CHA Cambridge Health Alliance	**INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask the study doctor or study staff to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this study.

Study Title: Enhancing Systems of Care: Supporting Families and Improving Youth Outcomes (E-SOC)

Child's Name:	**Parent/Guardian's Name:**

Not including this study, is your child taking part in any research now? ☐**Yes** ☐**No**

Name of Principal Investigator: Katherine E. Grimes, MD, MPH

Name of Co-Investigator(s): Gregory Hagan, MD, FAP

Consent form version date or number: 08/30/19

Name and telephone number of study contact to call with questions: Katherine Grimes, MD, MPH 617-806-8729

CHA IRB Number: CHA-IRB-1062/04/17 **IRB Approval Date:** September 3, 2019 **IRB Expiration Date:** September 2, 2020	**Study Sponsor(s):** Substance Abuse and Mental Health Services Administration (SAMHSA)

Introduction

Your family is invited to take part in a research study done by Dr. Katherine E. Grimes, MD, MPH and people who work with this doctor.

Taking part in this study is voluntary. You and your child have the choice to take part or not. If your family takes part in the study, you may leave the study at any time for any reason. If your family doesn't want to take part, the standard health care your family will receive at Cambridge Health Alliance will not change.

If your family decides to take part in this study, you will be asked to sign this consent form, and your child who is 12 years old or older will be asked to sign an assent form. You will also be asked to sign this consent form for us to interview you about the needs of your child and your past care experience. Your family will be given a copy of any signed forms. Please keep your copy for your records. It has information, including important names and telephone numbers, for future reference.

New Findings

We will tell your family if new findings become known that might cause you or your family to change your mind about being in this study.

Purpose for the Study

The purpose of this research study is to learn if this new way of helping youth and their families is effective.

This study is made possible by a federal grant to Cambridge Health Alliance (CHA) supporting efforts to get appropriate mental health care to children and adolescents sooner, and in ways that work better for families. To meet this aim, E-SOC team members will partner with primary care clinicians to help CHA families find the right resources to manage the mental health, school or other behavioral health needs of their children. E-SOC brings experienced Clinical Care Managers and Family Support Specialists into the primary care clinic, so that mental health assessments can happen on-site for any child referred by their PCP.

Some children experience difficulties that make everyday life challenging for them and their families. For these children, additiona supports may be available through the study, by means of cooperative Child and Family Teams, which bring together community programs, the schools, or other providers, to provice individualized, family-driven care. Over time, we hope such strategies will lead to healthier and happy children, better supported families and stronger, safer communities.

Reasons why you have been invited to be in this study

We are inviting your family to participate in this study because you or your child's doctor have expressed concerns about your child's feelings and/or behavior or in follow-up to his or her recent Well-Child screening visit.

Your child's PCP spoke with your family about a mental health referral and has asked the E-SOC team to help you obtain a child mental health assessment and consultation.

If, after hearing more about the study, your family chooses to participate, the child mental health assessment will take place within the primary care setting, in collaboration with the PCP.

Youth whose mental health needs (based on standard measures) require more intensive services, will be offered the chance to participate in the E-SOC Child and Family Team model, in which individual Clinical Care Managers (child mental health clinicians) and Family Support Specialists (parent professionals who are experienced with helping families navigate health care). The E-SOC Child and Family Team will connect with the people your family identifies as providing key support and via organized goal-setting and treatment matching activities, will help your family develop resources so your child can be maintained at home and attend school within their community.

Period of Participation (how long you will be in this study)

If your family chooses to participate in this research study, there will be three study related visits. Your child will be given a comprehensive mental health assessment at your child's primary care doctor's office. An E-SOC researcher will meet with your family two additional times (at 6 and 12 months) after your child joins the study at a place of your family's choosing to gather additional information. If your child needs more intensive services through a Child and Family Team, additional information will be gathered via the interviews at 6 and 12 months, as required by the SAMHSA Grant National Evaluation. The study expects to enroll about 500 families.

The funding for this research into ways to improve child mental health systems for children and families

comes from the federal Substance Abuse and Mental Health Services Administration (SAMHSA). Every year, SAMHSA creates reports to Congress on how the money was spent. The "National Evaluation" gathers trends across the country in grantee sites use of hospitals, or other types of care, to measure "barriers to - and achievements resulting from - interagency collaborating in providing community-based services to children with a serious emotional disturbance". The National Evaluation also includes "assessments by parents of the effectiveness of the systems of care", for those who consent to participate.

Procedures (what will happen during this study)

If your family decides to take part in this research study, the following procedures will be done:

With your consent, your child will be given a comprehensive mental health assessment at your child's primary care doctor's office, including interviews of you and your child with the Clinical Care Manager, the Family Support Specialist, and a Child Psychiatrist (if appropriate) about school, personal and family life. This information provides "baseline" information about what your child's needs are at the beginning of your family's participation in the study, and guides the team's recommendations about treatment, including what level of care might be needed. For those with the greatest need, as indicated on standard surveys of child well-being, the option to participate in a Child and Family Team, will be provided.

As part of the comprehensive assessment, with your permission, information from your child's medical record will be gathered to help us better understand your child's needs. We will also collect data for our outcomes reporting about the numbers of children we worked with, and what types of needs they had. (All information about your child will be kept confidential and reports will only show anonymous totals, such as "we interviewed sixty 8-year olds, of whom 20% were African American" or "35% of children had asthma")

If your family chooses to access the E-SOC Child and Family Team service option, a Clinical Care Manager and a Family Support Specialist will work with you to help coordinate your child's care. If you want to include other people important to you or your child (such as teachers, or therapists) we will ask you to sign a CHA Release of Information (ROI) so that those team members can share information. Caregivers will have control over information sharing and all information sharing decisions will be documented.

