Low Intensity Family Support for Refugees in an LMIC

National Clinical Trial Number: NCT03978533

Principal Investigator:

Stevan Weine, MD, University of Illinois Chicago, Department of Psychiatry

Supported by:

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Approved: July 28, 2019

OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Office for the Protection of Research Subjects (OPRS)
Institutional Review Board
FWA# 00000083

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Initial Review Application: Social and Behavioral Sciences

Version: 5.0; Date: 06/01/17

Date application completed by the Investigator: 7.22.19

I. Research Title: Low Intensity Family Support for Syrian Refugees in an LMIC

II. Personnel

A. Principal Investigator (PI)

Name (Last, First) **Weine, Stevan**	Degree(s) **MD**	Net ID (e.g., NetID@uic.edu) **smweine**
Department **Psychiatry**	College **COM**	University Status ☐ Student/Fellow/Resident ☒ Faculty/Staff
Mailing Address **1601 W. Taylor Street**		
Phone Number	UIC E-mail Address **smweine@uic.edu**	

B. Faculty Sponsor – Complete only when PI is a student, fellow, or resident

Name (Last, First)	Degree(s)	Net ID (e.g., NetID@uic.edu)
Department	College	
Mailing Address		
Phone Number	UIC E-mail Address	

C. Primary Contact Other Than PI – Complete only if the primary contact person is different than the PI

Name (Last, First)	Net ID (e.g., NetID@uic.edu)
Phone Number	UIC E-mail Address

☐ Principal Investigator grants this personnel access to OPRS Live for this protocol

D. List all co-investigators and key research personnel on Appendix P and upload with this application packet.

III. Performance Sites

Definition of a Performance Site: A performance site is a location at which the research is conducted, data is gathered from subjects and/or records, and/or subjects are consented into the research. Sites are performance sites whether the research activities there are funded or not funded.

A. Non-UIC Performance Sites:

1. Are there non-UIC performance sites?
- ☐ No – Skip to Section IV.
- ☒ Yes – Complete Appendix K and upload with this application packet

2. Are there international performance sites?
- ☐ No
- ☒ Yes – Complete Appendix I and upload with this application packet

IV. Research Funding

A. Is this research funded?
- ☐ No – Skip to Section V.
- ☒ Yes
- ☐ Pending

B. Check all of the appropriate boxes for funding sources (including pending sources) for this research.
- ☒ *Federal Agency Name: **National Institutes of Health**
- ☐ Foundation Name:
- ☐ *State Agency Name:
- ☐ *Department of Defense – Complete Appendix Q and upload with this application packet
- ☐ *Sub-contract from non-UIC agency or institution: Name:
- ☐ Other - Name:

C. Funding Identification: For funding sources identified with an * above, provide the following information. *If the study is supported by more than one funding source identified with an *, complete and upload **Appendix Z** for each additional funding source.*

1. Institutional Proposal (IP) Number: **00396146**

2. a. Name of the PI on the grant or contract received directly from the sponsor: **Stevan Weine**

b. Is the PI of this grant or contract affiliated with UIC?
- ☐ No – Identify the agency or institution with which the above PI is affiliated:

Explain the relationship between that agency or institution and UIC:

☒ Yes – Upload a copy of the grant, contract, or funding submission to OPRS Live as it is required for review.

c. Grant, contract or sub-contract title: **Low intensity family support for refugees in an LMIC**

d. Grant, contract or sub-contract number: **1R21MH11775**

V. Conflict of Interest (COI)

All investigators must disclose all real, apparent, or potential Significant Financial Interest (SFI) to the IRB. For more information, see the ***Investigator Conflict of Interest Disclosure Policy for Human Subjects***.

A. Disclosure

1. At present or in the 12 months prior to this disclosure, did or does any investigator or investigator's family members have a significant financial interest (SFI) with the research sponsor or any subcontract recipient; or have a SFI reasonably related to a product (e.g., drug, device, method, treatment, etc.) that is the subject of the research; or have any other relationships (e.g. fiduciary, even if uncompensated) that may present a potential conflict of interest with this research?

☒ No
☐ Yes – See Section B below.

2. Are you aware of an institutional conflict of interest with this study?

☒ No
☐ Yes – See Section B below.

B. Management

If **YES** is checked for any of these questions, complete the disclosure and management plan via START myDisclosures application (https://myresearch.uillinois.edu/myDisclosures/). Guidance can be found on the COI website at http://research.uic.edu/compliance/coi under "Managing Conflicts". Final IRB approval of the research cannot be provided until a management plan is in place and is approved by the IRB. For additional assistance contact the COI Office at **(312) 996-3642 / (312) 996-4070** or email *coi@uic.edu*.

VI. Protocol Components

A. Provide a description of the background and rationale for the proposed research. Cite appropriate literature to support the relevance and importance of this research.
This research project will develop and pilot testing a novel model for helping urban refugee families in low- and middle-income countries (LMICs) with common mental disorders (CMD) and no access to evidence-based mental health services. It delivers a transdiagnostic low resource-intensity family

support intervention for CMD in health sector and non-health sector settings. The proposed project is located in Istanbul, where there are 500,000 refugees from Syria. This project examines and advances strategies to adopt and integrate evidence-based health interventions into community and clinical settings so as to improve patient outcomes and benefit population health.

B. State the research objectives/hypothesis being explored by the current research. Please include primary and secondary aims.

AIM 1 To form a Family Support Design Team (FSDT) to adopt the Problem Management Plus (PM+) and Coffee and Families Education and Support (CAFES) manuals into a family support (FS) intervention for use with Syrian refugee families by lay providers in community sites and nurses in clinical sites using a four-session multiple family group format.

AIM 2 To pilot FS with families in community and clinical sites, and then through observations and qualitative interviews, to assess FS's feasibility, fidelity, the impact of context and local capacity, the experiences of intervention delivery, and practitioner and organizational perspectives on scale up.

AIM 3 To conduct pre, immediate post, and 3-month post assessments of the Syrian refugee families who received FS through all the sites, to demonstrate the kind of pre-post changes that have been reported for comparable interventions and to determine key parameters of interest with sufficient accuracy and precision.

C. Clearly describe the study design/intervention. The description should demonstrate how the stated objectives will be met.

Aim 1 activities include convening the family support design team (FSDT) and drafting the FS manual. After the manual is drafted, then 8 families will participate in a whole-day run through of the Family Support model followed by a feedback session.

Aim 2 involves partnering with the 7 community and clinical sites, training 14 facilitators (2 from each site), having facilitators administer the intervention with a practice round to 42 families (1 group with 6 families at each site) and then to 84 families for the actual intervention (2 groups with 6 families at each site), and then conducting observations, process measures, and qualitative interviews to assess implementation issues. Qualitative interviews will be conducted with 9 of the 84 families, 4 community workers, and 3 nurses.

Aim 3 involves conducting pre, immediate post, and 3-month post assessments using a questionnaire to the 84 families who received the intervention.

D. Describe in chronological order all the tasks/tests or procedures subjects will be asked to complete in participating in this research. Distinguish between tasks performed solely for research and those being performed for non-research purposes.

