable participating for various reasons. We suggest all staff participate but please respect the wishes of those who choose to abstain.
PROCESS

Unlike other auditory hallucination simulations, instead of passively listening, this computer-based program requires you to complete several tasks. Before you begin, please do the following:

☐ Be sure to wear headphones. Just listening through speakers will not give you the same effect. Make sure the volume is high enough to block out any environmental noise.

☐ You will need something to write with and a piece of paper. Do not use your phone or other devices for any section.

☐ Please take a moment to answer the debriefing questions after completing the simulation. It is a part of the entire experience.

☐ If at any point you become disoriented or want to stop, stop. Simply remove the headphones and proceed to debriefing.

☐ And most importantly, if you have been diagnosed with a mental illness and have experienced auditory hallucinations, DO NOT DO THIS EXERCISE.

OUTCOMES

After the experience, it is common to feel anxiety, confusion, frustration, or exhaustion. Take a few minutes to identify exactly how you are both physically and emotionally. It is nearly impossible to comprehend continually living with auditory hallucinations. The fact is, many individuals can experience other hallucinations such as visual, olfactory (sense of smell), tactile (sense of touch) and gustatory (sense of taste).

We will send a link to the simulation as soon as your site is ready to proceed.
A strong link exists between chronic illnesses and suicide. Individuals who are diagnosed with a chronic condition have 363% higher odds of suicide. Individuals wishing to enter a clinical research study and have had suicidal thoughts within the last 12 months may not meet criteria. STARR 911 will help connect individuals with suicidal ideations immediately to suicide prevention specialists and share potential life-saving information for others.
Individuals living with chronic and persistent illnesses have a much higher propensity for suicide. Up to 20% of individuals with a diagnosis of mental illness complete suicide. Research has also found that 90% of those who die by suicide experience mental illness. People considering suicide usually seek help: for example, 64% who attempt suicide visit a doctor a month before their attempt. Again, having a chronic condition increases the odds of suicide by 363%.

WHAT IS STARR 911?

Research facilities receive calls on a daily basis. For many individuals, contacting research sites about possible enrollment for a clinical study may be their first attempt to reach out for help. Therefore, research has an obligation to help make suicide prevention education and support a part of their first contact process and culture.

STARR 911 is a concept to build collaboration between clinical research and suicide prevention. The concept will train operators on techniques to recognize callers who may have suicidal ideation. A simple, brief questionnaire on each call is given to the caller to quickly assess suicidal thoughts. Options include information on who to call and/or giving a “warm” hand off to a suicide prevention specialist.

STARR 911 gives research the opportunity to use its resources to impact suicide prevention. Research will gain credibility as being a part of the health care community, gain credibility for drug development and increase education to sites on suicide prevention resources.
Most important; the human factor. Statistics speak volumes for the need for a program like STARR 911. Linking individuals with support systems which meet their immediate needs is crucial for stability. This is a vital link in the chain of recovery.

THE PROCESS

If an individual is ineligible for participating in a clinical research study due to suicidal ideation, the screener will follow a script to determine whether the individual needs contact information to the Suicide Prevention Lifeline or the need to be given a warm handoff to a suicide prevention specialist. The process is simple and easy to follow.

*Staff are able to be trained by watching a short video here:*

https://youtu.be/lHT4xv2-eqI

The following is information from the brochure used during the screening process:

Guide to inform and assist individuals being screened for a clinical trial with suicidal ideation.

We hope this will help guide those who are having thoughts of suicide to resources they need. Screeners are not expected to act as a suicide prevention specialist; experts are trained in these procedures. The American Foundation for Suicide Prevention Lifeline exists to help people, do not be afraid of doing a “warm handoff” if the caller is in need.
The operator would begin each conversation by establishing that the individual is interested in joining a trial.

**Once established**

The operator would let the person know that there are a few questions they need to go over before they get into the details of applying to join the trial. The operators would continue the conversation in their normal tone, friendly and supportive.

***Initial Question***

**if YES**

“In the past month, have you had thoughts about killing yourself or thoughts of suicide?”

**if NO**

“The operator would let the person know that there are a few questions they need to go over before they get into the details of applying to join the trial. The operators would continue the conversation in their normal tone, friendly and supportive.

**if YES**

“Are you currently having thoughts about suicide or killing yourself? Have you made any specific plans or acted on these thoughts?”

**if NO**

“The operator would let the person know that there are a few questions they need to go over before they get into the details of applying to join the trial. The operators would continue the conversation in their normal tone, friendly and supportive.