Possible Risks, Discomforts, Side Effects, and Inconveniences

Since this study involves mental health needs and family stressors, some of the questions that your family will be asked are of a personal nature and could make you somewhat uncomfortable. There are no other risks to you from participating in this study. Your family may ask to see the questions before deciding whether or not to participate in this study.

Your family's part in this research study consists of allowing the research team to study the results of this project, by gathering data from your child's medical record and those of the other children in the study. The tests and treatments your child receives are part of the standard care for your child's condition. This study does not require your child to have any additional procedures or treatments. Therefore, being in this study does not involve any risks that your child would not face during routine treatment and care.

We will be happy to answer any question your family has about risks and/or side effects. Please talk with a study team member if your family has any study-related questions or concerns.

Alternatives to Participation

The alternative to this study is to continue receiving pediatric and mental health care as usual from Cambridge Health Alliance.

If you and your child have a referral but do not wish to participate in the study, we will work with your child's PCP to connect to appropriate child mental health assessment resources, either within psychiatry at CHA or outside CHA, whichever is most convenient.

Benefits (good that may come from being in this research)

Participating in this study will provide new knowledge about what helps families of children with mental health needs the most, so that pediatricians and child mental health clinicians can provide more effective care to children in the future.

Costs

There will be no cost to your family for access to the E-SOC resources, including the Family Support Specialist, Clinical Care Manager, and Child and Family Team, or for participating in this research study.

Payment

There is no compensation for your family's participation. If your child needs more intensive services through a Child and Family Team and the team gathers additional information as required by the SAMHSA Grant National Evaluation, a gift card will be provided to your family upon completion of the study.

Voluntary Participation

Taking part in this study is voluntary. If your family does not take part, your family will not be punished or lose benefits that your family has the right to receive. The quality of your family's medical care will be the same at Cambridge Health Alliance whether your family takes part in the study, refuses to take part, or decides to leave the study.

If your family chooses to take part and then decides to stop, tell any member of the research team. Any information collected from your family before the date your family leaves the study will be used in the research study.

Privacy / Confidentiality

We follow national and state laws that protect your child's health information to keep it private. Your child's identity, medical records, and study data will be kept confidential, except as required by law.

We will protect all of your child's health information, including your child's Protected Health Information or "PHI." Your child's PHI is your child's individually identifiable health information.

If your family takes part in this study, you agree to let the research team use your child's medical information to help us understand how to better serve children and families. Do not take part in this study if you do not want the research team to access your child's health information.

We will follow these guides:

- The research team will view your child's health information only during the life of this study.
- We will not include any information that could identify your child in any publication.
- At the end of the study, we will remove all of your child's identifiable information (name, address, telephone number, *etc.*) from the study database.

We will make every effort to keep your child's information private, but we cannot guarantee it. The Cambridge

Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect your child. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify your child.

Sometimes, we are required to share your child's study records with others, too, including:

- Other researchers conducting this study,
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study
- Accrediting agencies,
- Clinical staff not involved in the study, but involved in your regular treatment

If any of these groups ask to look at your child's information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. Your family can search this web site at any time.

Period of Authorization

Your authorization remains in effect until the end of the study. If you change your mind and want to withdraw your authorization, please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, your family may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If your family has questions about this study, please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Questions may be directed to the Principal Investigator:

Dr. Katherine Grimes, MD, MPH
Telephone: 617-806-8729

If you or your child has questions about your child's rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair: Dr. Lior Givon, MD, PhD
Telephone: 617-806-8702

Patient Relations Manager: Lorraine Vendetti
Telephone: 617-665-1398

Confirmation from Person Obtaining and Documenting Consent

I, _____, am the parent or legal guardian of _____
Print your name — Print your child's name

and consent to his/her participation in the overall E-SOC study, including a comprehensive child mental health assessment (supported by questionnaires and medical record information) with treatment recommendations and support, and, later on, follow-up interviews and data collection.

In addition, if after the initial assessment the team determines my child's mental health needs (based on standard measures) require intensive services, I consent to his/her participation in the E-SOC Child and Family Team, to be led by my child's E-SOC Clinical Care Manager according to goals set by myself and my child.

I understand the team's role is to help create an individualized Care Plan for my child, building on his/her needs and strengths, and to help my family with coordinating services and supports for my child.

I also understand that these resources are part of the E-SOC grant from SAMHSA, and that I will be interviewed at the beginning (baseline), with follow-up interviews and data collection in the middle (6 months later) and end (12 months later) of the study, as part of SAMHSA's National Evaluation.

I also understand that I am a study participant, and have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Signature of Parent or Legal Guardian Participant, who is also the Child Participant's Legally Authorized Representative — Date

_____
Printed Name of Parent or Legal Guardian Participant, who is also the Child Participant's Legally Authorized Representative

I have informed the study participants,

_____ and _____ of:
Parent or Legal Guardian Participant Printed Name — Child Participant Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How the child's health information may be used, shared, and reported, and;
- His/her privacy rights.

The parent/guardian has been provided with a signed copy of this form.

_____ _____
Signature of Researcher Obtaining Consent — Date

_____
Printed Name of Researcher Obtaining Consent

_____ _____

Printed Name of Interpreter (if used) Date

Interpreter Role: CHA employee _____
Other_____

This form is valid only if it has the IRB stamp of approval.