Aim 1:

In months 2 - 6, The Family Support Design Team, which includes the principal investigator and co-investigators, low- and middle-income researchers, and 8 community advocates, nurses, and physicians, will convene. The FSDT will first meet face-to-face for three days in month 2 in Istanbul, followed by regular Skype calls and ongoing e-mails, and a follow-up three day meeting in month 6. These meetings involve FSDT members revising the PM+ and CAFES manuals to build the Family Support model, which will be a 4 session multiple family support group format. FSDT members will be compensated $120 for their participation in each of the 3-day face-to-face meetings.

In month 5, 8 families will be invited to participate in a whole-day run through of the Family Support model followed by an immediate feedback session where they will identify components of the model that were helpful and those that need modification. Feedback will be used to informs final modifications of the Family Support model. The feedback session following the run through will be no longer than 60 minutes. Families who participate in the whole-day run through of the family support model will be compensated $20.

Aim 2:

Facilitators: We will recruit 14 community workers and nurses from 7 community based organizations (2 at each that work with Syrian refugees in Istanbul where the Family Support Group will take place. The community workers and nurses will receive 20 hours of training to facilitate the Family Support Group. Each pair of facilitators will conduct one practice Family Support Group, and then will conduct two pilot Family Support Groups. Each Family Support Group in the practice and pilot is 4 sessions and each session is 2 hours. The facilitators will also be asked to complete process measures which includes a self-report on their delivery of the Family Support Group and a facilitator delivery satisfaction checklist.

Following the Family Support Group intervention, a sub-set of 7 facilitators (3 nurses and 4 community workers, which is one from each organization) will be asked to complete a qualitative interview that will last approximately 60 minutes. Facilitators will receive $10 for participating in the interview and the interview will be audio recorded.

Families:

We will conduct the Family Support Group at 7 community based organizations. There will be a pair of facilitators at each organization who will recruit families from their organization. There will be one practice group with 6 families carried out at each organization (7 orgs x 6 families = 42 practice families) and then two pilot groups with 6 families in each group conducted at each organization (7 orgs x 6 families x 2 groups = 84 families). Each Family Support Group is 4 sessions that each last 2 hours.

In addition to participating in the Family Support Group, each family will be asked to complete 3 surveys (one at the start of the first session, one at the end of the last session, and one 3 months after the intervention). Each survey will last approximately 60 minutes. Each family member who participates in the intervention (which includes both adult caregivers and at least one of their adolescent children) will be asked to complete each individual survey.

Following the final 3 month follow up survey, 9 of the 84 families will be asked to complete a qualitative family interview that will last approximately 60 minutes. Families will receive $10 for participating in the interview. The interview will be audio recorded.

E. Describe the plans for data analysis. If applicable, include statistical considerations and justification for subject population and planned enrollment numbers.

The Family Support Design team will be providing feedback and revising manuals and notes will be taken. These notes will be used to modify the model.
The 60 minute feedback session will use a feedback guide and will be audio recorded. The recordings will be transcribed and feedback will be organized by themes that appear so that these can inform final modifications.

Quantitative Analysis. Our primary hypothesis is that FS primary participants will report fewer symptoms of depression, anxiety, and traumatic stress from baseline to immediate post and 3-month post. Our secondary hypothesis is that FS family members will report improved family members' knowledge and attitudes regarding responses to adversity, family support, family problem solving, and accessing external resources, and that these will explain improvements in CMD symptoms. We will conduct analyses: 1) to demonstrate the feasibility of the implementation and evaluation methods; 2) to explore patterns of attendance and retention to FS groups, to inform the researchers in making modifications; 3) to demonstrate the kind of pre-post changes that have been reported for comparable interventions, for both primary participants and family members; 4) to determine key parameters of interest with sufficient accuracy and precision. Data will be cleaned and scrutinized before analysis, with appropriate transformations applied if needed for conditional normality assumption in longitudinal data analysis.. SAS version 9.4 will be used for data analysis.[114] The analysis is a straightforward application of a two level mixed-effects regression model.[115,116] This model considers both random subject intercept and slope terms to explain variation of

trends of participants, allowing us to model population-averaged and subject-specific effects as well as longitudinal and cross-sectional profiles. Information on facilitators, clinical and community sites, different sessions or group indicators with multiple families, as well as indicators on the measurement waves, will be appropriately incorporated into the fixed and random parts of the mixed-effects regression model. The results of the analyses will be included in quantitative reports, inform qualitative data collection, and be integrated into mixed methods analyses.

Qualitative Analysis. Qualitative analysis will use a grounded theory approach and Atlas/ti 7 software. The text of transcribed interviews will be entered into Atlas/ti and analyzed in the following steps: 1) Initial review of the data; 2) Developing a coding scheme; 3) Coding; 4) Pattern coding; 5) Memoing, and; 6) Writing. This analysis will generate manuscripts incorporating: 1) narrative descriptions (e.g. of family members' experiences of FS); 2) content categories elaborating the phenomena in a given domain (e.g. how family members' behaviors changed), and; 3) mixed methods analysis and reports (e.g. combining the survey data demonstrating pre-post changes with the qualitative data explaining important meanings, change mechanisms, and contexts).

VII. Research Records

A. Indicate the type(s) of data being collected and/or recorded *(check all that apply)*:

- ☒ Interviews/Questionnaires
- ☒ Audio recordings
- ☐ Video recordings
- ☐ Photographs
- ☐ School/Student records
- ☐ Internet research data
- ☐ Lab, pathology and/or radiology results
- ☐ University of Illinois Hospital & Health System medical records
- ☐ Physician/clinic/hospital medical records from sources outside of UI Health System
- ☐ Psychotherapy Notes
- ☐ Billing records
- ☐ Data previously collected for research purposes
- ☐ Data containing no health information
- ☐ Study-generated health information
- ☐ Biological specimens
- ☒ Other. Describe: **observations**

B. Will any biological samples or specimens be stored, for future (planned or unplanned) analysis ***beyond the scope of the current research proposal***? *If the biological samples and specimens will be used and/or destroyed prior to the closure of the research, they are not considered to be stored; therefore, please answer "No".*

- ☒ No

☐ Yes – Complete Appendix D1 and upload with this application packet.

C. Will any identifiable data, or coded data where a master list to the codes exists, be entered into an existing database or stored for future use ***beyond the scope of the current proposal*** as a result of the research? *If the data will be used and/or destroyed prior to the closure of the research, they are not considered to be stored; therefore, please answer "No".*

☒ No
☐ Yes – Complete Appendix D2 and upload with this application packet.

Note: A plan for securely storing the data must be submitted for IRB review and approval if identifiable and/or coded data will be retained after the research has been completed. Development of a separate data/tissue repository/bank research protocol is recommended, especially if the investigator will be retaining data from multiple proposals.