**if YES**

“Are you working with a mental health professional and have you told them about these thoughts and that you have been having them recently?”

**if NO**

“The operator would let the person know that there are a few questions they need to go over before they get into the details of applying to join the trial. The operators would continue the conversation in their normal tone, friendly and supportive.

**if YES**

“It’s good to hear that you are working with your mental health professional about these thoughts. Because of your suicidal ideations, you are not currently eligible for this clinical trial. I would like to give you the number of the National Suicide Prevention Lifeline, 1-800-273-8255, in case you feel you are in a crisis and cannot reach your clinician. You can also text TALK to 741741 for help.”

**if NO**

“The operator would let the person know that there are a few questions they need to go over before they get into the details of applying to join the trial. The operators would continue the conversation in their normal tone, friendly and supportive.

**if YES**

“I would like to connect you with someone who can help you right now. First write down this number in case we get disconnected, 1-800-273-TALK (8255) or text TALK to 741741. I’ll stay on the line with you until we get you connected to the National Suicide Prevention Hotline. This should just take a minute.”

At this point the operator dials 833-STARR-911 (or 833-782-7791) and presses Option 1 to be transferred to the National Suicide Prevention Hotline. DO NOT GIVE THIS NUMBER TO THE CALLER (this number is just for the screener to use).
Project RockSTARR is a project created by the stakeholders of The STARR Coalition with the intent to give sponsors the opportunity to support local advocacy, empower volunteers to give back to their community, build relationships between local advocacy and research sites, and create goodwill among all participants.
CONCEPT

CNS clinical research faces unique challenges including misconceptions associated with mental health disorders as well as patients’ general skepticism of clinical research. We can talk about issues on a national level but the hearts and minds will only be changed at the community level, in the local cities and neighborhoods where research is taking place. The goal is to close the gap between research and the communities they serve.

The idea is simple. When a potential volunteer screens for a study, they are immediately provided informational handouts about all advocacy organizations within their community. At that moment, the volunteer is given the opportunity to choose to donate (up to $200 provided by the Sponsor) to one of the local advocacy organizations of their choice. This is a great way to empower subjects to give back to their community and for the Sponsor to honor the potential volunteer for their service.

Once every quarter, six months (depending on the Sponsor), The STARR Coalition will issue a check to the local advocacy groups and send them to the clinical research sites. The sites will then present the donations to the local advocacy group on behalf of the subjects who volunteered for the trial. This is a great opportunity to connect to advocacy and allow volunteers to have access to resources outside the clinical trial.
BENEFITS

This project will benefit participants in the following ways:

☐ Volunteers learn information about advocacy groups within their area

☐ Volunteers have access to resources outside the clinical research trial

☐ Volunteers feel a sense of giving back to their community

☐ Advocacy becomes more educated on clinical research trials in their area

☐ Advocacy benefits from the additional funding to help support local/state programming

☐ Research sites understand the mission of advocacy and their role in the community

☐ Advocacy involved in evolving healthcare landscape

☐ Builds bridges between volunteers, advocacy and clinical research

☐ Clinical trial sponsors have the opportunity to build upon their relationships with research volunteers

☐ Greater awareness ensures research as an option for all
OUTCOMES

Project RockSTARR has written support from leading national advocacy groups within behavioral health. If needed, national advocate leaders involved in this project will assist sites in building relationships with local advocates. This project will change the conversation between research and the communities they serve.

The donation is separate from their stipends. The choices of advocacy groups will be visible from a pre-selected and approved geo-targeted drop-down list. The subject does have the choice to decline participation if they so choose, although we believe this will be an uncommon occurrence.

Project RockSTARR will be initiated by Sponsors on participating studies. You will be informed of studies partnering with Project RockSTARR and will receive additional training and support as needed.

We hope Project RockSTARR becomes a standard within the industry. We envision Sponsors participating across all indications and disease states. From the ground up, we will change the way people engage CNS research. It will be perceived like all other indications, and we will ensure the millions of individuals living with CNS disorders have a fulfilling life within the communities they live.
Understanding the strengths, weaknesses, opportunities and threats within your community can help shape the mission of your site. Creating a simple SWOT analysis will lay the foundation of community outreach and integration. Identify the assets you possess at your site and ways to deploy them to make a positive impact on your community. Invite community leaders, treatment providers, hospitals, and others to your site to better understand the work you are doing. When we are able to convey an overlap of missions between stakeholders, i.e. helping to better the lives of those in the community, trust is built and partnerships are able to flourish.
ASSESSING YOUR COMMUNITY AND SITE

CONCEPT

For many clinical research sites, actively participating within the communities you serve has not been a priority. When making an assertive effort to be an active participant in the community, you must understand what you have to offer, what your community has to offer, ways to work together and barriers which arise when taking these vital steps. The clearest method to define these areas is a quick Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis. This process will give you a clear look at the landscape around you and can be the blueprint for community integration.