VIII. Research Subject Population

A. Indicate the anticipated subject enrollment number (This number cannot be exceeded without prior IRB review and approval via an amendment)**: Aim 1: 32 individuals (8 families with approximately 4 members per family). Aim 2 and 3: 168 individuals in practice groups (42 practice group families w/ approximately 4 members per family); 336 FS group participants (84 families w/ approx. 4 family members per family); 14 facilitators**

All aims total: 550 (please note, this is an estimate based on an average of 4 family members per family participating)

B. Indicate which populations below are the PRIMARY FOCUS of this research. *Please refer to the UIC HSPP policies regarding the incidental enrolment of select vulnerable populations (i.e., pregnant women, decisionally impaired, prisoners, etc.).*

Check all that apply

☒ Adults: Healthy Subjects or Control Subjects
☐ Adults: Patient Subjects
☒ Minors (17 years of age and younger)* – *Complete Appendix B and upload with this application packet*
☐ Pregnant Women, Neonates, Fetuses/Fetal Tissue* – Complete *Appendix U and upload with this application packet*
☐ Prisoners* – Complete *Appendix C and upload with this application packet* - ***Please note that certain types of research with prisoners approvable under the federal regulations may not be allowed under Illinois state law including, but not limited to, biomedical research.***
☐ UIC Employees*
☐ UIC Psychology Student Subject Pool* -
• *Complete Appendix S and a debriefing document and upload with this application packet;*

- *Complete Appendix B must be uploaded unless minor students will be excluded from the specific research drawing on Pool subjects. If minors will be excluded, then a scientific justification must be provided.*

☐ UIC Management Study Pool* - *Complete Appendix S and a debriefing document and upload with this application packet*
☐ Students* - *Complete Appendix S and upload with this application packet*
☐ Decisionally-Impaired* - *Complete Appendix V and upload with this application packet*
☒ Economically and/or Educationally Disadvantaged*
☐ Vulnerable to Coercion or Undue Influence*
☐ Other: specify

Please note the groups listed directly above marked with an asterisk (*) are considered "vulnerable" and require special consideration by the federal regulatory agencies and/or by the UIC IRB.

C. If including economically and/or educationally disadvantaged subjects, subjects vulnerable to coercion or undue influence, UIC Employees, and/or other populations that may be considered vulnerable, provide a rationale for their inclusion and what additional safeguards, if any, are in place to protect their rights and welfare:
The families are Syrian refugees residing in Turkey, which is the primary focus of our study. We believe that the translated consent form will clearly state their rights by not collecting identifiable information or having them sign any consent documents will safeguard their identity and rights.

D. Eligibility Criteria

1. Provide specific details regarding the following:

a. Inclusion Criteria: **FSDT members: include project researchers and community advocates, nurses, and physicians who work in clinical or community-based organizations with Syrian refugees in Istanbul.**
Family members: inclusion criteria includes 1) Syrian refugee family living in Istanbul; 2) contains both adult caregivers (18-55 years old) and at least one of their children (<18 and >11 years) living in one household; 3) one adult or one adolescent with >3 on the GHQ-12; 4) willing to participate in the intervention and research.
Facilitators: the 14 facilitators will be community workers and nurses who work in the organizations, they must be: 1) knowledgeable about family and mental health issues; 2) experienced health educators and group leaders; 3) open to task sharing principals and practices; 4) willing to participate in training and intervention delivery for one year.

b. Exclusion Criteria: **This project will exlcude families who do not meet the threshold of >3 on the GHQ-12 screener.**

2. Explain how and by whom potential subjects will be assessed to determine their eligibility for the research: **FSDT members: In addition to the research team, 8 community advocates, nurses, and physicians will be invited to participate in the Family Support Design Team. These participants will include persons from the six clinical and community sites where the intervention will occur in later aims of the study. We had reached out to these sites during the grant writing process and they agreed to participate as organizations who work with Syrian refugees in Istanbul (we will provide letters of support and appendix K for Aim 2 when these sites will be used as research sites for recruiting subjects). Their contact information is public and the research team will email the representtive at the organization to send either nurses, physicians, or advocates depending on if they are a clinical or community site for the FSDT so that we have 8 experts to provide input to the model on Syrian refugee's mental health.**

Families (aim 1): 8 families will be invited a whole-day run through. These famillies will be families who seek services at one of the six organizations and asked to attend the run through that will be conducted in a private room at that site. A nurse or community advocate from the organization will create a confidential list of 20 families using the surnames and phone numbers from their organization's records who attend the organization and who appear to meet criteria. Using a random number generator, the list will be reordered, then followed sequentially until 8 families are enrolled. The families will be contacted via phone by the nurse or community advocate using the contact information that the organization has on file. Using the approved recruitment script with the eligibility criteria, the nurse or community advocate will provide them with some information about the study and screen them for eligibility, and if eligibile, see if they are interested in participating in the run through. We will have the organiztion contact the families, rather than the researchers, so that their contact information is not shared with the research team. The list with the 20 families will be destroyed after Aim 1 data has been collected.

Families (aim 2 and 3): 42 families will be invited to participate in a practice group (one practice group with 6 families at each of the 7 sites) and 84 families will be invited to participate in the pilot of the Family Support Group (two pilot groups with 6 families each at each of the 7 sites). The purpose of the practice group is for the facilitator to practice and receive feedback from the research team before implementing the Family Support Group with the pilot families. No data is collected from the participants in the practice group. We will recruit these families for the Family Support Group intervention the same way at the aim 1 run through participants. These families will be families who seek services at one of the seven organizations and asked if they would like to participate in a Family Support Group intervention that is conducted in a private room at the organization where they are already seeking services. A nurse or community advocate from the

organization will create a confidential list of families using the surnames and phone numbers from their organization's records who attend the organization who appear to meet criteria. Using a random number generator, the list will be reordered, then followed sequentially until all families are enrolled. The families will be contacted via phone by the nurse or community advocate using the contact information that the organization has on file. Using the approved recruitment script with the eligibility criteria, the nurse or community advocate will provide them with some information about the study and screen them for eligibility, and if eligible, see if they are interested in participating in the Family Support Group. The organization will contact the families, rather than the researchers, so that their contact information is not shared with the research team. The list with the families will be destroyed after the qualitative interviews are complete.

Faciltators: We will recruit 14 Arabic speaking community workers and nurses from 7 community based organizations (2 at each) that work with Syrian refugees in Istanbul, where the family support groups will take place. These organizations have already agreed to participate and serve as sites and recruit families and facilitate groups. UIC and Turkish researchers will work with each organization to identify persons to serve as the facilitator. They will be formally recruited and consented to participate in both delivering the intervention and completing process measures, as well as for the follow up interviews with a sub-set of 7 of the facilitators.

3. Explain how initial eligibility will be documented (upload any screening documents): **Using a recruitment script and GHQ-12 screener.**

1. Explain how subjects will be monitored during the course of the research to ensure that they still meet the eligibility criteria and how their continuing eligibility will be documented:

OR
☒ N/A – Assessment of continued eligibility is not required

IX. Recruitment of Subjects

A. Describe how potential subjects will be initially identified for this research study.

Family members participating in run through and feedback session: In month 5, 8 families will be invited a whole-day run through. These famillies will be families who seek services at one of the six organizations and asked to attend the run through that will be conducted in a private room at that site. A nurse or community advocate from the organization will create a confidential list of 20 families who attend the organization and who appear to meet criteria. Using a random number generator, the list will be reordered, then followed sequentially until 8 families are enrolled. The families will be contacted via

phone by the nurse or community advocate using the contact information that the organization has on file. Using the approved recruitment script, the nurse or community advocate will provide them with some information about the study and see if they are interested in participating in the run through. We will have the organization contact the families, rather than the researchers, so that their contact information is not shared with the research team. If the family members indicates that they are interested, they will arrange a time for one of the Istanbul researchers to meet them at their home or to meet the researchers in a private room at the organization to be screened for eligibility. The adult family member will be asked to tell their family members about what the research, the run through, and verbal feedback session involves, and if the other members of the family are intersted in participating, to please bring family members who may be distressed to be screened (the person in distress may include either the person initially contacted, their spouse, or their adolescent child who is 12 or older). They will be told that a person in distress might include someone who may be feeling sad, scared, nervous, restless, or helpless.