PROCESS

Strengths and Weaknesses are defined as internal factors your site currently possesses such as:

- Company culture
- Reputation
- Partnerships
- Assets
- Resources
- Employees and Leadership
Weaknesses and Opportunities are defined as external factors which come from the larger environment surrounding your site such as:

- Medical providers
- Economy
- Potential Volunteers/Current Volunteers
- Advocacy
- Vendors
- Legislation/Regulations

There is no objective way of measuring how well you do a SWOT analysis. It is simply observing internal and external factors that can impact your site. It’s not about making accurate predictions; it’s about knowing what to plan for.

There are several steps in creating a SWOT analysis.

1. **Gather the right people** – While many decisions are made by upper management, it is important to open this process to all people with interest in your success as a site, even people who don’t fully understand your business. Including as many employees as possible will increase the buy-in and broaden valuable insight.

2. **Host a brainstorming session** – Gather your team and list all strengths, weaknesses, opportunities, and threats (better with smaller teams) or have individuals make their own lists (better with larger teams). Write everything down. Do not begin to close out ideas at this point.

3. **Fill the gaps** – Once ALL ideas are on the table, come up with four big lists. Start filling in the gaps and determine how important each item is on the list. Ask
each person to choose their top three items from each category. Most likely, patterns will emerge.

4. **Narrow the Lists** – Begin to fit all your ideas on a single page (included in module). Keep larger list for future review.

5. **Create strategies** – For each item on the final list, create a strategy to exploit the advantages and opportunities and deal with the weaknesses and threats. Keep the plan broad. Ask yourself the following: How can you use your strengths to improve your weaknesses? How can you exploit opportunities to neutralize your threats? Can you leverage your strengths to better take advantage of opportunities? Is there a weakness you need to prioritize in order to prevent a threat?

Once you’ve worked out the most important items, flesh out your action plan and start the work.

Sites have used this concept to proactively:

- Support local advocacy by joining boards, using site staff for helping educate advocacy and families about medicine, research, complexities of indications, etc.

- Providing funding for advocacy, participating in community events, building partnerships with medical providers and treatment facilities, etc.

- Utilize outreach into new areas of the community not previously explored.

- Design plans to become community leaders in research education and outreach.
Sites have also come across barriers as well:

- Resistance from advocacy to become associated with research.
- Medical and treatment community hesitant to educate consumers about potential research opportunities.
- Cautious when associating with research due to stigma around research.

It is important that you use The STARR Coalition and its stakeholders as a resource when you put your plan into action. We are here to ensure clinical research sites become a pillar of their community.

**CERTIFICATION EXPECTATIONS**

- Creation of SWOT analysis for your site with action plan.
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Site volunteered a combined 40 hours in the last calendar year for advocacy or local nonprofit organization in need. (For example, ten staff volunteer 4 hours at a fundraiser each year).

Site completed Advocacy Assessment form documenting contacts with advocacy.

Site signed up to work on one workgroup with other STARR stakeholders.

Implemented and actively using STARR 911 at your site. Completed use and effectiveness survey on STARR 911.

All participating staff working within CNS disorders completed Auditory Hallucination Simulation. Copies of Certificate of Completion for each staff submitted to The STARR.

When Project RockSTARR is implemented for a specific trial, all necessary staff were trained to follow guidelines of Project RockSTARR.

All STARR Certified Sites will complete necessary documentation for annual recertification. Each site must also sign release stating permission to contact local advocacy organizations to discuss your site.
The STARR Coalition (Stakeholders in Treatment, Advocacy, Research and Recovery) was created to bring together leaders in the areas of treatment, clinical research, pharmacology, education and advocacy to improve the systems impacting research and patient care. It is the responsibility of Coalition members to place the well-being of the individual with CNS Disorders at the heart of everything they do. We do this by broadening options for those seeking treatment, reducing stigma, and promoting cutting-edge research. We build cooperation among stakeholders to promote trust and strengthen relationships in the communities we serve throughout the nation.

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