When the family members meet the site staff in a private room at the organization or at their home, the person who the family has identified as being distressed will be screened using the General Health Questionnaire (GHQ-12), that will take less than 5 minutes. One or more family members may be screeed. Any family member(s) screened will be done one a time in the room with the site staff for privacy while other family members wait in another room at the home or organization, they will not see each other's results. The GHQ-12 scores will not be disclosed to members of the family unless the score indicates the need for an immediate distress plan response. If at least one family member scores >3 on the GHQ, then their family is eligible to participate. The site staff will provide them with information about the time and location of the whole day run through and feedback session, which will be held in a private room at the organization. At the arranged time of the run through, the researchers will be present and will go over the informed consent/assent procedures with parents and adolescents using the approved stamped consent/assent foms. If all family members agree to participate in the run through, they will proceed with verbal consent before proceeedint with the run through and immediate verbal feedback session. The run through will be in a group format. The researchers will explain to the participants that in the full Family Support model, there group will have 6 families and will meet over the course of 4 sessions. The researchers will then go through the model that was developed by the FSDT, will skim through the information in each session and have families participate in the case studies. After going through the manual and understanding the model, the families will be asked to provide feedback immediately following the full day run through to inform final modifications. The feedback session will last approximately 60 minutes, will be audio recorded, and families will be paid $20 for their participation.

Please note, families will be identified and recruited the same way for the aim 2 and 3 family support group, survey, and interviews as they were for the aim 1 run through. As stated earlier, the nurse and community workers will receive 20 hours of training, this will include training on recruitment and enrollment, in addition to conducting the family support group intervention.

Family members participating in Family Support Group intervention:
These families will be families who seek services at one of the seven organizations and asked if they would like to participate in a Family Support Group intervention that is conducted in a private room at the organization where they are already seeking services. A nurse or community advocate from the organization will create a confidential list of families using the surnames and phone numbers from their organization's records who attend the organization who appear to meet criteria. Using a random number generator, the list will be reordered, then followed sequentially until all families are enrolled. The families will be contacted via phone by the nurse or community advocate using the contact information that the organization has on file. Using the approved recruitment script with the eligibility criteria, the nurse or community advocate will provide them with some information about the study and screen them for eligibility, and if eligible, see if they are interested in participating in the Family Support Group. The organization will contact the families, rather than the researchers, so that their contact information is not shared with the research team. If the adult family member meets eligibility criteria from the recruitment script and indicates that they are interested in having their family participate, they will arrange a time for one of the Istanbul researchers to meet them at their home or to meet the researchers in a private room at the organization to be screened using the GHQ-12. The adult family member will be asked to tell their family members about what the research, the Family Support Group intervention, and surveys involve, and if the other members of the family are interested in participating, to please bring family members who may be distressed to be screened (the person in distress may include either the person initially contacted, their spouse, or their adolescent child who is 12 or older). They will be told that a person in distress might include someone who may be feeling sad, scared, nervous, restless, or helpless.

When the family members meet the site staff in a private room at the organization or at their home, the person(s) who the family has identified as being distressed will be screened using the General Health Questionnaire (GHQ-12), that will take less than 5 minutes. One or more family members may be screened. Any family member(s) screened will be done one a time in the room with the site staff for privacy while other family members wait in another room at the home or organization, they will not see each other's results. The GHQ-12 scores will not be disclosed to members of the family unless the score indicates the need for an immediate distress plan response. A score of >3 is the cutoff to participate, however, the person conducting the screening can quickly tally the scores on the spot, and based on the behavior of the individual and their scores (if they score >9) they will be instructed to implement the distress response plan. Since the

person conducting the screening in a nurse or community advocate who works at the organization, rather than a psychiatrist, they will be instructed to call the local Co-I, Dr. Gormez or if unavailable, the other local Co-I, Dr. Bikmazer, both are Co-Is on the project for Medeniyet University and both are Psychiatrists with medical degrees. This will initiate the first step of the distress response plan, where the Co- I will meet where the screening is occurring or will initiate a psych evaluation over the phone, then from there the procedures will be followed as listed in the distress response.

If at least one family member scores >3 on the GHQ, then their family is eligible to participate. The site staff will provide them with information about the time and location of the first session of the Family Support Group, which will be held in a private room at the organization. At the arranged time of the first session of the Family Support Group, the researchers will go over the informed consent/assent procedures with parents and adolescents using the approved stamped consent/assent forms and explain the intervention and research procedures, and ask if anyone has questions. If all family members agree to participate in Family Support Group intervention, they will proceed with verbal consent before proceeding with the baseline survey, then begin session 1 of the intervention.

For the follow up interviews, the same recruiters/facilitators who ran the family support group, will randomly contact nine families to participate in a family interview (3 families who were screened but did not participate, 3 families who participated in 1-2 sessions, and 3 families who participated in 3-4 sessions). Families will be contacted on the phone using the contact information on file following the final survey (3 months post-intervention). The recruitment will be the same for the previous aims. If they want to participate, the recruiter will ask the adult family member who he/she contacted on the phone to tell the other family members about the interview, then arrange a time to meet the family either at their home or private room at the clinic for conduct the follow up family interview.

For the facilitators: Note the research team from UIC and Turkey have already partnered with these organization during the grant development to receive their support and during the Family Support Design team to start working on modifying the manual. Because of this partnership, the research time has already identified with the organization, which nurse or community advocate at each organization will run the family support group sessions. Before training and recruitment of families begin, the facilitators will be formally recruited to ensure that they are eligible and meet criteria. The Turkish research will meet the facilitators at the organization where they work, and in a private room, go over the recruitment script. If they are eligible and want to participate in the intervention and process measures, the Turkish researchers will immediately move on to the consent process. After consented, the training with all the facilitators will be arranged. They will then be eligible to conduct the intervention and process measures. The randomly selected nine facilitators will be followed up in-person

at their organization by the Turkish researchers after the completion of the family support groups sessions. They will be re-consented and if agree to be interviewed, the interview will occur in a private room at their organization.

B. Describe how, where, when, and by whom subjects will be recruited for the research.

(explained above)

C. Explain the proposed measures to minimize the possibility of coercion or undue influence on potential subjects, particularly for subjects identified in VIII.B. as being vulnerable *(for example: how will you maximize the subject's autonomous decision-making; what if the investigator is also the participants healthcare provider, what if the participant is enrolled in a class the investigator is teaching, what if an employer/employee relationship exists)*.

Subjects will be told that the research is voluntary and they do not have to participate if they do not want to. Adolescent subjects will also be told that even if their parent wants to participate, they still do not have to. They will also be told that their decision to participate will not affect the services they receive at the community or clinical sites.

D. Will any identifiable data obtained at recruitment, including screening data from records, be retained without consent from subjects who failed to qualify or declined to participate?

☒ No
☐ Yes – Describe the screening data to be retained and justify the retention of such data:

E. Check and upload all materials that will be used for recruitment. Refer to the OPRS website for the Investigator Guidance: Recruitment Materials for additional information.

☐ No recruitment materials will be used
☐ Print materials (flyer, brochure, info sheets, etc.) – Describe:
☐ Ad (radio, TV, etc.) – Describe:
☐ Letter – Describe:
☒ Verbal script – Describe: **recruitment script will be read to adult participants on the phone before meeting in person**
☐ Electronic materials (e.g., website, mass mailing, email notice) – Describe:
☐ Social Media – Specify social media outlets:
☐ Other – Describe:

X. Reasonably Anticipated Risks of the Research

A. Identify all of the reasonably anticipated risks or discomforts that may result from participation in this research (actual and reasonably possible, current and future) and describe the expected frequency, degree of severity, and potential reversibility of those risks (if known). *Remember that risks can be psychological, physical, social, economic, or legal.* If any portion of the research involves review of medical records, the potential for loss of privacy or confidentiality of health information should be listed as a risk.
Confidentiality during recruitment and participation with other family members, discomfort, and safety.

B. Describe the measures taken to minimize the risks (other than undue influence or breaches of privacy and/or confidentiality) listed above. *Measures may include screening of subjects by qualified personnel, eligibility criteria, use of procedures already being used for clinical purposes, qualifications and experience of staff performing procedures, specialized facilities or equipment, medical or psychological services that may be required as a consequence of the research and frequency of monitoring.*
Confidentiality- every effort is made to protect the confidentiality of the research participants. First, nobody from the UIC research team is getting contact information from the participants. Instead, FSDT member's contact information in publicly available and the family members' contact information will only be seen by the community advocate or nurse who know the potential families. The list of contact information will be destroyed after Aim 1 data has been collected.
Only site staff will have the contact information, not researchers, to recruit and screen participants for the run through/feedback session for aim 1 and for the family support group participants for aim 2 and 3. No other identifiable information will be collected during the whole day run through and feedback session and the consent form will state that "All subjects participating in the run through and verbal feedback session will be asked to respect each other's privacy and confidentiality, and not repeat what others have said, however, this cannot be 100% guaranteed." Subjects will not be signing the consent form.
Discomfort- in the surveys and interviews we will be asking about mental health and that could make some participants uncomfortable. We will remind them prior to data collection that they do not have to answer anything they do not want to, that they can skip questions and can stop participation at any time without consequences.
Safety-Although we do not anticipate participants to experience distress and/or express thoughts of harm to oneself or others, we will have the same distress response plan in place that w used for aim 1 (separate document with distress plan details is subitted with this application).

C. Describe the process for reporting any unanticipated problems to the IRB and sponsor, as applicable.
If there are any problems that arise during the course of the screening and run through and feedback session, and during the family support groups, the

Istanbul researchers will keep a log of the issue and send it immediately to the UIC PI who will then provide it to UIC IRB so they can be made aware and assist with the issue.

XI. Reasonably Anticipated Benefits of the Research

A. Identify the potential for benefits to individual subjects, including those related to an experimental intervention or interaction that are available only in the context of the research. *Please note that participation in Social and Behavioral Sciences research (such as interviews, focus groups, surveys) rarely presents a direct benefit to the subject. Unless a direct benefit to subjects is anticipated (such as an educational benefit from a new curriculum, therapeutic benefit from a new service/therapy), please state that no direct benefits to subjects are anticipated.*

There are no direct benefits to the families who participate in the run through and feedback sessions, however, their feedback will inform the modification of the family support model that will be implemented in Aim 2 that will be used to provide famililes with knowledge and skills to better understand their reactions to adversity (anxiety, depression, stress) and how to manage their reactions (deep breathing), as well as family problem solving to improve their common mental disorders.

For families who participate in the Family Support Group intervention, they will gain knowledge and skills to better understand their responses to adversity, stress, depression, anxiety, and now to manage their reactions to these issues, such as by learning coping skills like deep breathing and grounding, as well as family problem solving and communication.

B. Indicate how the knowledge gained from the study could produce a benefit to society or to others who share the same disorder or condition.

The knowledge gained about providing low intensity family support for families experiencing adversity would be beneficial to many disadvantaged communities in low resource settings where this could be replicated.

XII. Privacy and Confidentiality

A. Describe the precautions taken to protect subject privacy during the initial identification of subjects, subject recruitment, and collection of data from the subjects *(for example: what precautions will be taken to protect the subject from being recognized as a research subject if recruitment or data collection occurs in a group setting or in public?)*.

For FSDT- we are only collecting their contact inforamtion so that they can be contacted for email/skype meetings and the second FSDT meeting. This will not be stored with the data.

For families- Every effort is taken to protect privacy and confidentiality of the research subjects. UIC researchers are not collecting their contact information, instead they will be contacted by a nurse or community advocate (site staff) at an organization where they received services. The site staff recruits and screens participants, then arranges for them the time/location of the run through where researchers will consent them and collect data. We also will not be asking them to sign the consent form since refugee families may feel uncomfortable signing official paperwork to keep their identity confidential. Additionally, the GHQ-12 screening will be done in a private room at the organization or at their home by site staff, and the run through will be in a private room at the organization. The family support group sessions will be conducted in a private room at the organization, and the surveys and interviews will be conducted either at the same time at the organization (for the first and second survey) or at the organization or at their home (for the third survey and follow up interview).
For intervention staff- they will complete their process measures during or immediately after each family support group session in the private room at their organization. The sub-set of intervention staff who will be asked to complete an interview following the family support group completion will also complete the interview in a private room in their organization

B. Data Security and Management Plan. This section asks you to describe provisions you will make to maintain the confidentiality of the research data.

1. Indicate the identifiable elements that will be collected and/or included in the research records.

Check all that apply

☐ Names ☐ Social Security Numbers* ☐ Device identifiers/Serial numbers
☒ Phone numbers ☐ Medical record numbers ☐ Web URLs
☐ Street address ☐ Health plan numbers ☐ IP address numbers
☐ City or state ☐ Account numbers ☐ Biometric identifiers[1]
☐ Zip Code ☐ Fax numbers ☐ Vehicle ID numbers
☐ E-mail address ☐ License/Certificate numbers ☐ Facial Photos/Images
☐ Financial account information (including student ID)
☐ All elements of dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age
☐ Date of Birth
☐ Identifiable UIC Student Records[2] ☐ University Identification Number (UIN)
☐ Any other unique identifier - Specify:
☐ **None of the identifiers listed above** – Skip to item C

[1] Biometric Identifiers are observable biological characteristics which could be used to identify an individual, e.g., fingerprints, iris/retina patterns, and facial patterns.

[2] Documentation of approval from the Registrar must be submitted unless prospective signed consent is obtained from the student or guardian

***NOTE:** If social security numbers will be collected, explain below why they are necessary and how they will be used:

2. Data Collection

a. Identify what methods you will use to collect data:

☐ Internet-based application/package – Specify:
- ☐ REDCap [define host ☐ CCTS/IHRP ☐ Other (define):]
- ☐ Qualtrics
- ☐ Survey Monkey or other commercial survey service – Specify:
- ☐ Other - A thorough description of the characteristics of the application/tool must be provided. This description should address the following elements if applicable: product/tool name, host, security measures, encryption mechanism, and how collected data is maintained and stored by the application/tool.

☐ Non-internet based application (i.e. directly on a desktop/laptop).

☒ Paper

☒ Recording Media - ☐ Photo ☐ Video ☒ Audio

☐ Subject Artifacts (such as classroom assignments, regular work products, lesson plans)

☐ Stored specimens

☐ Other:

Note: Any investigator who uses external survey software other than REDCap or Qualtrics for collecting UIC/UI Health PHI must provide evidence of a business associate agreement between the University and the external survey software provider. For more information, refer to the *POLICY: Research Data Security*.

b. Describe whether and how social media platforms will be used to collect data and/or communicate with subjects:

☒ Not applicable

☐ Facebook – Describe uses:

☐ Twitter – Describe uses:

☐ Google/Google+ – Describe uses:

☐ Other: Specify: – Describe uses:

3. Data Storage and Security

a. Describe how all types of data will be secured.

i. ☒ Indirectly with a code linked to the identity of the subject.

Describe the coding method, specify who will have access to the code/master key, indicate where the key is stored, and explain how it will be protected against unauthorized access: For aim 1, there will not be any code linked or any identifying information collected since family members will participate in a one-time run through and feedback

session. The list with 20 families that the site staff uses to recruit and screen participants will be destroyed after Aim 1 data collection. This list will remain at the site in a locked file cabinet, in a locked office.
For later aims 2 and 3, family member participants will be assigned an identification number, that ID number will be used for their attendance of the family support group sessions, surveys (initial, immediate post, 3 months post), and if they are also the 9 families who complete interviews. At the first family support session after consenting, since the site staff do the recruitment the researchers will have family members provide their name and contact information and they will be given an ID number, but they will be told that this is not used as part of the research and will be stored separately from their data. The ID number will appear on the hard copy of the questionnaire and it will also be stored on a paper log that contains the ID number with the matching family's name and contact information (phone number).
They will be reminded of confidentiality, that they do not have to sign consent forms, and only the researchers and site staff will know of their participation. The ID log with name and phone number will be stored in the Istanbul investigator, Dr. Gormez, locked offices at Medeniyet University. These will be stored in a separate locked file cabinet from the data. Contact information will be destroyed within immediately after data collection is complete.

ii. ☐ Directly, personal or private identifiers (identifiable elements) are maintained with the data.
Justify the inclusion of direct subject identifiers:

iii. ☐ Limited Data Set [Protected Health Information (PHI) subject to the Privacy Rule that includes elements limited to city, state, ZIP Code, elements of date, and other numbers, characteristics, or codes not considered as direct identifiers]. *Requires a Data Use Agreement.*

Please note:
- *Items i and ii require consent and/or authorization (if PHI is involved) from the subject or a Waiver of Consent and/or Waiver of Authorization (if PHI is involved) from the IRB.*
- *UIC and/or outside agencies may require the use of a data use/data transfer agreement that outlines the procedures necessary to protect identifiable or coded data that will be transferred or shared between agencies. You must contact the Office of Research Services (ORS) at 312-996-2862 for additional information and direction.*

b. Indicate the method(s) used to secure each data type.
☐ Password access
☐ Portable devices – Specify encryption software (required):
☐ Encryption software will be used – Specify encryption software:

☐ Secure network server will be used – Specify secure server:
☐ Stand alone desktop/laptop computer will be used to store data
  ☐ Not connected to server/internet
☐ An organization outside of the UIC will store the code key.
☒ Locked file cabinet
☒ Locked office/lab.
☐ Locked office suite.
☐ Locked refrigerator/freezer
☐ Other - Specify:

c. If collecting audio, video, or photo data, specify how the data will be stored:
Audio data will be transcribed and stored as word documents on a password protected computer in a locked office. Audio data will be transcribed by Bilal Makhlouta, the Research Coordinator in Istanbul, who is a native Arabic speaker and is fluent in Turkish and English.
☐ Not Applicable – No audio, video, or photo data will be collected.

d. Indicate when **identifiers** (including the master list) will be removed or destroyed.
☒ End of data collection
☐ End of data analysis
☐ Post publication/dissertation defense
☐ Waiver of authorization requested – Data will be retained for 6 years.
☐ Other – Specify: **NA**

4. Data Sharing

a. Will the data or specimens be shared with persons **other than** UIC investigators and research staff noted on the protocol application and Appendix P?
☒ No – Skip to item D
☐ Yes – Specify with whom the data will be shared:

b. Indicate the manner in which the data will be shared:
☐ As a de-identified dataset
☐ With direct identifiers
☐ With indirect identifiers (i.e., coded dataset) and/or Limited Data Set
  Identify who will have access to the code key or master list:

c. Specify how will identifiable data be transferred:
☐ Non-electronic transfer (hard copy or physical specimens) – Specify:
☐ Transmitted over a secure network – Specify network:
☐ Via UIC e-mail - Specify encryption:
☐ Cloud based data sharing program (*PHI may not be shared in this manner.*)
  Specify:
☐ Other - Specify:

C. Does the research protocol have a data and safety monitoring plan? *For more information refer to UIC OPRS HSPP policy Data and Safety Monitoring Plans (DSMPs), Data and Safety Monitoring Boards (DSMBs), and Data Monitoring Committees (DMCs).*

☐ Not Applicable.
☐ Yes – Describe the plan:

D. Will you be applying for a Certificate of Confidentiality?

☒ No
☐ Yes – Include the required template language in the consent document and refer to the Guidance for Investigators: Certificates of Confidentiality for more information regarding the submission process and regulatory requirements.

E. Is this research being funded by the National Institute of Justice?

☒ No
☐ Yes **–** Upload the NIJ Privacy Certificate with this submission.

XIII. Compensation

A. 1. Will subjects receive any compensation (for example: money, gifts, or gift certificates) directly related to research participation? *If subjects will be entered into a lottery, select "No" and skip to B.*

☐ No – Skip to item B.
☒ Yes - Indicate the type of compensation.
  ☒ Monetary (total amount: $ **Familty members- $20 for particpating in full day run through and feedback session; $10 for family and facilitators for each survey and interview completed**)
  ☐ Non-Monetary
  ☐ Both

2. Describe in detail:

a) How compensation will be prorated (e.g., $x for each visit, $y for subjects who do not qualify after screening visit, etc.): **NA**
b) When compensation will be provided (e.g., after each visit, at the completion of all visits, 6-8 weeks after the completion of all visits due to processing of check, etc.) **and** in what format (e.g., cash, check, VISA gift card, etc.): **Family members will receive compensation after the feedback session, surveys, or interviews.**

B. Will subjects be entered into a lottery for compensation (for example: money, gifts, or gift certificates) before, during, or after participation in the study?

☒ No
☐ Yes -
a. Provide a justification for conducting a lottery rather than compensation per subject:

b. Indicate the type of compensation:
c. Indicate the odds of winning the lottery:
d. Indicate when the winner will be notified and receive the compensation:

C. Does this study provide payments in exchange for referrals of potential participants (finder's fees) or payments designed to encourage or accelerate recruitment by being tied to the rate or timing of enrollment (bonus payment)?

☒ No
☐ Yes – Describe:

Payment in exchange for referrals of potential participants (finder's fee) and payments designed to encourage or accelerate recruitment by being tied to the rate or timing of enrollment (bonus payment) are generally unacceptable.

XIV. Procedures to Obtain Informed Consent/Assent

Please note that the Principal Investigator must indicate on Appendix P who has been delegated to obtain informed consent.

A. Indicate the type of consent you will obtain:

☐ Written
☒ Verbal
☐ Waiver of Informed Consent and/or Waiver of Signed Consent

B. Indicate where and when informed consent will be obtained from potential subjects.

Family members participating in run through, and family support group intervention consent / assent will occur in a private room at the organization before the whole day run through begins, or before the family support group first session begins . We will have parents and family members consented in separate rooms to ensure there is no pressure placed on the adolescent to consent to participate.

For follow up interviews- consent will either occur at their home or in a private room at the clinic or community organization.

For facilitators- consent will occur in a private room at the organization where they work.

C. Does the potential exist for enrolling subjects (or subjects' LARs) who do not understand English?

☐ No
☒ Yes – Describe how the consent process will be conducted (e.g., who will convey information to the subject or LAR in a language they understand, whether the consent will be documented using a translated consent form or short form).

For the family members- consent will be conducted in Arabic by the Istanbul Research Coordinator, Makhlouta, who is of Syrian descent and native Arabic speaker, and who also is fluent in English and Turkish.

For information about the involvement of non-English speaking subjects in research, including use of the short form, please refer to the Guidance: Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago.

D. Will any portion of the research involve deception?
☒ No
☐ Yes - Upload Appendix J and a debriefing statement with this application.

XV. HIPAA Compliance

A. Does your research use and/or disclose Protected Health Information (PHI)*?
☒ No – Skip this section.
☐ Yes

**Data is considered to represent PHI when an individual's health information, including billing records, contains or is linked to one of the identifiers listed in #XII.B.1.. For example, health-related information is considered PHI if any of the following are true:*

- *The researcher obtains the information directly from a provider, billing records, health plan, health clearinghouse or employer (other than records relating solely to employment status);*
- *The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR*
- *The researcher obtains it directly from the study subject in the course of providing treatment to the subject.*

Health-related information is not considered PHI if the researcher obtains it from:

- *Student records maintained by a school;*
- *Employee records maintained by an employer related to employment status; OR*
- *The research subject directly, if the research does NOT involve treatment.*

B. Will PHI be used for the purposes of identifying and/or recruiting potential subjects for the research?
☐ No
☐ Yes

C. Will subjects be selected from records outside the UI Health System?
☐ No
☐ Yes – Indicate who gave approval for the use of the records:

- Upload the protocol, consent documents, letters, etc., for securing consent of the subjects for the use of the records if the records are "private" medical or student records.
- Upload written documentation for cooperation/permission from the institutional holder or custodian of the records.

D. Will any research related information be put into the health information records or any other permanent record of the subject?

☐ No
☐ Yes - Explain:

APPROVAL
STARTS 7/28/2019 — EXPIRES 2/20/2020
UIC UNIVERSITY OF ILLINOIS AT CHICAGO
INSTITUTIONAL REVIEW BOARD

University of Illinois at Chicago
Assent for Participation in Social, Behavioral, or Educational Research
Low Intensity Family Support for Syrian Refugees in an LMIC

Hello, my name is _____. I am working on a research project in partnership with the University of Illinois at Chicago (UIC) in the United States, Medeniyet University in Istanbul, Turkey, and the Centre for Global Health at the University of Prishtina, Kosovo.

This project is focusing on designing a family support model to help Syrian refugee families who are who are experiencing difficulties and emotional problems.

If you agree to be part of this research, we will ask you to participate in the following:

If you agree to be part of this research, we will ask you to participate in the following:

Intervention and Satisfaction Checklist:
We will ask you and your family to participate in the family support group and complete a satisfaction checklist after the last session. The support group will meet once a week for 2 hour sessions for four weeks.

Surveys:
We will ask family members (at least one parent/primary caregiver and one child) to participate in 3 individual surveys (initial, immediate after the last session, and 3 months after the last session) that will ask some questions about stress and your family. Some of the questions may be personal or sensitive. The survey will last 60 minutes or less.

Participation in this research project is voluntary. You may refuse to answer any questions during the intervention and survey. Even if your parents give their permission for you to participate, you do not have to participate if you do not want to and nothing bad will happen if you decide not to participate.

There are some potential benefits to participating in this research. By participating in intervention, you and your family will learn about how to better understand and cope with stressors and improve family problem solving and communication.

We do want to share with you some possible risks associated with participation in this project.

Other people in the family support group will be asked to not repeat anything that was said in the group, but we cannot guarantee that they will not talk with anyone. We will do everything we can to protect your family's privacy. Your name and other identifying information will not be available to anyone outside of the research team, and no identifying information will appear anywhere on any documents that could identify you. Throughout data collection, field notes and data collection instruments will be either in direct possession of the investigators or secured in a locked location. All paper data and audiotapes will be held by the Co-Investigator in a separate

locked cabinet at the same office at Medeniyet University. De-identified research materials and transcripts will be securely transferred weekly to the University of Illinois at Chicago. In Chicago, all data will be kept in the locked offices of the research team. The field notes will be kept indefinitely by the Principal Investigator in Chicago for documentary and your family's contact information will be deleted immediately after data collection is complete.

A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at anytime. The Clinical Trial ID number is: NCT03978533.

Your family will be paid $10 as a unit for each of the three surveys completed.

Do you have any questions about the research?

The local Co-Investigator from Medeniyet University is Dr. Vahdet Gormez and he can be reached at vahdetgormez@gmail.com. The US Principal Investigator is Dr. Stevan Weine and he can be reached via Dr. Gormez or directly at smweine@uic.edu. If you have any questions, please contact us.

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research subject, you may call University of Illinois at Chicago Office for the Protection of Research Subjects (OPRS) at +1-312-996-1711 or e-mail OPRS at uicirb@uic.edu. You can also contact Medeniyet University, Health Sciences Ethical Committee at 0 216 570 91 90 or e-mail the Ethical Committee President, Professor Mahmut at mahmut.gumus@medeniyet.edu.tr.

Would you like to participate in the research?

(Note, explain this is a verbal consent. Offer the subjects a copy of this document.)

APPROVAL
STARTS 7/28/2019 — EXPIRES 2/20/2020
UIC UNIVERSITY OF ILLINOIS AT CHICAGO INSTITUTIONAL REVIEW BOARD

University of Illinois at Chicago
Consent and Parental Permission for Participation in Social, Behavioral, or Educational Research
Low Intensity Family Support for Syrian Refugees in an LMIC

Principal Investigator/Researcher Name and Title: Stevan Weine, MD
Department and Institution: Department of Psychiatry, University of Illinois at Chicago
Address and Contact Information: 1601 W. Taylor Street, Chicago, IL 60612, contact smweine@uic.edu
Sponsor: National Institutes of Health

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to say "no" to this research or may choose to stop participating in the research at any time. Deciding not to participate, or deciding to stop participating later, will not result in the loss of any services, class standing, and/or professional status to which you are entitled, and will not affect your relationship with the University of Illinois at Chicago (UIC) or any of the agencies or organizations collaborating in this research.

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you are member of a Syrian refugee family living in Istanbul with at least one family member who is experiencing distress.

126 Syrian refugee families will be enrolled in this research study. A family consists of both adult caregivers and at least one adolescent child

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to develop and run a family support model for helping Syrian refugee families in Istanbul with common mental disorders with limited access to mental health services.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	You and your family will be invited by an organization where you receive services to participate in a family support group intervention. The family support group will last 2 hours once a week for 4 weeks. We will also ask each enrolled family member to complete individual satisfaction checklists of the support group session as well as three individual surveys (before the first session, at the end of the last session, and 3 months after the last session). We are also asking a random sample of families to participate in one audio-recorded qualitative family interview that will last approximately 60 minutes. We may ask your family to also participate in this family interview at a later time. For more information, please see the "What Procedures Are Involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	The family support group intervention will last four weeks for two hours each week. The satisfaction checklist will take no more than 15 minutes and the surveys will take approximately 60 minutes to complete.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Being in this research study you and your family will learn about how to better understand and cope with stressors and improve family problem solving and communication.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The primary risks presented by this research study are breaches of privacy (others outside of the study may find out you are a subject) and/or confidentiality (others outside of the study may find out what you did, said, or information that was collected about you during the study). While researchers will ask others in the family support sessions to respect each other's privacy, and not repeat what is said to others outside of the group, this confidentiality cannot be guaranteed.

DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	Your participation in this research is voluntary and you have the option to decide not to take part at all or stop at any time without any consequences. We will also ask your child if he/she is willing to participate. Even if you agree, your child does not have to agree participate. If he/she does not want to participate, then your family will not be enrolled.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact the local Co-Investigator from Medeniyet University, Dr. Vahdet Gormez at vahdetgormez@gmail.com or you can contact the US Principal Investigator, Dr. Stevan Weine via Dr. Gormez or directly at smweine@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at +1 312-996-1711 or e-mail OPRS at uicirb@uic.edu. You can also contact Medeniyet University, Health Sciences Ethical Committee at 0 216 570 91 90 or e-mail the Ethical Committee President, Professor Mahmut at mahmut.gumus@medeniyet.edu.tr.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.

What procedures are involved?

You and/or other family members have already completed a screener and your family has been determined to be eligible. Now we would like to explain more about what procedures are involved if you choose to participate.

If you agree to be in this research, then we would ask your family to participate in the following:

Intervention and Satisfaction Checklist:

We will ask you and your family to participate in the family support group intervention. These multi-family group sessions will last approximately 2 hours once a week for 4 weeks. A family consists of at least one parent/primary caregiver and at least one child. We will also ask you and your family members to each complete an individual brief satisfaction checklist after the last support group session. Each session will also be observed and evaluated by the researchers.

Surveys:
We will ask your and your family members who participate in the Family Support Group Intervention to each participate in 3 individual surveys (initial, immediate after the last session, and 3 months after the last session). This survey will ask questions about anxiety, depression, post-traumatic stress disorder, as well as family functioning. Some of the questions may be personal or sensitive. The survey is expected to be completed in 60 minutes or less.

Interviews:
Following the final follow up survey 3 months after the Family Support Group, 9 of the 84 families will be asked to complete a qualitative family interview, to completed as a family not individually, that will last approximately 60 minutes. The interview will be audio recorded.

What are the potential risks and discomforts of the study?
We do want to share with you some possible risks associated with participation in this project.

Discomfort. During the family support group we will be discussing depression, anxiety, and family issues. We realize that sometimes these types of questions may make people uncomfortable. We remind you prior to the family support sessions that you do not have to answer any question that you do not want to.

Although we do not anticipate participants to experience distress and/or express thoughts of harm to oneself or others, if this happens we have a plan in place. At any time during this research, if you or another family member is experiencing unpleasant feelings and emotions that are disrupting their functioning and/or makes threats to harm themselves or others, we will break confidentiality for their own safety. We will call the local investigator who is a medical doctor with a psychiatry degree and he will do an evaluation. Depending on how intense the thoughts of harm are and/or the feelings of distress, either you or your family member will be provided with referrals for treatment at a local mental health clinic or if there is more severe distress, the investigator will arrange for you or your family member to be taken to a hospital for safety. In this case, the site staff will wait with you and your family until assistance arrives to transport you or your family member to a hospital. If either of these happens, participation will not be continued and your family will not be able to be enrolled to participate in the family support group.

What about privacy and confidentiality?
Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and state university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.

- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health

A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at anytime. The Clinical Trials ID number is: NCT03978533.

A possible risk of the study is that your participation in the study or information about you might become known to individuals outside the study. The field notes and data collection instruments will be transcribed and stored on a password protected computer at Medeniyet University to prevent access by unauthorized personnel. Your study information will be securely transferred to the the Principal Investigator at the University of Illinois at Chicago with your information in a de-identified format.

To minimize these risks, the researchers will ask all members of family support group to respect each other's privacy and confidentiality, and not identify anyone in the group or repeat what was said during the group discussion, but other members of the group may accidentally disclose this information.

We are not collecting any identifiable information other than your phone number which will not be stored with the data. We will keep your phone number until after the interview phase of the research as been completed. However, if any data is identifiable, it will be stripped of all identifiers during the transcription process.

Please remember that there is an exception to protecting subject privacy and confidentiality if the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities.

What are the costs for participating in this research?
There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?
You and your family as a unit will receive $10 in-person immediately after completing each survey. If selected to participate in the later interview, your and your family as a unit will receive $10 for participating in the family interview.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty. Your decision whether or not to participate will not affect your relations with the community or clinical organization where you receive services. If you decide

to participate, you are free to withdraw at any time without affecting that relationship. At any point during feedback session, if you do not want to answer any questions, that is fine.

The researchers and/or funder also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You were to object to any future changes that may be made in the study plan.

Remember:
Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Illinois at Chicago or with the service providers and/or agencies collaborating in this research. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Consent of Subject and Permission of Parent

I have read the above information. I have been given an opportunity to contact the researchers and ask questions, and my questions have been answered to my satisfaction. I agree to participate in this research and I agree to allow my child to participate in this research.

Are you willing to have your contact information retained by the researchers so that we can contact you following the Family Support Group intervention to see if you are interested in participating in an audio-recorded qualitative family interview?

(Note, explain this is a verbal consent. Offer the subjects a copy of this document.)